

Selection Criteria:

|                            |                                     |             |     |             |
|----------------------------|-------------------------------------|-------------|-----|-------------|
| Product Name:              | LEXAPRO                             |             |     |             |
| Product Active Ingredient: |                                     |             |     |             |
| Active Ingredient:         | [ESCITALOPRAM,ESCITALOPRAM OXALATE] |             |     |             |
| Active Moiety:             |                                     |             |     |             |
| FDA Received Date:         | From:                               | 01-Jan-1990 | To: | 31-Dec-2019 |
| MedDRA® Version* :         | 22.0                                |             |     |             |
| Total Cases**:             | 25146                               |             |     |             |
| Number of Pages:           | 9368                                |             |     |             |

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

\*, "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

\*\*, "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

| Field Heading     | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FDA Received Date | The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available. |
| Case #            | A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.                                                                                                                                                                                                                                                                                                                       |
| Case Type         | There are three case types in FAERS:<br>Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events<br>Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting.<br>Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.                                                                       |
| Health Prof       | Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported                                                                                                                                                                                                                                                                                                                         |
| Outcomes          | Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.                                                                                                                  |
| Mfr Control #     | The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.                                                                                                                                                                                                                                                                                                                                                                  |
| 503B Facility     | Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.                                                                                                         |
| Age               | The patient's age, with age unit, based on information provided in the report.                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Sex               | Patient sex (Male, Female, Unknown).                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

**FDA Adverse Event Reporting System**  
**Freedom of Information Act (FOIA)**  
**Detailed Report**

|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Country        | The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Preferred Term | A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products. |
| Product        | Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Comp.          | Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.                                                                                                                                                                                                                                                                                        |
| OTC            | Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Role           | There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.                                                                                                                                                                                                                                                                                                                                                                                 |
| Route          | Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dosage Text    | Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Duration       | The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Mfr            | The manufacturer of the product, as indicated in the report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 24-Apr-2000                  | 3463581                | NON-EXPEDITED      | Y                  | OT              | A001296              |                              | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective             | Viagra                 |                    |                    | S               | Oral                 | 100.00 Mg Total, Daily, Oral |                 | Not Reported |                |
|                              | Lexapro                |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                              | Unspecified Ingredient |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                              | Unspecified Ingredient |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Oct-2001                  | 3697588                | EXPEDITED (15-DAY) | Y                  | DE              | T01-FIN-01573-01     |                              | 49 YR           | Male         | FIN            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning;           | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 | Not Reported |                |
| Aspiration; Cardiac Arrest;  | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Qd Po                  |                 | Not Reported |                |
| Chest Pain; Circulatory      | Unspecified Ingredient |                    |                    | S               |                      |                              |                 | Not Reported |                |
| Collapse; Dermatitis;        | Alcohol                |                    |                    | S               |                      |                              |                 | Not Reported |                |
| Fatigue; Libido              |                        |                    |                    |                 |                      |                              |                 |              |                |
| Decreased; Sudden            |                        |                    |                    |                 |                      |                              |                 |              |                |
| Death; Vomiting              |                        |                    |                    |                 |                      |                              |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2001                  | 6747114                | EXPEDITED (15-DAY) | Y                  | HO, LT          | T01-FIN-01527-01     |                              | 25 YR           | Female       | FIN            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Arterial Disorder;           | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Qd Po                  |                 | Not Reported |                |
| Confusional State; Fall;     | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 | Not Reported |                |
| Hallucination; Injury; Joint | Ibusal (Ibuprofen)     |                    |                    | C               |                      |                              |                 | Not Reported |                |
| Dislocation; Pelvic          | Rennie                 |                    |                    | C               |                      |                              |                 | Not Reported |                |
| Fracture; Toxicologic Test   | Ibuprofen              |                    |                    | C               |                      |                              |                 | Not Reported |                |
| Abnormal; Urinary Bladder    | Ibuprofen              |                    |                    | C               |                      |                              |                 | Not Reported |                |
| Rupture; Wrist Fracture      | Ibuprofen              |                    |                    | C               |                      |                              |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|----------------------|----------------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| 26-Oct-2001                                                                                                                                                                                                                                                                                                                                  | 3701320                                                                                                                              | EXPEDITED (15-DAY) | Y                  | HO                         | T01-UKI-01263-01     |                                  | 89 YR           | Male                                                                                         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Chest X-Ray Abnormal;<br>Circulatory Collapse;<br>Coma; Femoral Neck<br>Fracture                                                                                                                                                                                                                                                             | Escitalopram Oxalate<br>Zoladex                                                                                                      |                    |                    | S<br>S                     | Oral                 | 10 Mg Qd Po                      |                 | Not Reported<br>Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 19-Nov-2001                                                                                                                                                                                                                                                                                                                                  | 3789982                                                                                                                              | DIRECT             | N                  | OT                         |                      |                                  | 46 YR           | Male                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Gynaecomastia                                                                                                                                                                                                                                                                                                                                | Escitalopram Oxalate                                                                                                                 |                    |                    | S                          | Oral                 | 30 Mg Oral                       |                 | Forest                                                                                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>                                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 26-Apr-2002                                                                                                                                                                                                                                                                                                                                  | 3789229                                                                                                                              | EXPEDITED (15-DAY) | Y                  | HO                         | T01-GER-01618-01     |                                  | 53 YR           | Female                                                                                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Alanine Aminotransferase<br>Increased; Blood<br>Cholinesterase Increased;<br>Blood Triglycerides<br>Increased; Diarrhoea;<br>Dilatation Atrial; Eye Pain;<br>Gait Disturbance; Gamma-<br>Glutamyltransferase<br>Increased; Hypertension;<br>Laboratory Test Abnormal;<br>Transient Ischaemic<br>Attack; Ventricular<br>Hypertrophy; Vomiting | Escitalopram Oxalate<br>Venlafaxine<br>Placebo<br>Levothyroxine Sodium<br>Metomerck (Metoprolol Tartrate)<br>Antra Mups (Omeprazole) |                    |                    | S<br>S<br>S<br>C<br>C<br>C | Oral<br>Oral         | 75 Mg Qd; Po<br>2 Capsule Qd; Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|---------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|----------------|----------------|
| 17-May-2002                                 | 6035453                | EXPEDITED (15-DAY) | Y                  | DE              | S02-SWI-00915-01     |                       | 53 YR           | Male           | CHE            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>     |                |
| Alcohol Use; Asphyxia;<br>Completed Suicide | Cipralext              |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported   |                |
|                                             | Lexotanil (Bromazepam) |                    |                    | C               |                      |                       |                 | Not Reported   |                |
|                                             | Somnium                |                    |                    | C               |                      |                       |                 | Not Reported   |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Sep-2002                                 | 3843398                | DIRECT             |                    | OT              |                      |                       | 50 YR           | Female         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>     |                |
| Feeling Jittery; Panic<br>Attack            | Lexapro                |                    |                    | S               |                      |                       |                 | Not Reported   |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 23-Sep-2002                                 | 3843988                | DIRECT             | N                  | LT              |                      |                       | 49 YR           | Female         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>     |                |
| Drug Withdrawal<br>Syndrome                 | Paxil                  |                    |                    | S               | Oral                 | 20 Mg 3 X Daily Oral  |                 | Glaxo Wellcome |                |
|                                             | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Once Daily Oral |                 | Glaxo Wellcome |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 30-Sep-2002                                 | 3848788                | DIRECT             | Y                  |                 |                      |                       | 15 YR           | Female         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>     |                |
| Medication Error                            | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Po              |                 | Forest         |                |
|                                             | Loxitane               |                    |                    | S               |                      | 10mg Po               |                 | Not Reported   |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 02-Oct-2002                                 | 3848219                | DIRECT             | N                  | OT              |                      |                       | 46 YR           | Female         | USA            |

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| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>             |                |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|------------------------|----------------|
| Confusional State;<br>Disorientation; Insomnia;<br>Movement Disorder; Pain<br>In Jaw; Paraesthesia;<br>Suicidal Ideation; Thinking<br>Abnormal | Lexapro                       |                  |                    | S               |                      | 10mg - A Tablet Daily |                 | Forest                 |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 09-Oct-2002                                                                                                                                    | 3851235                       | DIRECT           | Y                  | OT              |                      |                       |                 | Unknown                | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>             |                |
| Medication Error                                                                                                                               | Lexapro<br>Loxapine Succinate |                  |                    | S<br>S          |                      |                       |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 10-Oct-2002                                                                                                                                    | 4160684                       | DIRECT           | Y                  |                 |                      |                       | 43 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>             |                |
| Mania                                                                                                                                          | Lexapro                       |                  |                    | S               |                      |                       |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 15-Oct-2002                                                                                                                                    | 3853977                       | DIRECT           | Y                  | OT              |                      |                       | 78 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>             |                |
| Burning Sensation                                                                                                                              | Lexapro                       |                  |                    | S               |                      |                       |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 18-Oct-2002                                                                                                                                    | 3855981                       | DIRECT           | Y                  |                 |                      |                       |                 | Female                 | USA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>             |                |
| Dyskinesia                                                                                                                                     | Lexapro                       |                  |                    | S               | Oral                 | 10mg Po Daily         |                 | Not Reported           |                |

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| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2002                                                                                                                                               | 3850095                                        | EXPEDITED (15-DAY) | Y                  | OT              | T02-USA-02084-01     |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness Transient;<br>Migraine; Nausea;<br>Vasoconstriction;<br>Vasospasm; Vision<br>Blurred; Visual Field<br>Defect                                    | Lexapro                                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Depakote                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Celexa                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Trileptal                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Seroquel (Quetiapine)<br>(Quetiapine Fumarate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2002                                                                                                                                               | 3857267                                        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02227-01     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                   | Lexapro                                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Wellbutrin (Bupropion<br>Hydrochloride)        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Prozac                                         |                    |                    | S               |                      | 80 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                           | Prozac                                         |                    |                    | S               |                      | 40 Mg Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2002                                                                                                                                               | 3857274                                        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02254-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Confusional State;<br>Delirium; Disorientation;<br>Loss Of Consciousness;<br>Memory Impairment;<br>Respiratory Failure;<br>Syncope | Lexapro                                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Permax                                         |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Oct-2002                   | 3856038                 | DIRECT             | Y                  | RI, OT          |                      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Retinal Detachment | Lexapro                 |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
|                               | Trazodone Hydrochloride |                    |                    | S               |                      | 25 Mg Qhs            | 2 MTH           | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2002                   | 3858080                 | EXPEDITED (15-DAY) | Y                  | DS              | T02-USA-00199-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Type 2 Diabetes Mellitus      | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                               | Darvocet-N              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Zolpidem                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Ranitidine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Ibuprofen               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Phenergan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Nicotine                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Q-Bid La (Guaifenesin)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Cephalexin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Cough Syrup (Nos)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2002                   | 3858111                 | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-02406-01     |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure        | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2002                   | 3861036                 | EXPEDITED (15-DAY) | Y                  | LT              | S02-DEN-02491-01     |                      | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                       |   |      |             |  |  |  |  |              |
|------------------------|-----------------------|---|------|-------------|--|--|--|--|--------------|
| Hyponatraemia; Seizure | Cipralex              | S | Oral | 20 Mg Qd Po |  |  |  |  | Not Reported |
|                        | Alprox (Alprazolam)   | C |      |             |  |  |  |  | Not Reported |
|                        | Pacisyn (Nitrazepam)  | C |      |             |  |  |  |  | Not Reported |
|                        | Ostradiol (Estradiol) | C |      |             |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2002              | 3862765       | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02473-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Lexapro        |              |            | S           | Oral         | 10 Mg Once Po      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2002              | 3864123       | DIRECT           | Y                  | OT              |                      |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Atrioventricular Block<br>Second Degree;<br>Conduction Disorder;<br>Dizziness; Dyspnoea;<br>Heart Rate Decreased | Lexapro        |              |            | S           | Oral         | 10,G Qd Oral       |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2002              | 3866751       | EXPEDITED (15-DAY) | Y                  | DE              | S02-USA-02585-01     |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun<br>Shot Wound | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2002              | 4160676       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S02-USA-02611-01     |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation;<br>Bradycardia; Drug | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |             |   |           |  |              |
|--------------------------|-------------|---|-----------|--|--------------|
| Interaction; Hypotension | Atenolol    | S | 100 Mg Qd |  | Not Reported |
|                          | Xanax       | C |           |  | Not Reported |
|                          | Mevacor     | C |           |  | Not Reported |
|                          | Micardis    | C |           |  | Not Reported |
|                          | Hydrodiuril | C |           |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2002              | 6999061       | DIRECT           | Y                  | OT              |                      |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|------------|
| Asthenia; Atrioventricular Block Second Degree; Dizziness; Dyspnoea | Lexapro        |              |            | S           | Oral         | 10mg Once Daily Oral |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2002              | 3867741       | EXPEDITED (15-DAY) | Y                  | HO              | S020-USA-02751-01    |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urticaria             | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2002              | 3868104       | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2002US09514      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Drug Level Above Therapeutic; Fall | Tegretol                                  |              |            | S           | Oral         | 1000 Mg, Oral      |                 | Not Reported |
|                                              | Lexapro                                   |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |
|                                              | Imitrex "Cerenex" (Sumatriptan Succinate) |              |            | C           |              |                    |                 | Not Reported |
|                                              | Topimax (Topiramate)                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2002              | 3868510       | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02691-01     |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

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### Detailed Report

|                                                                       |                        |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Large Intestine Perforation                                           | Lexapro                |                    | S                  | Oral            | 10 Mg Qd Po          |                      | Not Reported    |              |                |
|                                                                       | Unspecified Ingredient |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2002                                                           | 3870307                | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2002US09578      |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                         | Trileptal              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                       | Lexapro                |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                       | Sonata                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Klonopin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | K-Dur                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Phenergan              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Vioxx                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2002                                                           | 3871236                | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | C2002-3228.01        |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;<br>Bradycardia; Drug<br>Interaction; Hypotension | Lexapro                |                    |                    | S               | Oral                 | 10mg Qd, Oral        |                 | Forest       |                |
|                                                                       | Atenolol               |                    |                    | S               | Oral                 | 100 Mg Qd, Oral      |                 | Not Reported |                |
|                                                                       | Alprazolam             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Lovastatin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Telmisartan            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Hydrochlorothiazide    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2002                                                           | 3869597                | DIRECT             | Y                  | OT              |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                                             | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Po Bid         |                 | Not Reported |                |



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| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Nov-2002                                            | 3869598                 | DIRECT                    | Y                           | OT                       |                               |                               | 23 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness                                              | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Po Bid                  | 3 DAY                    | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Nov-2002                                            | 3870097                 | DIRECT                    | Y                           | OT                       |                               |                               | 30 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dysphoria; Tremor                                      | Lexapro                 |                           |                             | S                        | Oral                          | 10mg Po Qd                    | 6 WEEK                   | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Nov-2002                                            | 3872086                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S02-USA-03135-01              |                               | 31 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                      | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Dec-2002                                            | 3871605                 | DIRECT                    | N                           | HO, OT                   |                               |                               | 28 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal;<br>Nausea; Panic Attack;<br>Vomiting | Lexapro                 |                           |                             | S                        | Oral                          | 10mg 1x Day Oral              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Dec-2002                                            | 3872426                 | DIRECT                    | Y                           | HO, RI                   |                               |                               | 72 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                               |                                                                      |                    |                    |                       |                            |                              |                 |                                                                              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------------|------------------------------|-----------------|------------------------------------------------------------------------------|----------------|
| Asthenia; Dizziness;<br>Hypertension;<br>Hyponatraemia; Nausea                                                                                                                                                                                                                                |                                                                      | Lexapro<br>Avalide | S<br>S             | Oral<br>Oral          | 10 Mg Qd Po<br>12.5 Bid Po | Not Reported<br>Not Reported |                 |                                                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
| 06-Dec-2002                                                                                                                                                                                                                                                                                   | 3873867                                                              | DIRECT             | N                  | OT                    |                            |                              | 24 YR           | Female                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Asthenia; Back Pain;<br>Dyskinesia; Gait<br>Disturbance; Headache;<br>Insomnia; Migraine;<br>Nausea; Tremor; Vomiting                                                                                                                                                                         | Lexapro                                                              |                    |                    | S                     | Oral                       | 10mg 1x A Day Oral           |                 | Forest                                                                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
| 06-Dec-2002                                                                                                                                                                                                                                                                                   | 3875689                                                              | EXPEDITED (15-DAY) | Y                  | HO                    | S02-USA-03137-01           |                              | 37 YR           | Male                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Migraine                                                                                                                                                                                                                                                                                      | Lexapro                                                              |                    |                    | S                     | Oral                       | 10 Mg Qd Po                  |                 | Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>       | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
| 09-Dec-2002                                                                                                                                                                                                                                                                                   | 3857922                                                              | EXPEDITED (15-DAY) | Y                  | HO, LT, RI            | S02-USA-02265-01           |                              | 45 YR           | Female                                                                       |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>               | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Affect Lability; Aggression;<br>Agitation; Brain Oedema;<br>Clonic Convulsion;<br>Hallucination, Auditory;<br>Hiatus Hernia;<br>Hyporeflexia;<br>Hypotension;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Muscle Injury; Myocardial<br>Infarction; Myocardial<br>Ischaemia; Oxygen | Lexapro<br>Celexa<br>Risperdal<br>Lithium<br>Trazodone Hydrochloride |                    |                    | S<br>S<br>C<br>C<br>C | Oral<br>Oral               | 10 Mg Qd Po<br>10 Mg Bid Po  |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

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Saturation Decreased;  
Polydipsia Psychogenic;  
Pulmonary Oedema;  
Rash; Serotonin  
Syndrome; Social  
Avoidant Behaviour;  
Supraventricular  
Tachycardia; Syncope;  
Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2002              | 3878243       | EXPEDITED (15-DAY) | Y                  | HO              | S02-UKI-02048-01     |                      | 43 YR      | Male       | GBR            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse;              | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Dizziness; Hypoaesthesia;          | Cipralelex     |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Nausea; Vertigo; Vision<br>Blurred |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2002              | 3879005       | EXPEDITED (15-DAY) | Y                  |                 | M1277-2002           |                      | 43 YR      | Male       | CHE            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;                            | Mirtazapine    |              |            | S           | Oral         | 30 Mg              |                 | Not Reported |
| Aggression; Amnesia;                           | Cipralelex     |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
| Injury; Loss Of<br>Consciousness;<br>Screaming |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2002              | 3871819       | EXPEDITED (15-DAY) | Y                  | DE, OT          | S02-UKI-03175-01     |                      | 64 YR      | Female     | GBR            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Plasma Cell Leukaemia;<br>Renal Failure | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 13-Dec-2002                              | 3879043                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S02-UKI-03389-01              |                               | 37 YR                    | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Schizophreniform Disorder                | Ciprallex               |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                              | 3880400                 | DIRECT                    | Y                           | OT                       |                               |                               | 25 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Psychomotor Hyperactivity                | Lexapro                 |                           |                             | S                        | Oral                          | 1/2 Tab(S) Po Oral            |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                              | 3891069                 | NON-EXPEDITED             | Y                           | HO                       | S02-USA-03049-01              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Intentional Overdose;<br>Suicide Attempt | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                              | 3891073                 | NON-EXPEDITED             | Y                           | HO                       | S02-USA-02974-01              |                               | 55 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradycardia; Malaise                     | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                              | 3891076                 | NON-EXPEDITED             | Y                           | OT                       | S02-USA-02282-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Rash                                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Dec-2002                       | 3891078                 | NON-EXPEDITED             | Y                           | OT                       | S02-USA-02223-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Somnolence                        | Lexapro                 |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                       | 3891084                 | NON-EXPEDITED             | Y                           | OT                       | S02-USA-02208-01              |                               | 17 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyperglycaemia                    | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Insulin Nos             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                       | 3891087                 | NON-EXPEDITED             | Y                           | HO                       | S02-USA-02133-01              |                               | 91 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Syncope                           | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Dec-2002                       | 3891091                 | NON-EXPEDITED             | Y                           | RI, OT                   | S02-USA-02005-01              |                               | 44 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chills; Headache;                 | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| Hypersensitivity; Nausea;         | Celexa                  |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| Neck Pain; Pain;                  | Vitamins Nos            |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| Paraesthesia;                     | Naproxen                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| Photophobia; Pruritus;            |                         |                           |                             |                          |                               |                               |                          | Not Reported        |                         |
| Pyrexia; Rash                     |                         |                           |                             |                          |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2002                       | 3878602                 | DIRECT                    | Y                           | DE                       |                               |                               | 48 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Death                            | Lexapro        |                    |                    | S               | Oral                 | 20mg Oral            |                 | Forest       |                |
|                                  | Klonopin       |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                  | Ambien         |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                  | Lexapro        |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2002                      | 3882535        | EXPEDITED (15-DAY) | Y                  | DE              | S02-UKI-03446-01     |                      | 82 YR           | Female       | GBR            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Sudden Death         | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2002                      | 3882543        | EXPEDITED (15-DAY) | Y                  | DS              | S02-SWI-03423-01     |                      | 43 YR           | Male         | CHE            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcohol Use; Amnesia | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                  | Remeron        |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2002                      | 3882568        | EXPEDITED (15-DAY) | Y                  | HO              | S02-UKI-03434-01     |                      | 18 YR           | Male         | GBR            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                          | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                  | Paracetamol    |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2002                      | 3881802        | DIRECT             | Y                  | OT              |                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Insomnia;             | Lexapro        |                    |                    | S               | Oral                 | 5mg Qd Oral          |                 | Forest       |                |

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Muscle Tightness;  
Psychomotor Hyperactivity

| <u>FDA Received Date</u>     | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 23-Dec-2002                  | 3891707           | NON-EXPEDITED    | Y                  | HO              | 200227030BWH         |                      | 53 YR           | Female                       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Liver Function Test Abnormal | Avelox<br>Lexapro |                  |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|----------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 24-Dec-2002                                  | 3866698                                   | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02610-01     |                      | 70 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Inappropriate Antidiuretic Hormone Secretion | Lexapro<br>Hydrochlorothiazide<br>Remeron |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 24-Dec-2002                                                                                                       | 3866731                           | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02658-01     |                      | 63 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Confusional State;<br>Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Memory Impairment; Speech Disorder | Lexapro<br>Sumanitrole<br>Alcohol |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2002              | 3866744        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02680-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |

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|         |             |   |      |             |              |
|---------|-------------|---|------|-------------|--------------|
| Seizure | Lexapro     | S | Oral | 10 Mg Qd Po | Not Reported |
|         | Lexapro     | S | Oral | 10 Mg Qd Po | Not Reported |
|         | Duragesic   | C |      |             | Not Reported |
|         | Hydrocodone | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2002              | 3879040       | EXPEDITED (15-DAY) | Y                  | HO              | S02-FRA-03401-01     |                      | 27 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Anuria;<br>Dysuria; Urinary Retention | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                       | Cyamemazine          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2002              | 3883104       | EXPEDITED (15-DAY) | Y                  | DE              | S02-USA-03289-01     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Poisoning; Drug<br>Level Below Therapeutic | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                    | Alcohol        |              |            | S           |              |                    |                 | Not Reported |
|                                                    | Xanax          |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2002              | 3883218       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S02-USA-03280-01     |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatinine<br>Increased; Blood Urea<br>Increased; Decreased<br>Appetite; Dehydration;<br>Dialysis; Diarrhoea; Drug<br>Level Above Therapeutic;<br>Oligodipsia; Toxicity To<br>Various Agents | Lexapro                                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                    | Lexapro                                       |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                                                                    | Eskalith - Slow Release(Lithium<br>Carbonate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Vioxx                                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Premarin                                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Synthroid                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                    | Lisinopril                                    |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 24-Dec-2002                                  | 3884353        | EXPEDITED (15-DAY) | Y                  | HO              | S02-UKI-03481-01     |                        | 96 YR           | Female       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion | Ciprallex      |                    |                    | S               | Oral                 | 5 Mg Qd Po             |                 | Not Reported |                |
|                                              | Frusemide      |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                              | Gliclazide     |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                              | Ramipril       |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2002                                  | 3891820        | NON-EXPEDITED      | Y                  | HO, OT          | A0383258A            |                        | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                      | Wellbutrin     |                    |                    | S               | Oral                 | Oral                   |                 | Not Reported |                |
|                                              | Lexapro        |                    |                    | S               | Oral                 | 10 Mg / Per Day / Oral |                 | Not Reported |                |
|                                              | Fluoxetine     |                    |                    | S               | Oral                 | 80 Mg / Per Day / Oral |                 | Not Reported |                |
|                                              | Fluoxetine     |                    |                    | S               | Oral                 | 40 Mg / Per Day / Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2002                                  | 3883577        | DIRECT             | Y                  | HO, RI          |                      |                        | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Sodium Decreased; Dysarthria | Lexapro        |                    |                    | S               | Oral                 | 10mg Daily Oral        |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2003                                  | 3886913        | EXPEDITED (15-DAY) | Y                  | HO, OT          | S02-USA-03345-01     |                        | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastritis Haemorrhagic; Haematemesis         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po            |                 | Not Reported |                |
|                                              | Coumadin       |                    |                    | C               |                      |                        |                 | Not Reported |                |

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|                                                                                                         |                                    |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Fosamax                                                                                                 |                                    | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| Protonix                                                                                                |                                    | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2003                                                                                             | 3887021                            | EXPEDITED (15-DAY) | Y                  | DE              | 2002139883US         |                      | 37 YR           | Female       |                |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning                                                                                       | Xanax                              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                         | Alcohol (Ethanol)                  |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                         | Lexapro                            |                    |                    | S               | Oral                 | See Image            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2003                                                                                             | 3888231                            | EXPEDITED (15-DAY) | Y                  | HO              | T02-FRA-00027-01     |                      | 62 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Fall; Femoral Neck Fracture                                                           | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Placebo                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Mediator(Benfluorex Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Adalate Lp                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Acetaminophen                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Inipomp                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Optruma                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2003                                                                                             | 3875692                            | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-03204-01     |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysgeusia; Glossitis; Glossodynia; Impaired Healing; Tongue Disorder; Tongue Haemorrhage; Tongue Oedema | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2003                              | 3888332                        | EXPEDITED (15-DAY) | Y                  | HO              | T01-CZE-01612-01     |                      | 18 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Suicide Attempt                | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                          | Placebo                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Defobin (Chlordiazeproxide)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Ibuprofen                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2003                              | 3888334                        | EXPEDITED (15-DAY) | Y                  | OT              | T01-UKI-01695-01     |                      | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Facial Paralysis; Nausea                 | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                          | Placebo                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2003                              | 3888335                        | EXPEDITED (15-DAY) | Y                  | OT              | T02-EST-00049-01     |                      | 29 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthritis; Mood Altered; Suicide Attempt | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Placebo                        |                    |                    | S               |                      | 1 Tablet Qd Po       |                 | Not Reported |                |
|                                          | Valerian                       |                    |                    | S               |                      | 27 Tablet Qd Po      |                 | Not Reported |                |
|                                          | Diclofenac (Diclofenac Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Ciprinol (Ciprofloxacin)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Novalis (Meloxicam)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2003                              | 3888337                        | EXPEDITED (15-DAY) | Y                  | OT              | T01-UK1-01694-01     |                      | 56 YR           | Male         | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                        |                      |   |      |             |              |
|----------------------------------------------------------------------------------------|----------------------|---|------|-------------|--------------|
| Anxiety; Disorientation;<br>Myocardial Ischaemia;<br>Nausea; Paraesthesia;<br>Vomiting | Escitalopram Oxalate | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                                                        | Placebo              | S |      |             | Not Reported |
|                                                                                        | Diazepam             | C |      |             | Not Reported |
|                                                                                        | Metoclopramide       | C |      |             | Not Reported |
|                                                                                        | Lansoprazole         | C |      |             | Not Reported |
|                                                                                        | Pravastatin Sodium   | C |      |             | Not Reported |
|                                                                                        | Fybogel              | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2003              | 3889566       | EXPEDITED (15-DAY) | Y                  | DE              | NSADSS2003000776     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Confusional State;<br>Pulmonary Embolism | Ortho Tri Cyclen   |              |            | S           | Oral         | 1 Table, Daily, Oral |                 | Not Reported |
|                                                                        | Lexapro            |              |            | S           | Oral         | 5 Mg, Daily, Oral    |                 | Not Reported |
|                                                                        |                    |              |            |             | Oral         | 5 Mg, Daily, Oral    |                 |              |
|                                                                        | Asthma Inhaler Nos |              |            | C           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2003              | 3888743       | DIRECT           | Y                  |                 |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Panic Disorder        | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2003              | 3888744       | DIRECT           | Y                  | OT              |                      |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Insomnia; Panic Disorder | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2003              | 3871537       | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-02976-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                                    |   |      |             |              |
|---------------------------------------------|------------------------------------|---|------|-------------|--------------|
| Cardiac Failure                             | Lexapro                            | S | Oral | 10 Mg Qd Po | Not Reported |
| Congestive; Oedema;<br>Pulmonary Congestion | Levothyroid (Levothyroxine Sodium) | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2003              | 3890843       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00006-01     |                      | 47 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epileptic Aura        | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Tegretol       |              |            | S           | Oral         | 600 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jan-2003              | 3891284       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00005-01     |                      | 50 YR      | Female     | GBR            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased | Cipralext      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                    | Olanzapine     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2003              | 3893759       | DIRECT           | Y                  | RI              |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rash Pruritic         | Lexapro                 |              |            | S           | Oral         | 10 Mg Po Qam       |                 | Not Reported |
|                       | Lasix                   |              |            | C           |              |                    |                 | Not Reported |
|                       | K                       |              |            | C           |              |                    |                 | Not Reported |
|                       | Dilantin                |              |            | C           |              |                    |                 | Not Reported |
|                       | Lithium                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Glucophage              |              |            | C           |              |                    |                 | Not Reported |
|                       | Famotidine              |              |            | C           |              |                    |                 | Not Reported |
|                       | Klonopin                |              |            | C           |              |                    |                 | Not Reported |
|                       | Singulair               |              |            | C           |              |                    |                 | Not Reported |
|                       | Verapamil Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                            |                       |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Asa                                                        |                       |                    | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2003                                                | 3870970               | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-02893-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                               | Lexapro               |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2003                                                | 3893175               | DIRECT             | Y                  | HO, RI          |                      |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                           | Zyprexa               |                    |                    | S               | Oral                 | 7.5mg Qhs Oral       |                 | Not Reported |                |
|                                                            | Lexapro               |                    |                    | S               | Oral                 | 10mg Qd Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2003                                                | 3893740               | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-03235-01     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Pain; Head Injury; Medication Error; Migraine; Seizure | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                            | Ativan                |                    |                    | S               |                      | 3 Mg Qd              |                 | Not Reported |                |
|                                                            | Demerol               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                            | Vicodin               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                            | Nicotine              |                    |                    | S               |                      | 14 Mg Qd             |                 | Not Reported |                |
|                                                            | Tylenol (Paracetamol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2003                                                | 3896275               | DIRECT             | N                  |                 |                      |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Disturbance In Attention;                  | Lexapro               |                    |                    | S               | Oral                 | 20mg Once Daily Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dizziness; Feeling Of  
Body Temperature  
Change; Headache;  
Irritability; Mania; Nausea;  
Paraesthesia

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2003                                                                                               | 3895984        | EXPEDITED (15-DAY) | Y                  | DE              | S02-UK1-03446-01     |                      | 82 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Cardiac Failure<br>Congestive; Myocardial<br>Ischaemia; Sudden Death                          | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Aspirin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Digoxin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Furosemide     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Lisinopril     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2003                                                                                               | 3896486        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00181-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Dystonia;<br>Hypokalaemia;<br>Hyponatraemia;<br>Hypotension; Intentional<br>Overdose; Vomiting | Lexapro        |                    |                    | S               |                      | 70 Mg Once Po        |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2003                                                                                               | 3896537        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00180-01     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Flushing;<br>Palpitations; Serotonin<br>Syndrome                                              | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jan-2003                                     | 3898157        | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-00260-01     |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Muscle Spasms;<br>Seizure; Vomiting    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                 | Celexa         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2003                                     | 3867749        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02750-01     |                      | 81 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Reglan         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Coumadin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Macrobid       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2003                                     | 3871764        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02964-01     |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenal Ulcer<br>Haemorrhage                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Klonopin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Synthroid      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Zocor          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Clonazepam     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2003                                     | 3883239        | EXPEDITED (15-DAY) | Y                  | OT              | T02-USA-03428-01     |                      | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Male Orgasmic Disorder;                         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Phlebitis                                                                                                                                                | Claritin               |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                          | Viagra                 |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                          | Wellbutrin Sr          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2003                                                                                                                                              | 3898231                | DIRECT             | Y                  | LT              |                      |                      | 95 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Biopsy Bone Marrow Abnormal; Bone Marrow Disorder; Cellulitis; Decreased Appetite; Malaise; Neutrophil Count Decreased; White Blood Cell Count Decreased | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Po Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2003                                                                                                                                              | 3898882                | EXPEDITED (15-DAY) | N                  | HO              | S03-USA-00215-01     |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Somnolence; Suicidal Ideation                                                                                                                | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                          | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                          | Topamax                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2003                                                                                                                                              | 3900187                | DIRECT             | Y                  | HO              |                      |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                         | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10mg Qd Po           | 2 WEEK          | Not Reported |                |
|                                                                                                                                                          | Unspecified Ingredient |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2003                                                                                                                                              | 3872117                | EXPEDITED (15-DAY) | N                  | HO              | S02-USA-03124-01     |                      | 15 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>     |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|----------------|----------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Weight Decreased                                                 | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 06-Feb-2003                                                                                                                                | 3904409                 | EXPEDITED (15-DAY) | Y                  | RI              |                      | 03P-163-0209312-00        | 39 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>     |                |
| Confusional State; Depression; Drug Interaction; Drug Withdrawal Syndrome; Fall; Head Injury; Migraine; Seizure; Tenderness; Tongue Biting | Vicodin                 |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Per Oral |                 | Not Reported   |                |
|                                                                                                                                            | Lexapro                 |                    |                    | S               |                      |                           |                 | Not Reported   |                |
|                                                                                                                                            | Lorazepam               |                    |                    | S               |                      |                           |                 | 3 Mg, 1 In 1 D | Not Reported   |
|                                                                                                                                            | Pethidine Hydrochloride |                    |                    | S               |                      | 14 Mg, 1 In 1 D           |                 | Not Reported   |                |
|                                                                                                                                            | Nicotine                |                    |                    | S               |                      |                           |                 | Not Reported   |                |
|                                                                                                                                            | Paracetamol             |                    |                    | C               |                      |                           |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 06-Feb-2003                                                                                                                                | 3904635                 | EXPEDITED (15-DAY) | Y                  | HO              |                      | S03-USA-00357-01          | 25 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>     |                |
| Influenza; Leukopenia; Thrombocytopenia                                                                                                    | Lexapro                 |                    |                    | S               |                      |                           |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 06-Feb-2003                                                                                                                                | 3932655                 | DIRECT             | Y                  | HO, RI          |                      |                           | 69 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>     |                |
| Abnormal Behaviour; Agitation; Blood Pressure Systolic Increased; Confusional State; Depression; Mental Status                             | Lexapro                 |                    |                    | S               | Oral                 | Oral                      |                 | Not Reported   |                |
|                                                                                                                                            | Aciphex                 |                    |                    | C               |                      |                           |                 | Not Reported   |                |
|                                                                                                                                            | Premarin                |                    |                    | C               |                      |                           |                 | Not Reported   |                |
|                                                                                                                                            | Vioxx                   |                    |                    | C               |                      |                           |                 | Not Reported   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                      |                       |                    |                    |                 |                      |                                                                    |                 |            |                |
|------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|------------|----------------|
| Changes; Psychomotor Hyperactivity                                                                   | Metoprolol Hctz       |                    |                    | C               |                      |                                                                    |                 |            | Not Reported   |
|                                                                                                      |                       |                    |                    | C               |                      |                                                                    |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Feb-2003                                                                                          | 3902999               | EXPEDITED (15-DAY) | Y                  | OT              | S03-FRA-00475-01     |                                                                    | 42 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u> |                |
| Amenorrhoea; Flushing; Syncope; Thyroid Disorder                                                     | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 5 Mg Qd Po                                                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Feb-2003                                                                                          | 3903002               | EXPEDITED (15-DAY) | Y                  | HO              | S03-IRL-00422-01     |                                                                    |                 | Male       | IRL            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u> |                |
| Urinary Retention                                                                                    | Lexapro               |                    |                    | S               |                      |                                                                    |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Feb-2003                                                                                          | 3904626               | EXPEDITED (15-DAY) | Y                  | OT              | HQWYE071329JAN03     |                                                                    | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u> |                |
| Confusional State; Eye Pain; Fall; Head Injury; Migraine; Seizure; Tenderness; Tongue Biting; Tremor | Ativan                |                    |                    | S               | Oral                 | 3 Mg 1x Per 1 Day, Oral                                            |                 |            | Not Reported   |
|                                                                                                      | Demerol               |                    |                    | S               | Oral                 | Oral                                                               |                 |            | Not Reported   |
|                                                                                                      | Lexapro               |                    |                    | S               | Oral                 | 10 Mg 1x Per 1 Day, Oral                                           |                 |            | Not Reported   |
|                                                                                                      | Nicotine              |                    |                    | S               | Transdermal          | 14 Mg 1x Per 1 Day, Transdermal                                    |                 |            | Not Reported   |
|                                                                                                      | Vicodin               |                    |                    | S               | Oral                 | Six To Eight Tablets Per Day For Three To Four Days Per Week, Oral |                 |            | Not Reported   |
|                                                                                                      | Tylenol (Paracetamol) |                    |                    | C               |                      |                                                                    |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Feb-2003                                                                                          | 3905275               | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00450-01     |                                                                    | 40 YR           | Male       | USA            |

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| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Generalised Tonic-Clonic Seizure                                                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Acyclovir               |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                                                                                                                           | Disulfiram              |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                                                                                                                           | Neurontin               |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                                                                                                                           | Seroquel                |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                                                                                                                           | Synthroid               |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2003                                                                                                                                                                                                               | 3905289                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00416-01     |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Dialysis; Mental Status Changes; Rhabdomyolysis                                                                                                                                                      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Dexatrim                |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2003                                                                                                                                                                                                               | 3867072                 | EXPEDITED (15-DAY) | Y                  | OT              | T02-USA-02780-01     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Epileptic Aura; Fall; Flushing; Generalised Tonic-Clonic Seizure; Head Injury; Headache; Hyperhidrosis; Malaise; Micturition Urgency; Nausea; Nervousness; Somnolence; Syncope; Urinary Incontinence; Vomiting | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Multivitamins With Iron |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2003                                                                                                                                                                                                               | 3906282                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00508-01     |                      | 54 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                              |                                                                    |   |      |             |              |
|------------------------------|--------------------------------------------------------------------|---|------|-------------|--------------|
| Depression; Drug Interaction | Ciprallex                                                          | S | Oral | 10 Mg Qd Po | Not Reported |
|                              | Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride) | S |      |             | Not Reported |
|                              | Unspecified Ingredient                                             | C |      |             | Not Reported |
|                              |                                                                    |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2003              | 3910758       | EXPEDITED (15-DAY) | N                  | HO, OT          | 2003005280           |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depression; Petit Mal Epilepsy; Stress; Treatment Noncompliance; Weight Decreased | Neurontin                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                            | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Oxcarbazepine            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Trazodone Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Fluoxetine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Insulin Nos              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2003              | 3906394       | DIRECT           | Y                  | RI              |                      |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Decreased; International Normalised Ratio Increased; Prothrombin Time Prolonged | Lexapro            |              |            | S           | Oral         | 20 Mg Daily Oral   |                 | Not Reported |
|                                                                                            | Coumadin           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Metoprolol         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Amlodipine         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Benazepril         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Divalproex Sodium  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Abilify            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Synthroid          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Pravastatin Sodium |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Rosiblitazone      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Geodon             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            |                    |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2003              | 3906842       | DIRECT           | Y                  | RI              |                      |                      | 82 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Haemorrhage; Implant Site Reaction; International Normalised Ratio Increased; Prothrombin Time Prolonged | Lexapro            |                    |                    | S               | Oral                 | 20 Mg Daily Oral     |                 | Not Reported |                |
|                                                                                                          | Demadex            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Losartan Potassium |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Duragesic          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Coumadin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Calcium Kcl        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2003                                                                                              | 3906903            | NON-EXPEDITED      | Y                  |                 | 2002136869US         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Interaction; Feeling Hot; Heart Rate Increased                                             | Zyvox              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Lexapro            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2003                                                                                              | 3910501            | EXPEDITED (15-DAY) | Y                  | HO, RI          | S03-USA-00532-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Amylase Increased; Biliary Tract Disorder; Gallbladder Disorder; Lipase Increased        | Lexapro            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Diovan             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2003                                                                                              | 3910504            | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00557-01     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Palpitations                                                                   | Lexapro            |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Lexapro            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 19-Feb-2003                                                                       | 3910512        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00469-01     |                                     | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Meningitis Aseptic; Otitis Media                                                  | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po                         |                 | Not Reported |                |
|                                                                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po                         |                 | Not Reported |                |
|                                                                                   | Lexapro        |                    |                    | S               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2003                                                                       | 3932666        | DIRECT             | Y                  | RI              |                      |                                     | 90 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage; International Normalised Ratio Increased; Prothrombin Time Prolonged | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Daily Oral                    |                 | Not Reported |                |
|                                                                                   | Coumadin       |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Nifedipine     |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Levothyroxine  |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Lasix          |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Oscal          |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Catapres-Tts   |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Tylenol        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2003                                                                       | 3906993        | DIRECT             | Y                  | HO              |                      |                                     | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Movement Disorder; Seizure; Staring; Tremor                                 | Lexapro        |                    |                    | S               | Oral                 | 10mg Po Qhs[~2 Days Prior To Event] |                 | Not Reported |                |
|                                                                                   | Ultrase        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Mt-12          |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Darvocet-N 100 |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Aricept        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Aciphex        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Librox         |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                   | Lorazepam      |                    |                    | C               |                      |                                     |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                              | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|---------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|----------------------------------------------|----------------|
| 20-Feb-2003                                                                           | 3909541                        | DIRECT             | Y                  | OT              |                      |                                              | 24 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Diarrhoea; Dizziness;<br>Flushing; Nausea                                             | Lexapro<br>Clonazepam          |                    |                    | S<br>C          | Oral                 | 20mg 1/2 Tab Po Qd                           |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 21-Feb-2003                                                                           | 3912172                        | EXPEDITED (15-DAY) | Y                  | OT              | A-US2003-01993       |                                              | 44 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Muscle Twitching;<br>Neuropathy Peripheral;<br>Tremor                                 | Tracleer<br>Lexapro            |                    |                    | S<br>S          |                      | 62.5; 125 Mg Q12hrs,<br>62.5; 125 Mg Q12hrs, |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 21-Feb-2003                                                                           | 6999074                        | DIRECT             | Y                  | HO              |                      |                                              | 30 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Dystonia; Muscle Spasms;<br>Trismus                                                   | Lexapro                        |                    |                    | S               | Oral                 | 10 Mg Qd Oral                                |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 24-Feb-2003                                                                           | 3891860                        | EXPEDITED (15-DAY) | Y                  | HO              | T03-USA-00078-01     |                                              | 66 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Depression;<br>Hallucinations, Mixed;<br>Skin Abrasion; Suicidal<br>Ideation | Lexapro<br>Lipitor<br>Klonopin |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po                                  |                 | Not Reported<br>Not Reported<br>Not Reported |                |



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| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 25-Feb-2003                  | 3883194        | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-03236-01     |                         | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                              | Alcohol        |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2003                  | 3911635        | DIRECT             | N                  |                 |                      |                         | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                      | Lexapro        |                    |                    | S               |                      | Oral Used One Time Only |                 | Not Reported |                |
|                              | Xanax          |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2003                  | 3913119        | EXPEDITED (15-DAY) | N                  | HO              | 2003-103077-NL       |                         |                 | Female       |                |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Suicidal Ideation | Remeron        |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                              | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd; Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2003                  | 3922592        | NON-EXPEDITED      | N                  |                 | SU-2003-000406       |                         | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;        | Benicar        |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
| Agitation; Hyperhidrosis;    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| Hypoacusis; Vision           | Lortab         |                    |                    | C               |                      |                         |                 | Not Reported |                |
| Blurred                      |                |                    |                    |                 |                      |                         |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2003                  | 3857286        | EXPEDITED (15-DAY) | Y                  | OT              | T02-USA-02309-01     |                         | 55 YR           | Female       | USA            |

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| <u>Preferred Term</u>                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Asthenia; Drug Level Increased; Fall; Nausea | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Tegretol              |                    |                    | S               | Oral                 | 1000 Mg Qd Po        |                 | Not Reported |                |
|                                              | Tegretol              |                    |                    | S               | Oral                 | 1000 Mg Qd Po        |                 | Not Reported |                |
|                                              | Topamax               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Imitrex (Sumatriptan) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2003                                  | 3909920               | EXPEDITED (15-DAY) | Y                  | DE              |                      | S03-BEL-00502-01     | 67 YR           | Female       | BEL            |
| <u>Preferred Term</u>                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                            | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Novothyral            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Remergon              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Zolpidem Tartrate     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Inderal               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Valium                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2003                                  | 3914948               | EXPEDITED (15-DAY) | Y                  | OT              |                      | S03-USA-00729-01     | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Narcolepsy; Road Traffic Accident            | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                              | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Hydrocodone           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Elavil                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2003                                  | 6035455               | EXPEDITED (15-DAY) | Y                  | OT              |                      | S03-UKI-00764-01     | 41 YR           | Female       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Neutropenia; Vertigo                | Ciprallex             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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|                                                        |                             |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Prochlorperazine                                       |                             | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| Microgynon                                             |                             | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2003                                            | 3913890                     | DIRECT             | N                  | OT              |                      |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Ejaculation Disorder; Somnolence            | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2003                                            | 3915348                     | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00744-01     |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Conversion Disorder; Dystonia; Tardive Dyskinesia; Tic | Lexapro                     |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Albuterol                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Trileptal (Oxcarbamazepine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2003                                            | 3916399                     | DIRECT             |                    |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error                                       | Loxitane                    |                    |                    | S               |                      |                      |                 | Watson       |                |
|                                                        | Lexapro                     |                    |                    | S               |                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2003                                            | 5946613                     | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00773-01     |                      | 29 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Dysphemia                                  | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Mar-2003                                                                                                                                                                                                 | 6035456                                       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00772-01     |                      | 40 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Feeling Abnormal; Physical Assault; Spousal Abuse                                                                                                                                               | Cipralext                                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                             | Lansoprazole                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Diclofenac                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2003                                                                                                                                                                                                 | 3916889                                       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00666-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Decreased Appetite; Initial Insomnia; Intentional Self-Injury; Irritability; Obsessive-Compulsive Disorder; Psychomotor Hyperactivity; Refusal Of Treatment By Relative; Treatment Noncompliance | Lexapro                                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                             | Lexapro                                       |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                             | Celexa                                        |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2003                                                                                                                                                                                                 | 3917492                                       | EXPEDITED (15-DAY) | Y                  | DS              | S03-UKI-00832-01     |                      | 59 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Generalised; Rash Pruritic; Urticaria                                                                                                                                                                  | Cipralext                                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                             | Sodium Citrate                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Norfloracin                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Nitrofurantoin                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Influvac (Influenza Virus Vaccine Polyvalent) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Tolterodine                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Fluticasone                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                             | Albuterol                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                                                                                            |                        |                    |                    |                 |                      |                      |                 |            |                |
|------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Potassium                                                                                                  |                        |                    | C                  |                 |                      | Not Reported         |                 |            |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2003                                                                                                | 3914109                | DIRECT             | Y                  | HO              |                      |                      | 25 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Pain In Extremity; Skin Discolouration                                                           | Lexapro                |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2003                                                                                                | 3918245                | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-00844-01     |                      | 20 YR           | Female     | GBR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Orthostatic Hypotension; Syncope                                                                           | Ciprallex              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                            | Dianette               |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Mar-2003                                                                                                | 3883099                | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-03287-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blindness; Drug Ineffective; Intracranial Pressure Increased; Meningioma; Papilloedema; Temporal Arteritis | Lexapro                |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                            | Unspecified Ingredient |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                            | Unspecified Ingredient |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                            | Celexa                 |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Mar-2003                                                                                                | 3918173                | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-03107-01     |                      | 37 YR           | Female     |                |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Memory Impairment; Seizure; Stress; Toxicity                                                               | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                   |          |   |      |             |              |
|-----------------------------------|----------|---|------|-------------|--------------|
| To Various Agents; Vision Blurred | Lexapro  | S | Oral | 10 Mg Qd Po | Not Reported |
|                                   | Tegretol | S |      | 800 Mg Qd   | Not Reported |
|                                   | Tegretol | S |      |             | Not Reported |
|                                   | Keppra   | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2003              | 3919200       | EXPEDITED (15-DAY) | Y                  | HO              | S03-UKI-00842-01     |                      |            | Female     | GBR            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse; Seizure | Cipralext      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2003              | 3919211       | EXPEDITED (15-DAY) | Y                  | DS              | S03-SWI-00912-01     |                      | 75 YR      | Female     | CHE            |

| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Muscle Spasms; Tonic Clonic Movements | Cipralext               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                       | Cipralext               |              |            | S           |              | 20 Mg Qd Po        |                 | Not Reported |
|                                       | Cipralext               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                       | Irfen(Ibuprofen)        |              |            | C           |              |                    |                 | Not Reported |
|                                       | Acetylcysteine          |              |            | C           |              |                    |                 | Not Reported |
|                                       | Kcl(Potassium Chloride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2003              | 3920258       | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-00925-01     |                      | 35 YR      | Female     | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neurosis              | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2003              | 3924219       | NON-EXPEDITED    | N                  | OT              | S02-USA-02455-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                         |   |      |             |              |
|----------------------------|-------------------------|---|------|-------------|--------------|
| Abdominal Pain; Agitation; | Lexapro                 | S | Oral | 10 Mg Qd Po | Not Reported |
| Colitis; Depression;       | Lexapro                 | S | Oral | 20 Mg Qd Po | Not Reported |
| Epistaxis; Hostility;      | Lexapro                 | S | Oral | 10 Mg Qd Po | Not Reported |
| Menorrhagia; Rectal        | Effexor                 | C |      |             | Not Reported |
| Haemorrhage                | Klonopin                | C |      |             | Not Reported |
|                            | Trazodone Hydrochloride | C |      |             | Not Reported |
|                            | Lorazepam               | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2003              | 3924220       | NON-EXPEDITED    | Y                  | HO              | S03-USA-00615-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2003              | 3924225       | NON-EXPEDITED    | Y                  | HO              | S03-USA-00596-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety               | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2003              | 3924246       | NON-EXPEDITED    | Y                  | HO              | S03-USA-00577-02     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension          | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2003              | 3924247       | NON-EXPEDITED    | Y                  | HO              | S03-USA-00577-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertension          | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Mar-2003                 | 3924248                             | NON-EXPEDITED    | Y                  | OT              | S03-USA-00279-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Depression | Lexapro                             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Lexapro                             |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2003                 | 3924249                             | NON-EXPEDITED    | Y                  | HO              | S03-USA-00444-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression       | Lexapro                             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Remeron                             |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2003                 | 3924250                             | NON-EXPEDITED    | Y                  | HO              | S02-USA-03205-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Syncope          | Lexapro                             |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2003                 | 3924251                             | NON-EXPEDITED    | Y                  | HO              | S02-USA-03344-01     |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia               | Lexapro                             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Triamterene And Hydrochlorothiazide |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Coumadin                            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Toprol XL                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Lanoxin                             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Amaryl                              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Lipitor                             |                  |                    | C               |                      |                      |                 | Not Reported |                |



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Vitamins Nos  
Chondroitin Sulfate  
(Bovine)\Glucosamine Sulfate

C  
C

Not Reported  
Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Mar-2003                       | 3924252                | NON-EXPEDITED             | Y                           | HO                       | S03-USA-00459-01              |                               | 65 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>                    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Intentional Overdose;<br>Malaise; Suicide Attempt | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Qd Po                 |                          | Not Reported        |
|                                                   | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                                   | Ambien                  |                       |                     | S                    | Oral                  | 75 Mg Once Po               |                          | Not Reported        |
|                                                   | Ambien                  |                       |                     | S                    | Oral                  | 5 Mg Qhs Po                 |                          | Not Reported        |
|                                                   | Wellbutrin              |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2003                       | 3923182                | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-USA-00937-01              |                               | 25 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Pain In Extremity; Skin<br>Discolouration | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2003                       | 3923614                | EXPEDITED (15-DAY)        | Y                           | DE                       | S03-FRA-01071-01              |                               | 40 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Completed Suicide;<br>Disinhibition | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                     | Tranxene T-Tab          |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                     | Zolpidem Tartrate       |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                     | Tanakan                 |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Mar-2003                       | 3923617                | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-UKI-00926-01              |                               | 20 YR               | Female              | GBR                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| Blood Glucose Decreased;<br>Haemoglobin Decreased;<br>Maternal Drugs Affecting<br>Foetus; Postpartum<br>Haemorrhage; Retained<br>Placenta Or Membranes | Cipralext           |                    |                    | S               | Oral                 | 10 Mg Qd Po                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2003                                                                                                                                            | 3922548             | DIRECT             | Y                  | HO              |                      |                                                | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Dehydration;<br>Dizziness; Drug<br>Interaction; Hypotension;<br>Lethargy; Renal Failure                                                   | Zanaflex            |                    |                    | S               | Oral                 | 4mg Qd Oral                                    |                 | Not Reported |                |
|                                                                                                                                                        | Atenolol            |                    |                    | S               | Oral                 | 50 Qd Oral                                     |                 | Not Reported |                |
|                                                                                                                                                        | Lexapro             |                    |                    | S               | Oral                 | 10mg Qd Oral                                   |                 | Not Reported |                |
|                                                                                                                                                        | Diovan              |                    |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Norvasc             |                    |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Vioxx               |                    |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Aspirin             |                    |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Hydrochlorothiazide |                    |                    | C               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Temazepam           |                    |                    | C               |                      |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2003                                                                                                                                            | 3923437             | EXPEDITED (15-DAY) | Y                  | HO              | PHEH2003US02008      |                                                | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Memory Impairment;<br>Seizure; Toxicity To<br>Various Agents; Vision<br>Blurred                                           | Tegretol            |                    |                    | S               |                      | 800 Mg, Qd; See Image<br>800 Mg, Qd; See Image |                 | Not Reported |                |
|                                                                                                                                                        | Lexapro             |                    |                    | S               |                      |                                                |                 | Not Reported |                |
|                                                                                                                                                        | Keppra              |                    |                    | C               |                      |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2003                                                                                                                                            | 3925537             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01053-01     |                                                | 92 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|-----------------|----------------|
| Dry Mouth; Insomnia;<br>Intraocular Pressure<br>Increased                                                                                       | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported    |                |
|                                                                                                                                                 | Synthroid                           |                    |                    | C               |                      |                             |                 | Not Reported    |                |
|                                                                                                                                                 | Unspecified Ingredient              |                    |                    | C               |                      |                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 21-Mar-2003                                                                                                                                     | 4119551                             | EXPEDITED (15-DAY) | Y                  | DE              | S03-UKI-01093-01     |                             | 62 YR           | Female          | GBR            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Sudden Death                                                                                                                                    | Cipralext                           |                    |                    | S               | Oral                 | 10 Mg Qd; Po                |                 | Not Reported    |                |
|                                                                                                                                                 | Spiriva                             |                    |                    | S               |                      | Respiratory<br>(inhalation) |                 | 18 Mcg, Unk, Ih | Not Reported   |
|                                                                                                                                                 | Temazepam                           |                    |                    | C               |                      |                             |                 | Not Reported    |                |
|                                                                                                                                                 | Budesonide                          |                    |                    | C               |                      | Not Reported                |                 |                 |                |
|                                                                                                                                                 | Morphine                            |                    |                    | C               |                      | Not Reported                |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Mar-2003                                                                                                                                     | 3879586                             | EXPEDITED (15-DAY) | Y                  | DE              | S02-USA-03224-01     |                             | 37 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Bradycardia; Cardio-<br>Respiratory Arrest;<br>Cardiomegaly;<br>Confusional State; Hepatic<br>Congestion; Pulmonary<br>Embolism; Sleep Disorder | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported    |                |
|                                                                                                                                                 | Lexapro                             |                    |                    | S               |                      | Oral                        |                 | 5 Mg Qd Po      | Not Reported   |
|                                                                                                                                                 | Ortho Tri Cyclen                    |                    |                    | S               |                      | 1 Tablet Qd                 |                 | Not Reported    |                |
|                                                                                                                                                 | Unknown Birth Control<br>Medication |                    |                    | C               |                      |                             |                 | Not Reported    |                |
|                                                                                                                                                 | Unknown Asthma Inhaler              |                    |                    | C               |                      |                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Mar-2003                                                                                                                                     | 3918159                             | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00791-01     |                             | 56 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Bradycardia; Dizziness;<br>Hypotension; Intentional                                                                                             | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported    |                |

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|                           |                |   |      |            |  |  |  |  |              |
|---------------------------|----------------|---|------|------------|--|--|--|--|--------------|
| Overdose; Suicide Attempt | Lexapro        | S | Oral | 5 Mg Qd Po |  |  |  |  | Not Reported |
|                           | Diltiazem      | S |      |            |  |  |  |  | Not Reported |
|                           | Diltiazem      | C |      |            |  |  |  |  | Not Reported |
|                           | Maxzide        | C |      |            |  |  |  |  | Not Reported |
|                           | Diovan         | C |      |            |  |  |  |  | Not Reported |
|                           | Tricor         | C |      |            |  |  |  |  | Not Reported |
|                           | Tranxene T-Tab | C |      |            |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2003              | 3907372       | EXPEDITED (15-DAY) | Y                  | OT              | T03-USA-00478-01     |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Alcohol Increased;<br>Haematemesis;<br>Hypokalaemia; Upper<br>Gastrointestinal<br>Haemorrhage | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                     | Zantac         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2003              | 3926399       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01145-01     |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pulmonary Embolism    | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2003              | 3918165       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00868-01     |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Idiopathic Intracranial<br>Hypertension; Nuclear<br>Magnetic Resonance<br>Imaging Brain Abnormal;<br>Papilloedema; Vertigo;<br>Visual Field Defect | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Glucophage     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                    | Yasmin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                    | Nexium         |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2003                              | 3929028        | EXPEDITED (15-DAY) | Y                  | LT              | S03-UKI-01165-01     |                      | 64 YR           | Male         | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenal Ulcer;<br>Haematemesis; Melaena | Cipraxel       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Ibuprofen      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Lansoprazole   |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2003                                                                                                                                     | 3929832           | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01204-01     |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Accident; Delusion Of<br>Grandeur; Fatigue; Injury;<br>Mania; Road Traffic<br>Accident; Somnolence;<br>Suicidal Ideation | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Lexapro           |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Lexapro           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Zyprexa           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Percocet          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Mar-2003              | 3929862                 | EXPEDITED (15-DAY) | Y                  | HO, RI          | S03-USA-00471-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis             | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Remicade                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Flagyl                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Nexium                  |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 31-Mar-2003              | 3929885        | EXPEDITED (15-DAY) | Y                  | DS              | S03-FRA-01170-01     |                      | 33 YR           | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                                          |                            |                    |                    |                 |                      |                      |                 |            |                |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Diplopia                                                                                                                 | Escitalopram Oxalate       | S                  | Oral               | 10 Mg Qd Po     | Not Reported         |                      |                 |            |                |
|                                                                                                                          | Oxazepam                   | C                  |                    |                 | Not Reported         |                      |                 |            |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2003                                                                                                              | 3910494                    | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00576-01     |                      | 85 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Electrocardiogram Qt Prolonged; Electrolyte Imbalance                                                                    | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                          | Multiple Medications (Nos) |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2003                                                                                                              | 3925543                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | S03-USA-01034-01     |                      | 57 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Potassium Increased; Feeling Abnormal; Gastrooesophageal Reflux Disease; Gravitational Oedema; Hyperparathyroidism | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                          | Trazodone Hydrochloride    |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                          | Imitrex                    |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                          | Vivelle (Estradiol)        |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2003                                                                                                              | 3928640                    | DIRECT             | Y                  | HO              |                      |                      | 88 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion                                                              | Lexapro                    |                    |                    | S               | Oral                 | 10mg Qd Po           | 1 WEEK          |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2003                                                                                                              | 3930508                    | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01213-01     |                      | 84 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                         |                        |                    |                    |                 |                      |                      |                    |                 |                |
|---------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Inappropriate Antidiuretic Hormone Secretion            | Lexapro                | S                  | Oral               | 10 Mg Qd Po     |                      |                      |                    | Not Reported    |                |
|                                                         | Advair Diskus          | C                  |                    |                 |                      |                      |                    | Not Reported    |                |
|                                                         | Multivitamin (Nos)     | C                  |                    |                 |                      |                      |                    | Not Reported    |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 03-Apr-2003                                             | 3928398                | DIRECT             | Y                  | OT              |                      |                      | 20 YR              | Female          | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Contusion                                               | Lexapro                |                    |                    |                 | S                    | Oral                 | 10 Mg Daily Oral   |                 | Forest         |
| <u>FDA Received Date</u>                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 04-Apr-2003                                             | 3930605                | DIRECT             | Y                  | LT              |                      |                      | 23 YR              | Male            | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Cardiac Arrest; Chest Pain; Respiratory Arrest; Seizure | Lexapro                |                    |                    |                 | S                    | Oral                 | 10 Mg Bid/Po       |                 | Not Reported   |
| <u>FDA Received Date</u>                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 10-Apr-2003                                             | 3931570                | DIRECT             | Y                  | OT              |                      |                      | 49 YR              | Female          | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Dysphonia; Infection                                    | Lexapro                |                    |                    |                 | S                    | Oral                 | 10 Mg Po Qd        |                 | Not Reported   |
| <u>FDA Received Date</u>                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 10-Apr-2003                                             | 3934717                | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01365-01     |                      | 80 YR              | Female          | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Bradycardia; Hypotension                                | Lexapro                |                    |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
|                                                         | Unspecified Ingredient |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                         | Plavix                 |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                         | Aspirin                |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |

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| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2003                                         | 3934756        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01366-01     |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                        | Lexapro        |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2003                                         | 3868165        | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-02890-01     |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Communication Disorder;<br>Kidney Infection; Tremor | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Celebrex       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Enalapril      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Premarin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Librium        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2003                                         | 3930541        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01189-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Failure; Hepatitis<br>Fulminant; Overdose   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                     | Tylenol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2003                                         | 3935654        | EXPEDITED (15-DAY) | Y                  | HO, RI          | S03-USA-01401-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Hypertension                | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Lipitor        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Naproxen       |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Apr-2003                                                                                                                                                                                                                                                                                                   | 3920479                      | EXPEDITED (15-DAY) | Y                  | HO              | T03-USA-00902-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Schizophrenia; Suicidal<br>Ideation                                                                                                                                                                                                                                                   | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Celexa                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Propranolol La (Propranolol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Zyprexa                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Ferrous Sulfate              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Synthroid                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2003                                                                                                                                                                                                                                                                                                   | 3934784                      | EXPEDITED (15-DAY) | Y                  | HO              | T03-USA-01358-01     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akinesia; Blood<br>Cholesterol Increased;<br>Cardiac Failure<br>Congestive; Coronary<br>Artery Restenosis;<br>Depression; Diabetes<br>Mellitus; Drug Interaction;<br>Ejection Fraction<br>Decreased; Hypotension;<br>Myocardial Ischaemia;<br>Syncope; Treatment<br>Noncompliance;<br>Ventricular Hypokinesia | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg, Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Toprol XL                    |                    |                    | S               | Oral                 | 50 Mg, Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Altace                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Lopid                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Glucophage                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Humalog                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Humalog                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Zocor                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | KCl (Potassium Chloride)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Fish Oil                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               |                              |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                               |                              |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2003                                                                                                                                                                                                                                                                                                   | 3934022                      | DIRECT             | Y                  | HO              |                      |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Dizziness;<br>Drug Interaction;                                                                                                                                                                                                                                                                 | Lexapro                      |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                                                                                                                                                                               | Alprazolam                   |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Emotional Distress

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Apr-2003                                             | 3935196        | DIRECT           | Y                  | HO              |                      |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypophagia; Oligodipsia;<br>Stevens-Johnson<br>Syndrome | Lamictal       |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                         | Lexapro        |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Apr-2003                         | 3937377        | DIRECT           | Y                  | HO              |                      |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure | Lexapro        |                  |                    | S               | Oral                 | 10mg Po Qd           |                 | Not Reported |                |
|                                     | Acyclovir      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Desulturam     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Levothyroxine  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Olanzapine     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Quetrapine     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Gabapentin     |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Apr-2003                                                          | 3937044        | DIRECT           | N                  | OT              |                      |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Withdrawal<br>Syndrome; Emotional<br>Disorder; Headache | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Day Oral       |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Apr-2003              | 3939546        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01482-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |                       |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Movement Disorder              | Lexapro               |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2003                    | 3939549               | EXPEDITED (15-DAY) | Y                  | DS              | S03-USA-01586-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphemia; Mental Impairment   | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                | Clonazepam            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Glucosamine           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Methylsulfonylmethane |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Vitamin B Complex     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Vitamin E             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2003                    | 3939569               | EXPEDITED (15-DAY) | Y                  |                 | S03-USA-01575-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Respiratory Arrest | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                | Xanax                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Zyprexa               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Tylenol (Paracetamol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2003                    | 3931399               | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01378-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Tongue Biting         | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                | Xanax                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2003                    | 3940614               | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01592-01     |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Tachycardia;            | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |         |   |      |            |              |
|---------------------|---------|---|------|------------|--------------|
| Disease Recurrence; | Lexapro | S | Oral | 5 Mg Qd Po | Not Reported |
| Extrasystoles       | Lexapro | S | Oral | 5 Mg Qd Po | Not Reported |
|                     | Ativan  | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2003              | 3940422       | DIRECT           | Y                  | DE              |                      |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| <div> Foetal Death; Maternal<br/> Drugs Affecting Foetus; </div> | Oxcarbazepine  |              |            | S           |              | 600 Mg Day         |                 | Not Reported |
| <div> Maternal Drugs Affecting<br/> Foetus </div>                | Lexapro        |              |            | S           | Oral         | 50 Mg Po           |                 | Not Reported |
|                                                                  | Zoloft         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2003              | 3940934       | EXPEDITED (15-DAY) | Y                  | DS              | S03-FRA-01601-01     |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| <div> Lyme Disease; Myalgia </div> | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                    | Alprazolam           |              |            | C           |              |                    |                 | Not Reported |
|                                    | Ixel (Milnacipran)   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2003              | 3941093       | EXPEDITED (15-DAY) | Y                  | OT              | S03-SWI-01604-01     |                      | 61 YR      | Female     | CHE            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| <div> Cholestasis; </div>          | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| <div> Hepatocellular Injury </div> |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2003              | 3967748       | NON-EXPEDITED    | Y                  | OT              | NSADSS2002042511     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Ultram         |              |            | S           |              | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                                          |                | S                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2003                                                      | 3942033        | EXPEDITED (15-DAY) | Y                  | HO              | 1671967A             |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Failure; Hepatitis Fulminant; Overdose                   | Tylenol        |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                  | Lexapro        |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2003                                                      | 3929878        | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-01258-01     |                      | 64 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety Disorder; Delirium; Headache; Nausea; Seizure | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Hypericin      |                    |                    | S               |                      | 900 Mcg Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2003                                                      | 3943740        | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-01691-01     |                      | 55 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dizziness; Loss Of Consciousness                      | Cipralax       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Antibiotics    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2003                                                      | 3961889        | NON-EXPEDITED      | N                  |                 | ZONI001059           |                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                                                             | Zonegran       |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                  | Lexapro        |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-May-2003                                                                                                                                  | 3942293              | EXPEDITED (15-DAY) | Y                  | HO              | S03-FRA-01830-01     |                      | 20 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Mydriasis;<br>Overdose; Somnolence                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 600 Mg Once Po       |                 | Not Reported |                |
|                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2003                                                                                                                                  | 3944555              | DIRECT             | Y                  | OT              |                      |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Chills; Insomnia;<br>Nasopharyngitis                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10mg Daily Oral      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2003                                                                                                                                  | 3945728              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01641-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcohol Use;<br>Condition Aggravated                                                                                             | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                              | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                              | Alcohol              |                    |                    | S               |                      | 7 Units Once         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2003                                                                                                                                  | 3883229              | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-03285-01     |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Angiopathy;<br>Asthenia; Aura; Brain<br>Scan Abnormal;<br>Contusion; Dyskinesia;<br>Fatigue; Fear; Feeling<br>Abnormal; Generalised | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                              | Ambien               |                    |                    | C               |                      |                      |                 | Not Reported |                |

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Tonic-Clonic Seizure; Jaw  
Fracture; Lethargy; Loss  
Of Consciousness; Mental  
Impairment; Mouth  
Haemorrhage; Muscle  
Atrophy; Muscular  
Weakness;  
Musculoskeletal Stiffness;  
Partial Seizures; Speech  
Disorder; Stress; Tooth  
Injury

| <a href="#">FDA Received Date</a>                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-May-2003                                                                                 | 3940924                 | EXPEDITED (15-DAY)        | Y                           |                          | S03-IRL-01600-01              |                               | 50 YR                    | Female              | IRL                     |
| <a href="#">Preferred Term</a>                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Melanocytic Naevus                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-May-2003                                                                                 | 3946906                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-USA-01827-01              |                               | 121 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastroenteritis Viral;<br>Maternal Exposure During<br>Breast Feeding; Metabolic<br>Acidosis | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-May-2003                                                                                 | 3862676                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S02-USA-02581-01              |                               | 24 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic<br>Seizure; Seizure                                                | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 12-May-2003                                                      | 3940879                                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01582-01     |                             | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Focal Dyscognitive<br>Seizures; Seizure | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported |                |
|                                                                  | Depakote                                |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                  | Tegretol Xr                             |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                  | Gabitril                                |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                  | Dilantin                                |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                  | Klonopin                                |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2003                                                      | 5946618                                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-SWE-01919-01     |                             | 37 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Neoplasm;<br>Hyperprolactinaemia                           | Ciprallex                               |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported |                |
|                                                                  | Fluoxetine Hydrochloride                |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2003                                                      | 3966572                                 | NON-EXPEDITED      | Y                  | OT              | 327494               |                             | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Tinnitus                                                         | Pegasys                                 |                    |                    | S               | Subcutaneous         | 1 Per Week;<br>Subcutaneous |                 | Not Reported |                |
|                                                                  | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Daily; Oral           |                 | Not Reported |                |
|                                                                  | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | S               | Oral                 | 2 Per Day; Oral             |                 | Not Reported |                |
|                                                                  | Ambien                                  |                    |                    | S               | Oral                 | 1 Per Day; Oral             |                 | Not Reported |                |
|                                                                  | Phenergan                               |                    |                    | S               |                      | 1 Per; Prn                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2003                                                      | 3948804                                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02001-01     |                             | 43 YR           | Female       | USA            |



# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Chills; Disorientation;<br>Fatigue; Seizure;<br>Syncope; Tremor                                                                                                                | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                                                                | Paxil Cr               |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                | Unspecified Ingredient |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                | Analgesic              |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2003                                                                                                                                                                    | 3948931                | DIRECT             | N                  | OT              |                      |                          | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dizziness; Heart<br>Rate Irregular; Nervous<br>System Disorder; Panic<br>Attack; Sleep Disorder                                                                       | Paxil                  |                    |                    | S               | Oral                 | Paxil 20 Mg Oral         |                 | Not Reported |                |
|                                                                                                                                                                                | Lexapro                |                    |                    | S               | Oral                 | Lexapro 10 Mg Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2003                                                                                                                                                                    | 3949757                | DIRECT             | N                  | OT              |                      |                          | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Discomfort;<br>Fluid Retention; Irritability;<br>Nervous System Disorder;<br>Suicidal Ideation; Tension;<br>Thinking Abnormal; Vision<br>Blurred; Weight Increased | Lexapro                |                    |                    | S               | Oral                 | One Pill Once Daily Oral |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2003                                                                                                                                                                    | 3919004                | EXPEDITED (15-DAY) | Y                  | DE              | S03-UKI-00910-01     |                          |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide                                                                                                                                                 | Cipralext              |                    |                    | S               |                      |                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2003                                                                                                             | 3936491        | EXPEDITED (15-DAY) | Y                  |                 | S03-USA-01478-01     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Coordination Abnormal;<br>Dyskinesia; Muscle<br>Spasms; Pupils Unequal                            | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2003                                                                                                             | 3944153        | EXPEDITED (15-DAY) | Y                  | DE              | T03-USA-01694-01     |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2003                                                                                                             | 3951492        | DIRECT             | N                  | OT              |                      |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema; Genital Pain;<br>Mucosal Discolouration;<br>Vaginal Disorder; Vaginal<br>Odour                                | Lexapro        |                    |                    | S               | Oral                 | Once Daily Oral      |                 | Not Reported |                |
|                                                                                                                         | Singulair      |                    |                    | C               | Oral                 | Once Daily Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2003                                                                                                             | 3951076        | DIRECT             | Y                  | HO              |                      |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Erythema<br>Multiforme; Hypophagia;<br>Pain; Stevens-Johnson<br>Syndrome; Stomatitis;<br>Tongue Ulceration | Lamictal       |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                         | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2003                                      | 3952732                         | DIRECT             | Y                  |                 |                      |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia                                       | Lexapro                         |                    |                    | S               |                      | 10 Mg One Qd         |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2003                                      | 3953057                         | DIRECT             | Y                  | OT              |                      |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism                                          | Lexapro                         |                    |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2003                                      | 3954981                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-02244-01     |                      | 77 YR           | Male         | DEU            |
| <u>Preferred Term</u>                            | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual;<br>Insomnia               | Ciprallex                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                  | Pizotifen                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Intralgin                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Lormetazepam                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Fluticasone                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Propionate\Salmeterol Xinafoate |                    |                    |                 |                      |                      |                 |              |                |
|                                                  | Atorvastatin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Coracten (Nifedipine)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Peptac                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2003                                      | 3937358                         | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-01477-01     |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide; Drug Interaction | Lexapro                         |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                  | Reglan                          |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                      |   |              |
|----------------------|---|--------------|
| Norvasc              | C | Not Reported |
| Flomax               | C | Not Reported |
| Glucosamine          | C | Not Reported |
| Zyrtec               | C | Not Reported |
| Nabumetone (Relafen) | C | Not Reported |
| Halcion              | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2003              | 3939564       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01593-01     |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Optic Ischaemic Neuropathy; Optic Neuritis; Visual Field Defect | Lexapro        |              |            | S           |              | 15 Mg Qd Po        |                 | Not Reported |
|                                                                 | Neurontin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Provigil       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2003              | 3953139       | DIRECT           | Y                  | RI              |                      |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                                                                                                             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Dyskinesia; Speech Disorder; Tongue Disorder | Abilify        |              |            | S           |              | Wellbutrin For 2 Days Only<br>Side Effects Continued<br>After Wellbutrin Was<br>Stopped For 2 More Days<br>Dx<br>Wellbutrin For 2 Days Only<br>Side Effects Continued<br>After Wellbutrin Was<br>Stopped For 2 More Days<br>Dx |                 | Not Reported |
|                                              | Lexapro        |              |            | S           |              |                                                                                                                                                                                                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-May-2003              | 3955418       | EXPEDITED (15-DAY) | Y                  | LT              | S03-USA-02187-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                     |                    |                    |                 |                      |                      |                    |                 |                |
|----------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Seizure                                                  | Lexapro             |                    |                    | S               |                      |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 30-May-2003                                              | 3955425             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02161-01     |                      | 30 YR              | Female          | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>      |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Condition Aggravated;<br>Depression; Rash;<br>Somnolence | Lexapro             |                    |                    |                 | S                    |                      | 10 Mg Qd Po        |                 | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 30-May-2003                                              | 3955434             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02159-01     |                      | 47 YR              | Female          | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>      |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Alcohol Poisoning; Loss<br>Of Employment                 | Lexapro             |                    |                    |                 | S                    |                      | 10 Mg Qd Po        |                 | Not Reported   |
|                                                          | Wine                |                    |                    |                 | S                    |                      |                    |                 | Not Reported   |
|                                                          | Lorazepam           |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 30-May-2003                                              | 3955439             | EXPEDITED (15-DAY) | Y                  | RI              | S03-USA-02127-01     |                      | 45 YR              | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>      |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Priapism                                                 | Lexapro             |                    |                    |                 | S                    |                      | 10 Mg Qd Po        |                 | Not Reported   |
|                                                          | Prozac              |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                          | Terbutaline Sulfate |                    |                    |                 | C                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 30-May-2003                                              | 3955488             | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-02188-01     |                      | 17 YR              | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>      |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Completed Suicide                                        | Lexapro             |                    |                    |                 | S                    |                      |                    |                 | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 30-May-2003                                                                                                                                                              | 3955500                         | EXPEDITED (15-DAY) | Y                  | OT              | T02-USA-03191-01     |                        | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                  | Lexapro                         |                    |                    | S               | Oral                 | 20 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                          | Aenolol                         |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Doxycycline                     |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Depakote (Valproate Semisodium) |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Ultram                          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Hydrocodone                     |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2003                                                                                                                                                              | 3862781                         | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-02474-01     |                        | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depressed Level Of Consciousness; Dizziness; Drug Withdrawal Syndrome; Dyslexia; Insomnia; Irritability; Memory Impairment; Panic Attack; Seizure; Somnolence | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                          | Buspar                          |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Lisinopril                      |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Hydrochlorothiazide             |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Atenolol                        |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2003                                                                                                                                                              | 3807587                         | EXPEDITED (15-DAY) | Y                  | HO, LT          | T02-USA-01012-01     |                        | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Aspiration; Blood Alcohol Increased; Body Temperature Decreased; Coma; Dilatation Atrial; Drug Level Increased; Eye                                           | Escitalopram Oxalate            |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                          | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 20 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                          | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 20 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                          | Tylenol                         |                    |                    | S               |                      | See Image<br>See Image |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                    |         |   |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|
| Movement Disorder;<br>Incoherent; Intentional<br>Overdose; Mental Status<br>Changes; Metabolic<br>Acidosis; Respiratory<br>Acidosis; Shift To The<br>Left; Suicidal Ideation;<br>Suicide Attempt;<br>Tachycardia; Vomiting;<br>White Blood Cell Count<br>Increased | Alcohol | C | Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Jun-2003                               | 3941507        | EXPEDITED (15-DAY) | Y                  | OT              | T03-USA-01534-01     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                           | Amitriptyline  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Bextra         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Desyrel        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Neurontin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Topamax        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2003                               | 3951678        | EXPEDITED (15-DAY) | Y                  | LT, RI          | S03-USA-02020-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident                  | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                           | Allegra-D      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2003                               | 3952239        | EXPEDITED (15-DAY) | Y                  | HO, LT, RI      | S03-USA-02126-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery<br>Dissection; Myocardial | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                |                                  |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Infarction                                                                                                                                                                                                     | Lexapro                          |                    | S                  | Oral            | 5 Mg Qd Po           |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2003                                                                                                                                                                                                    | 3958164                          | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-02292-01     |                      | 56 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hallucination; Visual; Hypophagia; Insomnia                                                                                                                                                         | Cipraxel                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                | Thyroxine (Levothyroxine Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Aumenon (Estradiol)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2003                                                                                                                                                                                                    | 3958209                          | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02310-01     |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased; Generalised Tonic-Clonic Seizure                                                                                                                                                      | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2003                                                                                                                                                                                                    | 3957857                          | DIRECT             | N                  | HO              |                      |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder; Dehydration; Diarrhoea; Dizziness; Dyspnoea; Hyperhidrosis; Incoherent; Malaise; Micturition Urgency; Migraine; Nausea; Peripheral Coldness; Renal Pain; Somnolence; Tremor; Viral Infection | Lexapro                          |                    |                    | S               | Oral                 | 5mg 1 X Day Oral     |                 | Forest       |                |



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| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2003                                                            | 3959073                                 | EXPEDITED (15-DAY) | Y                  | DE              | S03-IRL-02369-01     |                      |                 | Male         | IRL            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                             | Lexapro                                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2003                                                            | 3959299                                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02420-01     |                      | 57 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                        | Lotrel                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Xanax                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2003                                                            | 3959321                                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02426-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriospasm Coronary;<br>Myocardial Infarction                        | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Estradiol                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Aspirin                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2003                                                            | 3959323                                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02395-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Disorientation;<br>Dizziness; Nausea;<br>Serotonin Syndrome | Lexapro                                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jun-2003                        | 3960191                                | EXPEDITED (15-DAY) | Y                  | DE              | S03-UKI-02368-01     |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                  | Cipralext                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                    | Fluanxol (Flupentixol Dihydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Temazepam                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Bumetanide                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003                        | 3960516                                | EXPEDITED (15-DAY) | Y                  | DE              | S03-UKI-02367-01     |                      | 33 YR           | Male         | GBR            |
| <u>Preferred Term</u>              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Mental Disorder | Cipralext                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                    | Antabuse                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Stelazine                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Diazepam                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003                        | 3988899                                | NON-EXPEDITED      | Y                  | OT              | S03-USA-02002-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parosmia                           | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                    | Corgard                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                    | Prilosec                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003                        | 3988901                                | NON-EXPEDITED      | Y                  | HO              | S02-USA-03199-03     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                            | Lexapro                                |                    |                    | S               | Oral                 | 20- Mg Qam Po        |                 | Not Reported |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jun-2003                | 3988902        | NON-EXPEDITED    | Y                  | HO              | S03-USA-00665-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Headache       | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Zoloft         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Risperdal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003                | 3991310        | NON-EXPEDITED    | Y                  | HO, OT          | S02-USA-03346-01     |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Syncope;       | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Ventricular Extrasystoles  | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003                | 3991315        | NON-EXPEDITED    | Y                  | HO              | S03-USA-01026-01     |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Thromboplastin       | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Decreased;                 | Prozac         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hypermagnesaemia;          | Lipitor        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hyperventilation;          | Zantac         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hypocalcaemia;             | Xanax          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hypochloraemia;            | Compazine      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hypokalaemia;              | Multivitamins  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Hypomagnesaemia;           |                |                  |                    |                 |                      |                      |                 |              |                |
| Hyponatraemia;             |                |                  |                    |                 |                      |                      |                 |              |                |
| Hypophosphataemia;         |                |                  |                    |                 |                      |                      |                 |              |                |
| Laboratory Test Abnormal;  |                |                  |                    |                 |                      |                      |                 |              |                |
| Leukocytosis; Pollakiuria; |                |                  |                    |                 |                      |                      |                 |              |                |
| Thrombocytosis             |                |                  |                    |                 |                      |                      |                 |              |                |

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| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jun-2003              | 3991318                    | NON-EXPEDITED    | Y                  | HO              | S03-USA-01218-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia              | Lexapro                    |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003              | 4008503                    | NON-EXPEDITED    | N                  | HO              | S03-USA-01599-01     |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Injury         | Lexapro                    |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Blood Pressure Medications |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003              | 4008506                    | NON-EXPEDITED    | Y                  | HO              | S03-USA-01483-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Lexapro                    |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Unspecified Ingredient     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Desipramine Hydrochloride  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2003              | 4008511                    | NON-EXPEDITED    | Y                  | OT              | S03-USA-01305-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                 | Lexapro                    |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro                    |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro                    |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro                    |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jun-2003                                                                                                                                                                           | 4008513                              | NON-EXPEDITED      | Y                  | HO              | S03-USA-01296-01     |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Arthritis; Chest Pain; Hypertonia                                                                                                                                            | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                       | Calcium With Vitamin D               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Vitamins Nos                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Estraderm                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Glucosamine                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Fish Oil                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Vitamin B1                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Vitamin E                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Aspirin                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Seroquel                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Zyprexa                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2003                                                                                                                                                                           | 3902099                              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00354-01     |                      | 95 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Failure; Cellulitis; Disease Recurrence; Fatigue; Feeling Abnormal; Haemoglobin; Lymphocyte Morphology Abnormal; Platelet Count; Weight Decreased; White Blood Cell Count | Lexapro                              |                    |                    | S               | Oral                 | 5 Mg Qd; Po          |                 | Not Reported |                |
|                                                                                                                                                                                       | Unspecified Ingredient               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Flomax Mr (Tamsulosin Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Proscar                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Sonata                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Coreg                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Plavix                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Bumex                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Norvasc                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Imdur                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Baby Aspirin                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Unspecified Ingredient               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                       | Oxygen                               |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 13-Jun-2003                                                                                                                                           | 3959683                         | DIRECT             | N                  | OT              |                      |                       | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Crying; Drug Withdrawal Syndrome; Feeling Abnormal; Increased Appetite; Malaise; Maternal Drugs Affecting Foetus; Pregnancy; Weight Increased | Lexapro                         |                    |                    | S               | Oral                 | 20 Mg Once A Day Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2003                                                                                                                                           | 3935650                         | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01402-01     |                       | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Phosphokinase Increased; Electrocardiogram Change; Serotonin Syndrome                                                                  | Lexapro                         |                    |                    | S               | Oral                 | 20 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                       | Celexa (Citalopram Hdrobromide) |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Levaquin                        |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Solu-Medrol                     |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Neurontin                       |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Synthroid                       |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Ambien                          |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Melatonin                       |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Propranolol                     |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Rocephin                        |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                                                                       | Cetaben                         |                    |                    | C               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2003                                                                                                                                           | 3956568                         | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02309-01     |                       | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoglycaemia                                                                                                                                         | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jun-2003                                                                    | 3958160              | EXPEDITED (15-DAY) | Y                  | OT              | S03-FRA-02288-01     |                      | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Oedema; Localised Oedema; Oedema Peripheral; Swelling Face              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2003                                                                    | 3962377              | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-02432-01     |                      | 29 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Gingival Bleeding; Menorrhagia                                      | Cipraxel             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2003                                                                    | 3962385              | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02485-01     |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Embolism                                                             | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2003                                                                    | 3962633              | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2003US04897      |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus | Trileptal            |                    |                    | S               | Oral                 | 600 Mg, Qd, Oral     |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                | Zoloft               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                | Vitamin B12          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2003                                                                    | 3963824              | EXPEDITED (15-DAY) | Y                  | HO, RI          | S03-USA-02041-01     |                      | 65 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia Postoperative;<br>Drug Interaction;<br>Hypotension; International<br>Normalised Ratio<br>Increased; Laboratory<br>Test Abnormal; Post<br>Procedural Complication;<br>Prothrombin Time<br>Prolonged; Toxicity To<br>Various Agents; Urinary<br>Retention | Lexapro                              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Coumadin                             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Lovenox                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Protonix Pharmacia<br>(Pantoprazole) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Carafate                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Ferrous Sulfate                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Elavil                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Peri-Colace                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Zetia                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Robaxin                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Reglan                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Multi-Vitamin                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Nystatin                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Sodium Chloride                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Lortab                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Toprol XL                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Diovan Ciba-Geigy (Valsartan)        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2003              | 3963888       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02531-02     |                      | 88 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Petit Mal Epilepsy    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Haldol         |              |            | S           |              | See Image          |                 | Not Reported |
|                       | Ativan         |              |            | C           |              |                    |                 | Not Reported |
|                       | Risperdal      |              |            | C           |              |                    |                 | Not Reported |
|                       | Vasotec        |              |            | C           |              |                    |                 | Not Reported |
|                       | Lopresor       |              |            | C           |              |                    |                 | Not Reported |
|                       | Nitroglycerin  |              |            | C           |              |                    |                 | Not Reported |
|                       | Hydrodiuril    |              |            | C           |              |                    |                 | Not Reported |
|                       | Potassium      |              |            | C           |              |                    |                 | Not Reported |
|                       | Slow-Mag       |              |            | C           |              |                    |                 | Not Reported |
|                       | Premarin       |              |            | C           |              |                    |                 | Not Reported |
|                       | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
|                       | Alphagan P     |              |            | C           |              |                    |                 | Not Reported |
|                       | Levaquin       |              |            | C           |              |                    |                 | Not Reported |



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|  |  |                                        |   |   |  |  |  |  |              |
|--|--|----------------------------------------|---|---|--|--|--|--|--------------|
|  |  | Lidex                                  |   | C |  |  |  |  | Not Reported |
|  |  | Aspirin                                |   | C |  |  |  |  | Not Reported |
|  |  | Tylenol (Paracetamol)                  |   | C |  |  |  |  | Not Reported |
|  |  | Vicodin Es                             |   | C |  |  |  |  | Not Reported |
|  |  | Protonix "Pharmacia"<br>(Pantoprazole) |   | C |  |  |  |  | Not Reported |
|  |  | Prilosec                               |   | C |  |  |  |  | Not Reported |
|  |  | Gaviscon                               |   | C |  |  |  |  | Not Reported |
|  |  | Maalox                                 | Y | C |  |  |  |  | Not Reported |
|  |  | Milk Of Magnesia                       |   | C |  |  |  |  | Not Reported |
|  |  | Theragram Vitamins                     |   | C |  |  |  |  | Not Reported |
|  |  | Vitamin E                              |   | C |  |  |  |  | Not Reported |
|  |  | Unspecified Ingredient                 |   | C |  |  |  |  | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2003              | 3961466       | DIRECT           | Y                  | HO              |                      |                      | 48 YR      | Female     | USA            |

  

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Seizure;<br>Tremor | Lexapro        |              |            | S           | Oral         | Once Daily Oral    |                 | Not Reported |
|                                | Remeron        |              |            | S           | Oral         | 15 Mg Tid Oral     |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jun-2003              | 3964532       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00023-01     |                      | 35 YR      | Female     | USA            |

  

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic<br>Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2003              | 3883094       | EXPEDITED (15-DAY) | Y                  | OT              | S02-USA-03231-01     |                      | 59 YR      | Female     | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tardive Dyskinesia    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lithium        |              |            | C           |              |                    |                 | Not Reported |
|                       | Glyburide      |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |              |
|-------------|---|--------------|
| Glucophage  | C | Not Reported |
| Insulin Nos | C | Not Reported |
| Prevacid    | C | Not Reported |
| Synthroid   | C | Not Reported |
| Altace      | C | Not Reported |
| Xanax       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2003              | 3935409       | EXPEDITED (15-DAY) | Y                  | HO              | S02-USA-03219-01     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amenorrhoea; Blood         | Celexa         |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
| Androstenedione            | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Increased; Galactorrhoea;  |                |              |            |             |              |                    |                 |              |
| Headache;                  |                |              |            |             |              |                    |                 |              |
| Hyperprolactinaemia;       |                |              |            |             |              |                    |                 |              |
| Insulin-Like Growth Factor |                |              |            |             |              |                    |                 |              |
| Decreased; Oestradiol      |                |              |            |             |              |                    |                 |              |
| Decreased; Paraesthesia;   |                |              |            |             |              |                    |                 |              |
| Pituitary Tumour Benign;   |                |              |            |             |              |                    |                 |              |
| Treatment                  |                |              |            |             |              |                    |                 |              |
| Noncompliance; Tremor      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2003              | 3964922       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02612-01     |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Amnesia; Blood Glucose     | Aricept        |              |            | C           |              |                    |                 | Not Reported |
| Increased; Cerebral        | Premarin       |              |            | C           |              |                    |                 | Not Reported |
| Atrophy; Cognitive         | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
| Disorder; Confusional      | Ocuvite        |              |            | C           |              |                    |                 | Not Reported |
| State; Delusion; Dementia; | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
| Emphysema; Panic           | Vitamin E      |              |            | C           |              |                    |                 | Not Reported |
| Attack; Paranoia;          |                |              |            |             |              |                    |                 |              |
| Psychotic Disorder         |                |              |            |             |              |                    |                 |              |

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| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jun-2003               | 3965050                 | EXPEDITED (15-DAY) | Y                  | DS, LT          | S03-SWI-02587-01     |                      | 51 YR           | Female       | CHE            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose             | Cipralext               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Fluctuation; Depression;  | Glucophage              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Malaise; Nausea;          | Insulin Nos             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Persistent Depressive     |                         |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Suicide Attempt |                         |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jun-2003               | 3965063                 | EXPEDITED (15-DAY) | Y                  | CA, HO          | S03-DEN-02599-01     |                      | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;         | Cipralext               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Anencephaly; Maternal     | Vitamins                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Drugs Affecting Foetus;   | Gravitamon              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Maternal Drugs Affecting  | Haem-Jern (Iron)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Foetus                    | Kenacutan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Acetaminophen           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2003               | 3961138                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-02374-01     |                      | 35 YR           | Female       | GBR            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Asthenopia;      | Cipralext               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Dissociation; Dyspnoea;   | Cipralext               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Eye Disorder; Feeling     | Flixonase               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Abnormal; Myalgia; Visual | Zopiclone               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Impairment                | Diazepam                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Piriton (Chlorphenamine |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Maleate)                |                    |                    |                 |                      |                      |                 |              |                |

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| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jun-2003                                                                                                               | 3963532                    | EXPEDITED (15-DAY) | Y                  | DE              | S03-ARG-02592-01     |                      | 23 YR           | Male         | ARG            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                         | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2003                                                                                                               | 3965551                    | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-02651-01     |                      | 34 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Somnambulism                                                                                                        | Ciprallex                  |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2003                                                                                                               | 3958420                    | EXPEDITED (15-DAY) | Y                  | HO              | WAES 0306FRA00043    |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood                                                                                                          | Noroxin                    |                    |                    | S               | Oral                 |                      | 2 DAY           | Merck        |                |
| Bicarbonate Decreased;                                                                                                    | Escitalopram Oxalate       |                    |                    | S               | Oral                 |                      | 36 DAY          | Not Reported |                |
| Disorientation;                                                                                                           | Escitalopram Oxalate       |                    |                    | S               | Oral                 |                      | 9 DAY           | Not Reported |                |
| Hyperhidrosis; Memory                                                                                                     | Cola Nut\Crataegus\Passion |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
| Impairment; Tremor                                                                                                        | Flower\Valerian            |                    |                    |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2003                                                                                                               | 3965235                    | DIRECT             | Y                  | OT              |                      |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Anxiety; Dizziness;<br>Fatigue; Libido<br>Decreased; Treatment<br>Noncompliance; Verbal<br>Abuse | Lexapro                    |                    |                    | S               | Oral                 | 1 Table Daily Oral   |                 | Forest       |                |

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| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 01-Jul-2003                                                                                                                 | 3967198                 | EXPEDITED (15-DAY) | Y                  | RI              | 03P-163-0222363-00   |                            | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchitis; Drug Interaction; Fluid Retention; Oedema                                                                       | Biaxin                  |                    |                    | S               | Oral                 | 500 Mg, 2 In 1 D, Per Oral |                 | Not Reported |                |
| Peripheral; Pulmonary Hypertension; Tricuspid Valve Incompetence; Weight Increased                                          | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Per Oral  |                 | Not Reported |                |
|                                                                                                                             | Fexofenadine Hcl        |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Metformin Hydrochloride |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Glipizide               |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Iron                    |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Salbutamol              |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Fluticasone Propionate  |                    |                    | C               |                      |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2003                                                                                                                 | 3968386                 | EXPEDITED (15-DAY) | Y                  | HO, LT, RI      | ZANA001086           |                            | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Torsade De Pointes | Zanaflex                |                    |                    | S               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Oral              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2003                                                                                                                 | 3963856                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-USA-02555-01     |                            | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anoxia; Coma; Drug Interaction; Kidney Infection; Movement Disorder; Speech Disorder                                        | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg Qd Po                 |                 | Not Reported |                |
|                                                                                                                             | Taxol                   |                    |                    | S               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Cisplatin               |                    |                    | S               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Norco                   |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                             | Klonopin                |                    |                    | C               |                      |                            |                 | Not Reported |                |

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| Neurontin                                                            |                         | C                  |                    | Not Reported    |                      |                          |                 |              |                |
|----------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Oxycontin                                                            |                         | C                  |                    | Not Reported    |                      |                          |                 |              |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2003                                                          | 3969136                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02707-01     |                          | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Basal Ganglion Degeneration;<br>Coordination Abnormal;<br>Dysarthria | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                      | Celexa                  |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                      | Lipitor                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2003                                                          | 3969914                 | EXPEDITED (15-DAY) | Y                  | HO              | 03P-009-0222841-00   |                          | 38 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Generalised<br>Tonic-Clonic Seizure                       | Akineton                |                    |                    | S               | Oral                 | 4 Mg, 1 In 1 D, Per Oral |                 | Not Reported |                |
|                                                                      | Clozapine               |                    |                    | S               | Oral                 | See Image                |                 | Not Reported |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      | Haloperidol             |                    |                    | S               | Oral                 | See Image                |                 | Not Reported |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      | Cipralex                |                    |                    | S               | Oral                 | See Image                |                 | Not Reported |                |
|                                                                      |                         |                    |                    |                 | Oral                 | See Image                |                 |              |                |
|                                                                      | Buspirone Hydrochloride |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                      | Metoprolol Tartrate     |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                      | Enalapril Maleate       |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                      | Simvastatin             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                      | Omeprazole              |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2003                                                          | 3970445                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-AUT-02739-01     |                          | 38 YR           | Female       | AUT            |

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| <u>Preferred Term</u>                                                                                     | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|-----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Electroencephalogram Abnormal; Generalised Tonic-Clonic Seizure; Tongue Biting                            | Cipralext                   |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Haldol                      |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Janssen      |                |
|                                                                                                           | Haldol                      |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Janssen      |                |
|                                                                                                           | Biperiden Hydrochloride     |                  |                    | S               | Oral                 | 4 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 100 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 250 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 400 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 500 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 400 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Clozapine                   |                  |                    | S               | Oral                 | 300 Mg Qd Po         |                 | Novartis     |                |
|                                                                                                           | Bespar                      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Selokeen                    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Mepril (Enalapril Maleate)  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Omeprazole                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Tannalbin (Albumin Tannate) |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Zocor                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2003                                                                                               | 3968928                     | DIRECT           | Y                  | OT              |                      |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Phosphokinase Increased; Flushing; Product Quality Issue; Restlessness; Serotonin Syndrome | Lexapro                     |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2003                                                                                               | 3969744                     | DIRECT           |                    |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error                                                                                          | Bextra                      |                  |                    | S               |                      |                      |                 | Searle       |                |

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|                                                  |                      |                    |                    |                 |                              |                      |                 |            |                 |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|-----------------|
| Lexapro                                          |                      | S                  |                    | Forest          |                              |                      |                 |            |                 |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 10-Jul-2003                                      | 3958216              | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-02324-01             |                      | 38 YR           | Male       | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Completed Suicide                                | Lexapro              |                    |                    | S               |                              |                      |                 |            | Not Reported    |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 10-Jul-2003                                      | 3971551              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02802-01             |                      | 20 YR           | Female     | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Generalised Tonic-Clonic Seizure; Seizure        | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 |            | Not Reported    |
|                                                  | Depakote             |                    |                    | C               |                              |                      |                 |            | Not Reported    |
|                                                  | Hyoscyamine Sulfate  |                    |                    | C               |                              |                      |                 |            | Not Reported    |
|                                                  | Reglan               |                    |                    | C               |                              |                      |                 |            | Not Reported    |
|                                                  | Zantac               |                    |                    | C               |                              |                      |                 |            | Not Reported    |
|                                                  | Lactulose            |                    |                    | C               |                              |                      |                 |            | Not Reported    |
|                                                  | Adderall             |                    |                    | C               |                              |                      |                 |            | Not Reported    |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 11-Jul-2003                                      | 3967633              | EXPEDITED (15-DAY) | N                  | LT              | GB-GLAXOSMITHKLINE-B0303716A |                      | 58 YR           | Female     | GBR             |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Drug Interaction; Electrocardiogram Qt Prolonged | Lithium Carbonate    |                    |                    | S               | Oral                         | 800mg At Night       | 17 MTH          |            | Glaxosmithkline |
|                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                         | 20mg Per Day         |                 |            | Not Reported    |
|                                                  | Lansoprazole         |                    |                    | C               | Oral                         | 30mg Per Day         |                 |            | Not Reported    |
|                                                  | Levothyroxine Sodium |                    |                    | C               | Oral                         | 75ug Per Day         |                 |            | Glaxosmithkline |
|                                                  | Lamotrigine          |                    |                    | C               | Oral                         | 25mg Twice Per Day   |                 |            | Glaxosmithkline |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 11-Jul-2003                                      | 3969944              | DIRECT             | Y                  | OT              |                              |                      | 27 YR           | Male       | USA             |



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| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Intolerance                                                                                                            | Prozac                                              |                    |                    | S               | Oral                 | 40mg Po Qd           |                 | Not Reported |                |
|                                                                                                                             | Lexapro                                             |                    |                    | S               | Oral                 | 10mg Po Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2003                                                                                                                 | 3972583                                             | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-02873-01     |                      | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Autonomic Neuropathy;<br>Dysuria; Pancreatitis                                                     | Lexapro                                             |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                             | Darvocet-N 100                                      |                    |                    | S               |                      | 200 Mg Once Po       |                 | Not Reported |                |
|                                                                                                                             | Prevacid                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Allegra (Fexafenadine Hydrochloride)                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2003                                                                                                                 | 3959871                                             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02409-01     |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eating Disorder; Fatigue;<br>Fibromyalgia; Gait Inability;<br>Myoclonus; Parkinson'S Disease;<br>Sleep Disorder; Somnolence | Lexapro                                             |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                             | Lexapro                                             |                    |                    | S               |                      | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                             | Lexapro                                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Celebrex                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Ibuprofen                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Hyzaar                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Wellbutrin - Slow Release (Bupropion Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2003                                                                                                                 | 3973736                                             | EXPEDITED (15-DAY) | Y                  | HO              | 2003-01176           |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyarrhythmia; Bradycardia; Dizziness;                                                                                    | Diazepam                                            |                    |                    | S               | Oral                 | See Image            |                 | Watson       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |          |   |      |                         |           |              |
|----------------------------------------------------------------------------|----------|---|------|-------------------------|-----------|--------------|
| Drug Ineffective; Drug Interaction; Fatigue; Nausea; Product Quality Issue |          |   |      | Oral                    | See Image |              |
|                                                                            |          |   |      | Oral                    | See Image |              |
|                                                                            | Lexapro  | S | Oral | 1 Tablet, Daily, Oral   |           | Not Reported |
|                                                                            | Lexapro  | S | Oral | 1 Tablet, Daily, Oral   |           | Not Reported |
|                                                                            | Atropine | S | Oral | 2 Tablets, Single, Oral |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2003              | 3975314       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S03-USA-02890-02     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Caesarean Section; Ileus; Maternal Drugs Affecting Foetus; Neonatal Disorder; Transient Tachypnoea Of The Newborn | Lexapro        |              |            | S           | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2003              | 3963928       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02531-01     |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Insomnia; Petit Mal Epilepsy | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                              | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                              | Trileptal      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2003              | 3971482       | DIRECT           | N                  | OT              |                      |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Trismus               | Lexapro        |              |            | S           | Oral         | 10mg 1 Daily Oral  |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jul-2003                                                                                                | 3975831                         | EXPEDITED (15-DAY) | Y                  | LT              | S03-UKI-02779-01     |                      | 58 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged                                                     | Cipralext                       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lithium                         |                    |                    | S               | Oral                 | 800 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                            | Lansoprazole                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Thyroxine(Levothyroxine Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Lamotrigine                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2003                                                                                                | 3920259                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-00895-01     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Torsade De Pointes;<br>Ventricular Extrasystoles;<br>Ventricular Extrasystoles;<br>Ventricular Tachycardia | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro                         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                            | Valium                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Potassium Chloride              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Aspirin                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2003                                                                                                | 3947472                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01939-01     |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Petit Mal Epilepsy;<br>Treatment Noncompliance                                                             | Lexapro                         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                            | Tegretol                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2003                                                                                                | 3972133                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-BEL-02783-01     |                      | 67 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                         |                                                                              |                  |      |             |                                                              |
|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|
| Muscle Rigidity; Pyrexia;<br>Serotonin Syndrome;<br>White Blood Cell Count<br>Increased | Escitalopram Oxalate<br>Prolopa<br>Maniprex (Lithium Carbonate)<br>Clozapine | S<br>C<br>C<br>C | Oral | 10 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2003              | 3952230       | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-02078-01     |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| No Adverse Event      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2003              | 3976757       | DIRECT           | Y                  | OT              |                      |                      | 4 YR       | Unknown    | USA            |

| <u>Preferred Term</u>         | <u>Product</u>                                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |
|-------------------------------|--------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| Condition Aggravated;<br>Pain | Lexapro<br>Renapamil<br>Avapro<br>Ambien<br>Desyrel<br>Lasix<br>Humibid<br>Histavent |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | 10mg Po            | 26 DAY          | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2003              | 3978704       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03012-01     |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident;<br>Road Traffic Accident | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2003              | 3978707       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03013-01     |                      | 53 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blindness                                | Lexapro                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2003                              | 3978719                           | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03007-02     |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| International Normalised Ratio Increased | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Coumadin                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Coumadin                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Levaquin                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Uniphyl                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Digoxin                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Acid Blocker (Nos)                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Cardiazem                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2003                              | 3978730                           | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03007-01     |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| International Normalised Ratio Increased | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Lexapro                           |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                          | Coumadin                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Coumadin                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                          | Aricept (Conepezil Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2003                              | 3972130                           | EXPEDITED (15-DAY) | Y                  | LT              | S03-UKI-02841-01     |                      | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Eye Inflammation             | Ciprallex                         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                          | Enalapril                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Atorvastatin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |              |
|--------------------------------|---|--------------|
| Atenolol                       | C | Not Reported |
| Omeprazole                     | C | Not Reported |
| Dextropoxyphene/Paracetamol    | C | Not Reported |
| Aspirin (Acetylsalicylic Acid) | C | Not Reported |
| Isosorbide                     | C | Not Reported |
| Paroxetine Hydrochloride       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2003              | 3972132       | EXPEDITED (15-DAY) | Y                  | HO              | S03-UKI-02756-01     |                      | 32 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Syncope   | Ciprallex                                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Salbutamol                                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Beclomethasone (Beclomethasone Dipropionate) |              |            | C           |              |                    |                 | Not Reported |
|                       | Microgynon                                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2003              | 3979207       | EXPEDITED (15-DAY) | Y                  | HO              | S03-UKI-02930-01     |                      | 77 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epilepsy              | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Amlodipine     |              |            | C           |              |                    |                 | Not Reported |
|                       | Bendrofluazide |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2003              | 3979775       | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-02936-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination, Visual | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2003              | 3979473       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03018-01     |                      | 61 YR      | Female     | USA            |

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| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Keratitis             | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Fosamax        |              |            | C           |              |                    |                 | Not Reported |
|                       | Zyprexa        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2003              | 3979589       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03017-01     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Diastolic Decreased; Blood Pressure Increased; Cystitis; Sinus Tachycardia | Lexapro        |              |            | S           | Oral         | 10 Mg Qhs Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2003              | 3978906       | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>       |
|-----------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|------------------|
| Delayed Recovery From Anaesthesia; Hyperhidrosis; Muscle Rigidity; Nervous System Disorder; Rhabdomyolysis; Seizure; Tremor | Lexapro          |              |            | S           | Oral         | 10 Mg Qday Oral          |                 | Forest           |
|                                                                                                                             | Zyprexa          |              |            | S           | Oral         | 2.5 Mg, 20 Qam, Qhs Oral |                 | Eli Lilly And Co |
|                                                                                                                             | Phenergan        |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Toprol XL        |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Aspirin          |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Nitroglycerin SL |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Prilosec         |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Pepcid           |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Lasix            |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Potassium        |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Flomax           |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Reglan           |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Zoloft           |              |            | C           |              |                          |                 | Not Reported     |
|                                                                                                                             | Remeron          |              |            | C           |              |                          |                 | Not Reported     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jul-2003                                                                                                                                                                             | 3964896                     | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-02639-01     |                      | 90 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound                                                                                                                                                       | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Dilantin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Synthroid                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Captopril                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Lanoxin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Aspirin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Plavix                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2003                                                                                                                                                                             | 3971548                     | EXPEDITED (15-DAY) | Y                  |                 | S03-USA-02825-01     |                      | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Restless Legs Syndrome; Seizure                                                                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Coumadin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Toprol XL                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Aspirin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Restoril                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2003                                                                                                                                                                             | 3972131                     | EXPEDITED (15-DAY) | Y                  | HO              | S03-BEL-02784-01     |                      | 49 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Alanine Aminotransferase Increased; Amylase Increased; Aspartate Aminotransferase Increased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Depakine (Valproate Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Triazolam                   |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Potassium Increased;  
Blood Uric Acid Increased;  
C-Reactive Protein  
Increased; Confusional  
State; Drug Level Below  
Therapeutic;  
Haemodialysis; Lipase  
Increased; Protein Total  
Increased; Reticulocyte  
Count Increased;  
Rhabdomyolysis;  
Serotonin Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Jul-2003              | 3976312       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12283438 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Blood Glucose Increased;<br>Dry Mouth | Metaglip          |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                       | Lexapro           |              |            | S           |              |                    |                 | Not Reported         |
|                                       | Lipitor           |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Singulair         |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Alprazolam        |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Advair Diskus     |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Atrovent          |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Albuterol         |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Vitamin B12       |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Vitamin B Complex |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Aspirin           |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Magnesium         |              |            | C           |              |                    |                 | Not Reported         |
|                                       | Coffee            |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jul-2003                 | 3983566        | EXPEDITED (15-DAY) | Y                  | HO              | S03-UKI-03136-01     |                      | 38 YR           | Male         | DNK            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Subarachnoid<br>Haemorrhage | Cipraxel       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Seretide Mite  |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Salbutamol  
Fluticasone  
Propionate\Salmeterol Xinafoate

C  
C

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2003              | 3983574       | EXPEDITED (15-DAY) | Y                  | DS              | S03-UKI-03058-01     |                      | 78 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                  | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Hallucination; Lethargy;<br>Pain | Ciprallex                                     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                        | Dothiepin                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Salbutamol                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Fluticasone                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Gastrocote                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Ipratopium Bromide                            |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Steri-Neb Saline (Sodium Chloride)            |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Phyllocontin (Aminophylline)                  |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Alginic Acid                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Sodium Bicarbonate                            |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Sodium Alginate (Sodium Alginate)             |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Magnesium Trisilicate (Magnesium Trisilicate) |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Aluminum Hydroxide Gel                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2003              | 3983584       | EXPEDITED (15-DAY) | Y                  | OT              | S03-CZE-03076-01     |                      | 42 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperkalaemia         | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2003              | 3983770       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03157-01     |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |           |   |              |
|------------------------------------|-----------|---|--------------|
| Prolonged; Ventricular Tachycardia | Lipitor   | C | Not Reported |
|                                    | Proscar   | C | Not Reported |
|                                    | Oxycontin | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2003              | 3983790       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03103-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deep Vein Thrombosis  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2003              | 3982188       | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Anorgasmia; Fatigue; Headache; Nausea; Nightmare; Weight Increased | Lexapro        |              |            | S           | Oral         | 10mg Once Daily Oral |                 | Forest       |
|                                                                    | Prozac         |              |            | S           | Oral         | 10mg Once Daily Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2003              | 3982197       | DIRECT           | N                  | HO              |                      |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Attention Deficit/Hyperactivity Disorder; Fatigue; Paranoia; Psychotic Disorder | Lexapro        |              |            | S           | Oral         | 1 Table Daily Oral |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2003              | 3983926       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02681-01     |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug Level Increased; Fall; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                             |   |      |               |              |
|------------------|-----------------------------|---|------|---------------|--------------|
| Scapula Fracture | Lexapro                     | S | Oral | 20 Mg Qd Po   | Not Reported |
|                  | Dilantin                    | S | Oral | 375 Mg Bid Po | Not Reported |
|                  | Darvocet-N 100              | C |      |               | Not Reported |
|                  | Ms Contin                   | C |      |               | Not Reported |
|                  | Ms Contin                   | C |      |               | Not Reported |
|                  | Nortriptyline Hydrochloride | C |      |               | Not Reported |
|                  | Aciphex                     | C |      |               | Not Reported |
|                  | Ativan                      | C |      |               | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2003              | 3983980       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03158-02     |                      |            | Unknown    | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Aug-2003              | 3978579       | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12335709 |                      | 62 YR      | Male       | USA            |

  

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|----------------------|
| Depression; International<br>Normalised Ratio<br>Increased | Coumadin       |              |            | S           |              | Stable Dose For Many<br>Years.             |                 | Bristol Myers Squibb |
|                                                            | Lexapro        |              |            | S           | Oral         | Previous Dose Begun In<br>May-03 5 Mg/Day. |                 | Not Reported         |
|                                                            | Aricept        |              |            | C           |              |                                            |                 | Not Reported         |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Aug-2003              | 3978580       | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12335782 |                      | 67 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Depression; International<br>Normalised Ratio<br>Increased | Coumadin       |              |            | S           |              | Years.             |                 | Bristol Myers Squibb |
|                                                            | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                            | Cardizem       |              |            | C           |              |                    |                 | Not Reported         |
|                                                            | Levaquin       |              |            | C           |              |                    |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                   |                |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Uniphyl                                                                                                                                                                                                                                                                                                                                                           |                | C                  |                    | Not Reported    |                      | Not Reported         |                 | Not Reported |                |
| Digoxin                                                                                                                                                                                                                                                                                                                                                           |                | C                  |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2003                                                                                                                                                                                                                                                                                                                                                       | 3985555        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03196-01     |                      | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Renal Failure                                                                                                                                                                                                                                                                                                                                      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Norvasc        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Klonopin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Flomax         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Protonix       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Heparin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2003                                                                                                                                                                                                                                                                                                                                                       | 3971584        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02706-01     |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Anaemia; Antinuclear Antibody Positive; Aspartate Aminotransferase Increased; Autoimmune Disorder; Blood Albumin Decreased; Bone Marrow Failure; Liver Function Test Abnormal; Oedema; Pneumonia; Protein Total Decreased; Serum Ferritin Increased; Thrombocytopenia; Urinary Incontinence; White Blood Cell Count Decreased | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Celexa         |                    |                    | S               | Oral                 | 80 Mg, Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Valium         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Synthroid      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Neurontin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Ambien         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   |                |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|---------------|----------------|
| 05-Aug-2003                                                                                                                                                                                                              | 3984192        | DIRECT             | N                  | OT              |                      |                      | 17 YR           | Female        | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Abnormal Behaviour;<br>Anger; Cosmetic Body<br>Piercing; Delusion; Family<br>Stress; Fatigue; Feeling<br>Abnormal; Hallucinations,<br>Mixed; Insomnia;<br>Intentional Self-Injury;<br>Paraesthesia; Suicidal<br>Ideation | Lexapro        |                    |                    | S               | Oral                 | Daily Pill Oral      |                 | Not Reported  |                |
|                                                                                                                                                                                                                          | Paxil          |                    |                    | S               | Oral                 | Daily Pill Oral      |                 | Not Reported  |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
| 05-Aug-2003                                                                                                                                                                                                              | 3987208        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03197-01     |                      | 17 YR           | Male          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Extrapyramidal Disorder;<br>Overdose                                                                                                                                                                                     | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported  |                |
|                                                                                                                                                                                                                          | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported  |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
| 05-Aug-2003                                                                                                                                                                                                              | 3998189        | DIRECT             | N                  | RI, OT          |                      |                      | 27 YR           | Female        | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Dental Caries; Gingival<br>Atrophy                                                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | One/Per Oral         |                 | Not Reported  |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
| 06-Aug-2003                                                                                                                                                                                                              | 3986049        | DIRECT             | Y                  |                 |                      |                      |                 | Unknown       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Medication Error                                                                                                                                                                                                         | Lexapro        |                    |                    | S               |                      |                      |                 | Forest        |                |
|                                                                                                                                                                                                                          | Oxycontin      |                    |                    | S               |                      |                      |                 | Purdue Pharma |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 07-Aug-2003                                                                                                                      | 3989093                | EXPEDITED (15-DAY) | Y                  | HO              | 2003031837           |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis; Muscle Spasms; Muscle Spasms                                                                                      | Neurontin              |                    |                    | S               |                      | 2100 Mg (Daily),        |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg (Daily), Oral     |                 | Not Reported |                |
|                                                                                                                                  | Unspecified Ingredient |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2003                                                                                                                      | 3969803                | EXPEDITED (15-DAY) | Y                  | DS, LT, RI      | 03P-013-0222847-00   |                         | 49 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Coma; Crush Syndrome; Dialysis; Drug Level Decreased; Hyperkalaemia; Obsessive Thoughts; Serotonin Syndrome | Depakene               |                    |                    | S               | Oral                 | 1000 Mg, 1 In 1 D, Oral |                 | Not Reported |                |
|                                                                                                                                  | Sipralaxa              |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2003                                                                                                                      | 3990001                | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03273-01     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium Decreased; Fluid Retention; Protein Total Decreased; Renal Failure                                               | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2003                                                                                                                      | 3983985                | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03195-01     |                         | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |                                         |   |      |             |              |
|-------------------------------------------------|-----------------------------------------|---|------|-------------|--------------|
| Inappropriate Antidiuretic<br>Hormone Secretion | Lexapro                                 | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                 | Xanax                                   | C |      |             | Not Reported |
|                                                 | Hormone Replacement<br>Medication (Nos) | C |      |             | Not Reported |
|                                                 | Armour Thyroid                          | C |      |             | Not Reported |
|                                                 | Bone Density Medication (Nos)           | C |      |             | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Aug-2003                     | 3986126        | DIRECT           | Y                  | OT              |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Gingival<br>Bleeding | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Forest       |                |
|                                 | Prometrium     |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Aug-2003              | 3988941                                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03353-01     |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Necrosis         | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Imuran                                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          |                                         |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Aug-2003              | 3966014        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02648-01     |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chorea; Insomnia; Mania  | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Coumadin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Levoxyl        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Pravachol      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Plavix         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Accupril       |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Aug-2003                                                                                                                           | 3991199                      | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-UKI-03364-01     |                      | 78 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure                                                                                                                | Cipralext                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                       | Bendrofluazide               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Doxazosin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Fosamax                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Calcihew (Calcium Carbonate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2003                                                                                                                           | 5833349                      | DIRECT             | Y                  | HO              |                      |                      | 13 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant Syndrome                                                                                                        | Abilify                      |                    |                    | S               |                      | 10mg Daily           |                 | Not Reported |                |
|                                                                                                                                       | Lexapro                      |                    |                    | S               |                      | 10mg Daily           |                 | Not Reported |                |
|                                                                                                                                       | Topamax                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Aug-2003                                                                                                                           | 3940609                      | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-01591-01     |                      | 84 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Condition Aggravated;<br>Decreased Appetite;<br>Nausea; Pain; Sleep<br>Disorder; Vomiting; Weight<br>Decreased | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                       | Pravachol                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Cozaar                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Lopresor                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Hydrochlorothiazide          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Multi-Vitamin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2003                                                                                                                           | 3987538                      | EXPEDITED (15-DAY) | Y                  | HO              | WAES 0308USA01626    |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |           |   |      |  |        |  |  |              |
|---------------|-----------|---|------|--|--------|--|--|--------------|
| Rash Pruritic | Mustargen | S |      |  |        |  |  | Merck        |
|               | Lexapro   | S | Oral |  | 25 DAY |  |  | Not Reported |
|               | Lexapro   | S | Oral |  | 5 DAY  |  |  | Not Reported |
|               | Seroquel  | C |      |  |        |  |  | Not Reported |
|               | Valium    | C |      |  |        |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2003              | 3992687       | DIRECT           | Y                  | OT              |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pruritus; Rash        | Lexapro                 |              |            | S           | Oral         | 10 Mg Po Qhs       |                 | Forest       |
|                       | Celexa                  |              |            | S           | Oral         | 30 Mg Po Qhs       |                 | Forest       |
|                       | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Miconazole              |              |            | C           |              |                    |                 | Not Reported |
|                       | Diflucan                |              |            | C           |              |                    |                 | Not Reported |
|                       | Seroquel                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2003              | 3930555       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-01217-01     |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma | Lexapro                |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                        | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2003              | 3948810       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02000-01     |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Attention Deficit/Hyperactivity Disorder; Generalised Tonic-Clonic Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                            | Concerta       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2003              | 3970302        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02708-01     |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyarrhythmia;         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Dizziness; Fatigue;      | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Feeling Abnormal;        | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Hypotension; Nausea;     | Diazepam       |                    |                    | S               |                      | 10 Mg Tid            |                 | Not Reported |                |
| Paradoxical Drug         | Belladonna     |                    |                    | S               |                      | 0.4 Mg Once          |                 | Not Reported |                |
| Reaction; Sinus          | Diazepam       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Bradycardia              |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2003              | 3991312        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00781-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hip Fracture; | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Injury; Suicide Attempt; | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Tremor                   |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2003              | 3995277        | EXPEDITED (15-DAY) | N                  | HO              | S03-USA-03426-01     |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Psychiatric      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qhs Po         |                 | Not Reported |                |
| Symptom; Vomiting        |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2003              | 3995281        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03464-01     |                      | 94 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis             | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                   | Lexapro                              |                    | S                  | Oral               | 10 Mg Qd Po          |                      | Not Reported    |              |                |
|-------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|--------------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                   | Tequin                               |                    | C                  |                    |                      |                      | Not Reported    |              |                |
|                                                                                                                   | Flagyl                               |                    | C                  |                    |                      |                      | Not Reported    |              |                |
|                                                                                                                   | Norvasc                              |                    | C                  |                    |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2003                                                                                                       | 4019637                              | EXPEDITED (15-DAY) | Y                  | DS                 | S03-UKI-03442-01     |                      | 32 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Speech Disorder                                                                                       | Cipralext                            |                    |                    | S                  |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2003                                                                                                       | 3993490                              | DIRECT             | Y                  | DS, HO, LT, RI, OT |                      |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Cognitive Disorder; Crying; Depression; Flashback; Memory Impairment; Nightmare; Speech Disorder; Tremor | Lexapro                              |                    |                    | S                  |                      | Once Day             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2003                                                                                                       | 3954792                              | EXPEDITED (15-DAY) | Y                  | HO                 | S03-USA-02160-01     |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence; Diverticulitis; Fall; Inappropriate Antidiuretic Hormone Secretion                            | Lexapro                              |                    |                    | S                  | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Tylenol Extra-Strentgh (Paracetamol) |                    |                    | C                  |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Lotrel                               |                    |                    | C                  |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Nexium (Esomeprazole)                |                    |                    | C                  |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Levaquin                             |                    |                    | C                  |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Flagyl                               |                    |                    | C                  |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 25-Aug-2003                                                                                                                                                                              | 3994082                  | DIRECT             | N                  | OT              |                      |                      | 66 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain Upper;<br>Dyschezia                                                                                                                                                       | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg 1/Day Oral     |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Aug-2003                                                                                                                                                                              | 3994171                  | DIRECT             | Y                  | OT              |                      |                      | 36 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Depression;<br>Dizziness; Dyspepsia;<br>Fatigue; Hypoaesthesia;<br>Insomnia; Malaise;<br>Paraesthesia;<br>Somnolence; Weight<br>Increased; White Blood<br>Cell Count Increased | Lexapro                  |                    |                    | S               | Oral                 | 20 Daily Oral        |                 | Not Reported    |                |
|                                                                                                                                                                                          | Wellbutrin               |                    |                    | S               | Oral                 | 300 Daily Oral       |                 | Glaxosmithkline |                |
|                                                                                                                                                                                          | Nasonex                  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                          | Motrin                   |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Aug-2003                                                                                                                                                                              | 3997930                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03556-01     |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Seizure                                                                                                                                                                                  | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Aug-2003                                                                                                                                                                              | 3998022                  | EXPEDITED (15-DAY) | Y                  | HO              | S03-SWI-03571-01     |                      | 80 YR           | Female          | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Overdose; Stupor; Suicide<br>Attempt                                                                                                                                                     | Cipraxel                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                          | Flurazepam Hydrochloride |                    |                    | S               | Oral                 | 80 Tablet Once Po    |                 | Not Reported    |                |
|                                                                                                                                                                                          | Flurazepam Hydrochloride |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported    |                |

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|                                                                                                                          |                |                    |                    |                 |                                                 |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Prednisone                                                                                                               |                | C                  |                    | Not Reported    |                                                 |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2003                                                                                                              | 3998582        | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-03572-01                                |                      | 60 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Maculo-Papular                                                                                                      | Cipralext      |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Lofepramine    |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2003                                                                                                              | 3998679        | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-03542-01                                |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Maternal<br>Drugs Affecting Foetus;<br>Medication Error;<br>Overdose                                       | Lexapro        |                    |                    | S               | Oral                                            | 100 Mg Once Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2003                                                                                                              | 3999430        | NON-EXPEDITED      | Y                  | HO, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12322251 |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt                                                                                 | Abilify        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                          | Lexapro        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2003                                                                                                              | 3956595        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02308-01                                |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Blood Glucose<br>Increased; Drug<br>Withdrawal Syndrome;<br>Eosinophil Percentage | Lexapro        |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Lexapro        |                    |                    | S               | Oral                                            | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                          | Lexapro        |                    |                    | S               | Oral                                            | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                     |                    |        |  |  |  |  |  |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------|--|--|--|--|--|------------------------------|
| Increased; Factor Xi Deficiency; Immune Thrombocytopenic Purpura; Lymphocyte Percentage Decreased; Monocyte Percentage Decreased; Neutrophil Percentage Increased; White Blood Cell Count Increased | Lipitor<br>Norvasc | C<br>C |  |  |  |  |  | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2003              | 3988943       | EXPEDITED (15-DAY) | Y                  |                 | S03-USA-03349-01     |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2003              | 3998439       | EXPEDITED (15-DAY) | Y                  | HO              | 2003PL000055         |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Necrosis      | Imuran                               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Lexapro                              |              |            | S           | Oral         | 10 Mg;Daily;Oral   |                 | Not Reported |
|                       | Wellbutrin (Bupropion Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2003              | 3942888       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01643-01     |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicologic Test Abnormal | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2003              | 3978700       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03009-01     |                      | 59 YR      | Male       | USA            |

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| Preferred Term                                                                                                    | Product    | Comp.              | OTC         | Role     | Route            | Dosage Text      | Duration | Mfr          |         |
|-------------------------------------------------------------------------------------------------------------------|------------|--------------------|-------------|----------|------------------|------------------|----------|--------------|---------|
| Parkinsonism                                                                                                      | Lexapro    |                    |             | S        | Oral             | 20 Mg Qd Po      |          | Not Reported |         |
|                                                                                                                   | Xanax      |                    |             | C        |                  |                  |          | Not Reported |         |
| FDA Received Date                                                                                                 | Case #     | Case Type          | Health Prof | Outcomes | Mfr Control #    | 503B Facility    | Age      | Sex          | Country |
| 02-Sep-2003                                                                                                       | 3997066    | DIRECT             | N           | HO, RI   |                  |                  | 50 YR    | Female       | USA     |
| Preferred Term                                                                                                    | Product    | Comp.              | OTC         | Role     | Route            | Dosage Text      | Duration | Mfr          |         |
| Anxiety; Asthenia; Drug Withdrawal Syndrome; Feeling Of Body Temperature Change; Flushing; Headache; Hypokalaemia | Lexapro    |                    |             | S        | Oral             | 1 Per Day Oral   |          | Not Reported |         |
|                                                                                                                   | Adipex-P   |                    |             | S        | Oral             | 1/2 Per Day Oral |          | Not Reported |         |
|                                                                                                                   | Atacand    |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Norvasc    |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Adipex-P   |                    |             | C        |                  |                  |          | Not Reported |         |
| FDA Received Date                                                                                                 | Case #     | Case Type          | Health Prof | Outcomes | Mfr Control #    | 503B Facility    | Age      | Sex          | Country |
| 02-Sep-2003                                                                                                       | 3998122    | DIRECT             | Y           | HO       |                  |                  | 38 YR    | Male         | USA     |
| Preferred Term                                                                                                    | Product    | Comp.              | OTC         | Role     | Route            | Dosage Text      | Duration | Mfr          |         |
| Alcohol Use; Blood Albumin; Blood Magnesium; Hyponatraemia; Seizure                                               | Trileptal  |                    |             | S        | Oral             | 300 Mg Po Bid    | 1 WEEK   | Not Reported |         |
|                                                                                                                   | Lexapro    |                    |             | S        | Oral             | 25 Mg Po Daily   |          | Not Reported |         |
|                                                                                                                   | Detrol     |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Trileptal  |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Clonazepam |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Haldol     |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Pamelor    |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Zestril    |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Inderal La |                    |             | C        |                  |                  |          | Not Reported |         |
|                                                                                                                   | Zyprexa    |                    |             | C        |                  |                  |          | Not Reported |         |
| FDA Received Date                                                                                                 | Case #     | Case Type          | Health Prof | Outcomes | Mfr Control #    | 503B Facility    | Age      | Sex          | Country |
| 02-Sep-2003                                                                                                       | 4000950    | EXPEDITED (15-DAY) | Y           | HO       | S03-USA-03622-01 |                  | 45 YR    | Female       | USA     |
| Preferred Term                                                                                                    | Product    | Comp.              | OTC         | Role     | Route            | Dosage Text      | Duration | Mfr          |         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                   |         |   |      |             |              |
|-----------------------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Coma; Facial Bones Fracture; Fall; Lethargy; Nausea; Petit Mal Epilepsy; Vomiting | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|-----------------------------------------------------------------------------------|---------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2003              | 4001177       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03627-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2003              | 4001064       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-03578-01     |                      | 38 YR      | Female     | GBR            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome; Serotonin Syndrome | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                              | Diflucan       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2003              | 4002732       | DIRECT           |                    | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Weight Increased      | Lexapro        |              |            | S           | Oral         | 10 Mg 1 Daily By Mouth |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2003              | 3993816       | EXPEDITED (15-DAY) | Y                  | DE              | S03-NOR-03363-01     |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Ciprallex         |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                       | Sobril (Oxazepam) |              |            | C           |              |                    |                 | Not Reported |

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| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Sep-2003                                                                                            | 3995289                                                | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-USA-03512-02              |                               | 12 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Electroencephalogram Abnormal; Petit Mal Epilepsy; Pyrexia                                             | Lexapro                                                |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                        | Lexapro                                                |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |
|                                                                                                        | Albuterol                                              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                        | Ritalin - Slow Release (Methylphenidate Hydrochloride) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2003                                                                                            | 4000702                                                | DIRECT                    | Y                           | OT                       |                               |                               | 22 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Tearfulness; Visual Impairment                                                                | Lexapro                                                |                           |                             | S                        | Oral                          | 20 Daily Oral                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2003                                                                                            | 4001031                                                | DIRECT                    | Y                           | OT                       |                               |                               | 25 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Behaviour; Irritability; Memory Impairment; Middle Insomnia; Restlessness; Retrograde Amnesia | Lexapro                                                |                           |                             | S                        | Oral                          | 10 Mg Oral                    |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Sep-2003                                                                                            | 4001023                                                | DIRECT                    | Y                           | OT                       |                               |                               | 78 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Medication Error                                                                                       | Lexapro                                                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2003                              | 4008508                | NON-EXPEDITED    | Y                  | OT              | S03-USA-01375-01     |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt | Lexapro                |                  |                    | S               |                      | 20 Tablet Once Po    |                 | Not Reported |                |
|                                          | Alcohol                |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                              | 4061449                | NON-EXPEDITED    | Y                  | OT              | S03-USA-02910-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                            | Lexapro                |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                              | 4061518                | NON-EXPEDITED    | Y                  | HO              | S03-USA-02883-01     |                      | 84 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression;<br>Hyponatraemia             | Lexapro                |                  |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Captopril              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Xanax                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Atenolol               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                          | Pepcid                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                              | 4061576                | NON-EXPEDITED    | Y                  | HO              | S03-USA-03010-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt | Lexapro                |                  |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Unspecified Ingredient |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                              | 4061614                | NON-EXPEDITED    | N                  | HO              | S03-USA-03352-01     |                      | 58 YR           | Female       | USA            |

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| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dermatitis                                     | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                | Lexapro        |                    |                    | S               |                      | 10 Mg Qd Po          | 4 DAY           | Not Reported |                |
|                                                | Seroquel       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Valium         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                                    | 4061697        | NON-EXPEDITED      | N                  | OT              | S03-USA-03253-01     |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Intentional Overdose; Suicide Attempt | Lexapro        |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                | Xanax          |                    |                    | S               |                      | 26 Tablet Once Po    | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                                    | 4061725        | NON-EXPEDITED      | N                  | OT              | S03-USA-02017-01     |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphemia; Memory Impairment; Tremor           | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          | 11 DAY          | Not Reported |                |
|                                                | Amoxicillin    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Darvocet-N 100 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2003                                    | 4061799        | NON-EXPEDITED      | Y                  | HO              | S02-USA-02963-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                                        | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                | Lexapro        |                    |                    | S               |                      | 10 Mg Once Po        | 2 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2003                                    | 3995291        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03513-01     |                      | 29 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abnormal Dreams;<br>Agitation; Alcohol<br>Withdrawal Syndrome;<br>Dehydration; Dizziness;<br>Feeling Abnormal; Feeling<br>Hot; Hyperhidrosis; Loss<br>Of Consciousness;<br>Nausea; Postictal State;<br>Rash Pruritic; Retrograde<br>Amnesia; Seizure;<br>Serotonin Syndrome;<br>Somnolence; Tongue<br>Biting; Vomiting | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Alcohol                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Allegra                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Nexium (Esomeprazole)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Unspecified Ingredient    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2003                                                                                                                                                                                                                                                                                                            | 4004737                   | DIRECT             | Y                  | RI              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cold Sweat;<br>Heart Rate Increased                                                                                                                                                                                                                                                                           | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Thiamine                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Folic Acid                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Valproic Acid             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Acetaminophen             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Oxazepam                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2003                                                                                                                                                                                                                                                                                                            | 4008398                   | EXPEDITED (15-DAY) | Y                  | HO              | S03-SWI-03871-01     |                      | 27 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug Screen<br>Positive; Loss Of<br>Consciousness; Mental<br>Disorder; Overdose;<br>Oxygen Saturation<br>Decreased; Somnolence;<br>Suicide Attempt                                                                                                                                                        | Ciprallex                 |                    |                    | S               |                      | 3 Tablet Once Po     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Ciprallex                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Bromazepam                |                    |                    | S               |                      | Tablet Once Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Bromazepam                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Diphenhydramine\Lorazepam |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                        | Diphenhydramine\Lorazepam |                    |                    | S               |                      | Tablet Once Po       |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Sep-2003                                                                                                                                                                                               | 3988975        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03323-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Faeces Discoloured; Fatigue; Nausea                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                           | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2003                                                                                                                                                                                               | 4001070        | EXPEDITED (15-DAY) | Y                  | DE              | S03-BRA-03664-01     |                      | 53 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                           | Alprazolam     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2003                                                                                                                                                                                               | 4008938        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03835-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Optic Neuritis                                                                                                                                                                                            | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2003                                                                                                                                                                                               | 4160678        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03893-01     |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Potassium Decreased; Chest Pain; Diplopia; Dizziness; Hyperhidrosis; Tachycardia; Tattoo; White Blood Cell Count | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                           | Insulin Nos    |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Sep-2003                       | 3979599                | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-USA-03015-01              |                               | 39 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Arthropod Bite; Aspartate Aminotransferase Increased; Dehydration; Encephalitis; Musculoskeletal Stiffness; Myalgia; Nausea; Pyrexia; Thrombocytopenia | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                                                                                                                                        | Quinine Sulfate         |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Sep-2003                       | 3994055                | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-USA-03526-01              |                               | 44 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Amnesia; Loss Of Consciousness; Seizure | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Qd Po                 |                          | Not Reported        |
|                                         | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                         | Depakote                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                         | Tegretol                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                         | Tegretol                |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Sep-2003                       | 4009597                | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-USA-03852-01              |                               | 55 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Asthenia; Inappropriate Antidiuretic Hormone Secretion; Mental Status Changes; Restlessness | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                                                                             | Hydrochlorothiazide     |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Sep-2003                       | 4010045                | EXPEDITED (15-DAY)        | Y                           | HO                       | 2003-02803                    |                               | 39 YR               | Female              | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|---------------|----------------|
| Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cinchonism; Dehydration; Encephalitis; Myalgia; Thrombocytopenia | Quinine Lexapro     |                    |                    | S<br>S          | Oral                 | 10 Mg Daily, Oral    |                 | Watson Forest |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
| 22-Sep-2003                                                                                                                        | 4061258             | NON-EXPEDITED      | Y                  | OT              | S02-USA-03279-01     |                      | 72 YR           | Male          | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Dehydration; Epistaxis                                                                                                             | Celexa              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported  |                |
|                                                                                                                                    | Celexa              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported  |                |
|                                                                                                                                    | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported  |                |
|                                                                                                                                    | Nitroglycerin Patch |                    |                    | S               |                      | 0.4 Mg Q1hr          |                 | Not Reported  |                |
|                                                                                                                                    | Nitroglycerin Patch |                    |                    | S               |                      | 0.6 Mg Q1hr          |                 | Not Reported  |                |
|                                                                                                                                    | Norvasc             |                    |                    | S               |                      |                      |                 | Not Reported  |                |
|                                                                                                                                    | Zaroxolyn           |                    |                    | S               |                      |                      |                 | Not Reported  |                |
|                                                                                                                                    | Prinivil            |                    |                    | S               |                      | 40 Mg Qd             |                 | Not Reported  |                |
|                                                                                                                                    | Lasix               |                    |                    | S               |                      |                      |                 | Not Reported  |                |
|                                                                                                                                    | Aldactazide         |                    |                    | S               |                      |                      |                 | Not Reported  |                |
| Digoxin                                                                                                                            |                     |                    | C                  |                 |                      |                      | Not Reported    |               |                |
| Lipitor                                                                                                                            |                     |                    | C                  |                 |                      |                      | Not Reported    |               |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>    | <u>Country</u> |
| 23-Sep-2003                                                                                                                        | 4010592             | EXPEDITED (15-DAY) | Y                  | LT              | S03-UKI-03874-01     |                      | 38 YR           | Female        | GBR            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>    |                |
| Generalised Tonic-Clonic Seizure                                                                                                   | Cipralext           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported  |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 23-Sep-2003                                                                                            | 4010643             | EXPEDITED (15-DAY) | Y                  | DE              | S03-UKI-03957-01     |                         | 58 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Ineffective                                                                    | Cipralext           |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2003                                                                                            | 3966022             | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-01403-01     |                         | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Asthenia; Blood Pressure Increased; Cerebrovascular Accident; Hemiparesis; Lacunar Infarction | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                        | Atenolol            |                    |                    | S               |                      | 50 Mg Qd                |                 | Not Reported |                |
|                                                                                                        | Hydrochlorothiazide |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                        | Ambien              |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                        | Naproxen            |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2003                                                                                            | 3983925             | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03158-01     |                         | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                       | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                        | Ambien              |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2003                                                                                            | 4011274             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03894-02     |                         | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Disorder; Neonatal  | Lexapro             |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                        | Lexapro             |                    |                    | S               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tachypnoea; Weight Gain  
Poor

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Sep-2003                                                  | 4012151        | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-03955-01     |                      | 40 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoventilation; Loss Of Consciousness; Somnolence; Vomiting | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2003                             | 3985499        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03198-01     |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Eye Haemorrhage; Retinopathy | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                         | Desogen        |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Oct-2003                                                                                                                                                                                                                                              | 3994038              | EXPEDITED (15-DAY) | Y                  | OT              | T03-USA-02443-01     |                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction; Arthralgia; Bronchospasm; Cough; Discomfort; Drug Hypersensitivity; Erythema; Laboratory Test Abnormal; Musculoskeletal Stiffness; Nasal Congestion; Platelet Count Increased; Rash Pruritic; Serum Sickness; Urticaria; Wheezing | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1 Tablet Qd Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                          | Placebo              |                    |                    | S               | Oral                 | 1 Tablet Qd Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                          | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------------|------------------------|-----------------|--------------|----------------|
| 01-Oct-2003                                                                          | 4012360        | DIRECT             | Y                  | OT              |                                       |                        | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Parasomnia;<br>Somnambulism                                                          | Lexapro        |                    |                    | S               |                                       | 10 Mg /D               |                 | Not Reported |                |
|                                                                                      | Amitriptyline  |                    |                    | S               |                                       | 200 Mg /D [Long Term]  |                 | Not Reported |                |
|                                                                                      | Celexa         |                    |                    | S               |                                       | 20 Mg /D               |                 | Not Reported |                |
|                                                                                      | Neurontin      |                    |                    | C               |                                       |                        |                 | Not Reported |                |
|                                                                                      | Hydrocodone    |                    |                    | C               |                                       |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2003                                                                          | 4014732        | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-04039-01                      |                        | 15 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased                                                   | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg Qd Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2003                                                                          | 4013096        | DIRECT             | Y                  | HO              |                                       |                        | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Urine; International Normalised Ratio Increased                                | Coumadin       |                    |                    | S               | Oral                                  | 5 Mg Po Qd             |                 | Not Reported |                |
|                                                                                      | Lexapro        |                    |                    | S               |                                       |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2003                                                                          | 4012828        | DIRECT             | Y                  | HO              |                                       |                        | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Blood Pressure Increased; Drug Interaction; Heart Rate Increased | Linezolid      |                    |                    | S               | Intravenous (not otherwise specified) | 600mg Q12h Intravenous |                 | Not Reported |                |
|                                                                                      | Lexapro        |                    |                    | S               | Oral                                  | 10 Mg Q24 Oral         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Oct-2003                                                                                                                             | 3976750              | EXPEDITED (15-DAY) | Y                  | OT              | S03-FRA-02869-01     |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                         | Inipomp              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                                                             | 4000965              | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03626-01     |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Oedema                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                         | Lasix                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Zaroxolyn            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                                                             | 4006569              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03747-01     |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroenteritis Viral;<br>Insomnia; Lymphocyte<br>Count Increased; Nausea;<br>Pyrexia; Renal Pain;<br>Retching; Somnolence;<br>Vomiting | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                                                             | 4010591              | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-03876-01     |                      | 21 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Decreased Appetite;<br>Urinary Incontinence                                                                       | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Oct-2003                                                                                   | 4013283        | DIRECT             | Y                  | HO              |                      |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Insomnia; Lethargy;<br>Nausea; Palpitations;<br>Tachycardia; Vomiting | Remeron        |                    |                    | S               | Oral                 | 15 Every Day Oral    |                 | Organon      |                |
|                                                                                               | Lexapro        |                    |                    | S               | Oral                 | 10 Every Day Oral    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                   | 4013299        | DIRECT             | Y                  | OT              |                      |                      | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nervous System Disorder                                                                       | Effexor Xr     |                    |                    | S               | Oral                 | 37.5 To 2 Times Oral |                 | Wyeth Ayerst |                |
|                                                                                               | Lexapro        |                    |                    | S               | Oral                 | 10mg Once A Day Oral |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                   | 4015815        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04079-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness                                                                                     | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                                   | 4015816        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04029-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Postictal<br>State             | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Oct-2003                                                                             | 4015818               | EXPEDITED (15-DAY) | Y                  | LT              | S03-USA-04019-02     |                      | 5 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Fetus; Neonatal Seizure                                        | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2003                                                                             | 4015871               | EXPEDITED (15-DAY) | Y                  | OT              | S03-BRA-04045-01     |                      | 19 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Loss Of Consciousness; Overdose; Suicide Attempt; Tachycardia | Lexapro               |                    |                    | S               | Oral                 | 60 Mg Once Po        |                 | Not Reported |                |
|                                                                                         | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Zoloft                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                         | Rivotril (Clonazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2003                                                                             | 3963816               | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02530-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                 | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2003                                                                             | 4000130               | EXPEDITED (15-DAY) | N                  | RI              | S03-USA-03617-01     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dental Caries; Gingival Recession                                                       | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2003                                                                             | 4017566               | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04120-01     |                      |                 | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hyperhidrosis; Nausea;<br>Serotonin Syndrome | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                              | Ambien                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2003                                  | 4017581                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04098-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                 | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2003                                  | 4063593                  | NON-EXPEDITED      | N                  | OT              | 2003171096US         |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt     | Xanax                    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                              | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2003                                  | 4018170                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04172-01     |                      | 36 YR           | Female       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome                  | Ciprallex                |                    |                    | S               | Oral                 | 1 Qd Po              |                 | Not Reported |                |
|                                              | Calcipotriol             |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                              | Hyoscyamine Hydrobromide |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                              | Paroxetine Hydrochloride |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2003                                  | 4018612                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03450-01     |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Flushing; Hypomania;<br>Increased Appetite;  | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |                                    |   |      |            |              |
|-----------------------------------------------------------|------------------------------------|---|------|------------|--------------|
| Insomnia; Joint Swelling;<br>Oedema Peripheral;<br>Tremor | Lexapro                            | S | Oral | 5 Mg Qd Po | Not Reported |
|                                                           | Ambien                             | C |      |            | Not Reported |
|                                                           | Clarinox                           | C |      |            | Not Reported |
|                                                           | Astelin (Azelastine Hydrochloride) | C |      |            | Not Reported |
|                                                           | Flonase                            | C |      |            | Not Reported |
|                                                           | Hyoscyamine Sulfate                | C |      |            | Not Reported |
|                                                           | Inderal                            | C |      |            | Not Reported |
|                                                           | Imitrex                            | C |      |            | Not Reported |
|                                                           | Zanaflex                           | C |      |            | Not Reported |
|                                                           | Flexeril                           | C |      |            | Not Reported |
|                                                           | Vioxx                              | C |      |            | Not Reported |
|                                                           | Protonix                           | C |      |            | Not Reported |
|                                                           | Tagamet                            | C |      |            | Not Reported |
|                                                           | Xanax                              | C |      |            | Not Reported |
|                                                           | Buspar                             | C |      |            | Not Reported |
|                                                           | Premarin                           | C |      |            | Not Reported |
|                                                           | Progesterone                       | C |      |            | Not Reported |
|                                                           | Talacen                            | C |      |            | Not Reported |
|                                                           | Tylenol With Codeine               | C |      |            | Not Reported |
|                                                           | Aspirin                            | C |      |            | Not Reported |
|                                                           | Fibercon                           | C |      |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2003              | 7223377       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04099-01     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Aphasia;<br>Confusional State;<br>Drooling; Dysgeusia; Eye<br>Disorder; Headache; Loss<br>Of Consciousness;<br>Postictal State; Simple<br>Partial Seizures | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                     | Effexor Xr     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                     | Levoxyl        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                     | Phenergan      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                     | Lortab         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                     | Topamax        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2003              | 4000961       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03621-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |              |   |      |             |              |
|-----------------------------|--------------|---|------|-------------|--------------|
| Blood Glucose Increased;    | Lexapro      | S | Oral | 10 Mg Qd Po | Not Reported |
| Ecchymosis;                 | Plavix       | S |      | 75 Mg Qd    | Not Reported |
| Encephalopathy; Fall;       | Haldol       | C |      |             | Not Reported |
| Gastritis; Gastrointestinal | Zoloft       | C |      |             | Not Reported |
| Haemorrhage;                | Procardia XI | C |      |             | Not Reported |
| Hallucination, Visual;      | Toprol XI    | C |      |             | Not Reported |
| Impaired Gastric            | Clonidine    | C |      |             | Not Reported |
| Emptying; Insomnia; Iron    | Aspirin      | C |      |             | Not Reported |
| Deficiency Anaemia;         | Altace       | C |      |             | Not Reported |
| Large Intestine Polyp;      |              |   |      |             |              |
| Mental Status Changes;      |              |   |      |             |              |
| Nuclear Magnetic            |              |   |      |             |              |
| Resonance Imaging Brain     |              |   |      |             |              |
| Abnormal; Occult Blood      |              |   |      |             |              |
| Positive; Oesophagitis      |              |   |      |             |              |
| Ulcerative; Stereotypy;     |              |   |      |             |              |
| Treatment Noncompliance     |              |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2003              | 4009659       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03788-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;    | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Depression; Pancreatitis | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2003              | 4014530       | DIRECT           | Y                  | OT              |                      |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Muscle Twitching;     | Lexapro        |              |            | S           | Oral         | 1 Po Qd            |                 | Not Reported |
| Myoclonus             |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2003              | 4014906       | DIRECT           | Y                  | OT              |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                        |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Galactorrhoea                                                 | Lexapro                |                    | S                  | Oral            | 10mg Once Daily Oral |                      | Forest          |              |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2003                                                   | 4019390                | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04094-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Incision Site                                                 | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Haemorrhage; Platelet Aggregation Abnormal; Post Procedural   | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Haemorrhage; Post Procedural                                  | Aspirin                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Haemorrhage; Post Procedural Haemorrhage; Vaginal Haemorrhage | Unspecified Ingredient |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2003                                                   | 4019399                | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04122-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema                                                    | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                               | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                               | Ambien                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2003                                                   | 4019407                | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04123-01     |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Insomnia; Tooth Injury; Trismus                 | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                               | Cozaar                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Norvasc                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Hydrochlorothiazide    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Nasacort               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Aspirin                |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 10-Oct-2003                                                                                                                                                                                                                                     | 4015003           | DIRECT             | N                  | OT              |                      |                      | 42 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Dizziness;<br>Feeling Of Body<br>Temperature Change;<br>Hyperhidrosis; Neck Pain;<br>Speech Disorder; Thinking<br>Abnormal                                                                                                             | Lexapro           |                    |                    | S               | Oral                 | One Day Oral         |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Oct-2003                                                                                                                                                                                                                                     | 4008924           | EXPEDITED (15-DAY) | Y                  | OT              | T03-USA-03803-01     |                      | 38 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Body Temperature<br>Increased; Generalised<br>Tonic-Clonic Seizure;<br>Glossodynia;<br>Hypoaesthesia;<br>Respiratory Rate<br>Increased; Sensory<br>Disturbance; Skin<br>Abrasion; Tongue Biting;<br>Tongue Disorder;<br>Treatment Noncompliance | Lexapro<br>Librax |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Oct-2003                                                                                                                                                                                                                                     | 4020050           | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-04055-01     |                      | 20 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Antidepressant Drug Level<br>Increased; Completed<br>Suicide                                                                                                                                                                                    | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2003              | 4020053       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04152-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis          | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2003              | 4020111       | EXPEDITED (15-DAY) | Y                  | DS              | S03-DEN-04262-01     |                      | 81 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Diplopia; Dizziness; Fall; Gait Disturbance; Impaired Driving Ability; Infection; Multiple Injuries; Myalgia; Skin Abrasion; Wound | Ciprallex                           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                | Aspirin                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Apurin (Allopurinol)                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Selozok                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Cardopax (Isosorbide Dinitrate)     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Detrusitol (Tolterodine L-Tartrate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Potassium Chloride                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Burinex (Bumetanide)                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Warfarin Sodium                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Nitrolingual (Glyceryl Trinitrate)  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                | Losec (Omeprazole)                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2003              | 4020983       | EXPEDITED (15-DAY) | Y                  | RI              | S03-USA-04182-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Flushing; Lymphoma; Salivary Gland Cancer; Tension Headache | Lexapro             |              |            | S           | Oral         | 5 Mg Qd Po; See Image |                 | Not Reported |
|                                                             | Hydrochlorothiazide |              |            | C           | Oral         | 5 Mg Qd Po; See Image |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2003              | 4022475       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-UKI-04179-01     |                      | 40 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Dyspnoea;<br>Supraventricular<br>Tachycardia                                                                                                                                                                                                                                                                                         | Cipralexx               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Oct-2003                                                                                                                                                                                                                                                                                                                          | 4017716                 | DIRECT                    | N                           |                          |                               |                               | 66 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Distension;<br>Abdominal Pain; Back<br>Pain; Chills; Drooling; Eye<br>Irritation;<br>Gastrooesophageal Reflux<br>Disease; Hallucination;<br>Headache; Hyperhidrosis;<br>Hypoaesthesia Oral;<br>Oedema Peripheral; Pain;<br>Palpitations; Pruritus<br>Generalised; Restless<br>Legs Syndrome; Skin<br>Ulcer; Vision Blurred | Lexapro                 |                           |                             | S                        |                               | 10 Mg, Daily                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Oct-2003                                                                                                                                                                                                                                                                                                                          | 4015861                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-UKI-04033-01              |                               | 44 YR                    | Male                | UKR                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic<br>Seizure                                                                                                                                                                                                                                                                                                  | Cipralexx               |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                      | Cipralexx               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                      | Propantheline           |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Oct-2003                                                                                                                                                                                                                                                                                                                          | 4017024                 | DIRECT                    | Y                           | HO                       |                               |                               | 92 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                   |                                                                          |                                 |      |              |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------|------|--------------|--------------------------------------------------------------------------------------------------------|
| Abdominal Pain Upper;<br>Asthenia; Blood Chloride<br>Decreased; Blood Sodium<br>Decreased; Dizziness;<br>Pco2 Decreased; Vomiting | Lexapro<br>Levothroid<br>Celebrex<br>Fosamax<br>Hctz<br>Xanax<br>Norvasc | S<br>C<br>C<br>C<br>C<br>C<br>C | Oral | 10mg Qd Oral | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------|------|--------------|--------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2003              | 4018154       | DIRECT           | Y                  | HO              |                      |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                             |
|----------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------|
| Chest Pain; Dizziness;<br>Hypoaesthesia;<br>Paraesthesia | Lexapro<br>Lisinopril<br>Humalog<br>Humulin N<br>Loratadine |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg Once Oral    |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2003              | 4024403       | EXPEDITED (15-DAY) | Y                  | RI              | S03-USA-04276-01     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lupus-Like Syndrome   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2003              | 3975308       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02896-01     |                      | 10 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u>                                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|-----------------------------------|-------------------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Somnolence | Lexapro<br>Keppra<br>Clonazepam<br>Synthroid (Levothyroxine<br>Sodium)<br>Lupron<br>Vinblastine |              |            | S<br>C<br>C<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                | Multi-Vitamin      |                    | C               |                      |                      |                 |              | Not Reported   |
|-------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                             |                | Vitamin C          |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                             |                | Calcium            |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2003                                                 | 3981232        | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-03102-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Deja Vu;                                           | Lexapro        |                    |                    | S               | Oral                 | 10 Mg, Qd Po         |                 | Not Reported |                |
| Fatigue; Petit Mal Epilepsy                                 | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                             | Dilantin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2003                                                 | 4026816        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04353-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                          | Lexapro        |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                             | Reglan         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Prilosec       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2003                                                 | 4027548        | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-04388-01     |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Completed Suicide; Gun<br>Shot Wound | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2003                                                 | 4028517        | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04344-01     |                      | 27 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                     | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                    |                                 |                    |                    |                 |                      |                      |                 |                                              |                |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| Dothiepin                                                                                                                          |                                 | C                  |                    | Not Reported    |                      |                      |                 |                                              |                |
| Zolpidem                                                                                                                           |                                 | C                  |                    | Not Reported    |                      |                      |                 |                                              |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 28-Oct-2003                                                                                                                        | 4029062                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04080-01     |                      | 49 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abdominal Distension;<br>Asthenia; Fatigue;<br>Hepatitis B                                                                         | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 29-Oct-2003                                                                                                                        | 4011048                         | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-USA-03926-01     |                      | 62 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Coma; Decreased<br>Appetite; Guillain-Barre<br>Syndrome; Overdose;<br>Respiratory Arrest;<br>Respiratory Depression;<br>Somnolence | Lexapro                         |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 30-Oct-2003                                                                                                                        | 3964536                         | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-USA-02601-01     |                      | 49 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Bradycardia;<br>Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes                                                           | Lexapro<br>Zanaflex<br>Zanaflex |                    |                    | S<br>S<br>S     | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 30-Oct-2003                                                                                                                        | 4028719                         | EXPEDITED (15-DAY) | Y                  | HO              | S03-SWE-04409-01     |                      | 76 YR           | Female                                       | SWE            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                              |   |              |
|---------------------------------------|------------------------------|---|--------------|
| Infection; Toxic Epidermal Necrolysis | Ciprallex                    | S | Not Reported |
|                                       | Allopurinol                  | S | Not Reported |
|                                       | Tramadol Hydrochloride       | S | Not Reported |
|                                       | Seloken                      | C | Not Reported |
|                                       | Furosemide                   | C | Not Reported |
|                                       | Tamoxifen Citrate            | C | Not Reported |
|                                       | Celebra "Pfizer" (Celecoxib) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2003              | 4029581       | EXPEDITED (15-DAY) | Y                  | LT, OT          | S03-USA-04384-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Road Traffic Accident; Seizure | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2003              | 4025441       | DIRECT           |                    |                 |                      |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Medication Error      | Lexapro        |              |            | S           |              | Tablet             |                 | Not Reported |
|                       | Celexa         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2003              | 4030263       | EXPEDITED (15-DAY) | Y                  | DE, HO, LT, OT  | KII-2003-0004112     |                      | 43 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acid Base Balance                                                | Oxycontin               |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Blood Glucose                                          | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Blood Lactic Acid Increased; Blood Pressure Decreased; | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Gabapentin              |              |            | S           |              | 400 Mg             |                 | Not Reported |
| Blood Pressure Increased;                                        | Quetiapine Fumarate     |              |            | S           |              | 200 Mg             |                 | Not Reported |
| Body Temperature Increased; Bradycardia;                         | Citalopram              |              |            | S           |              | 20 Mg              |                 | Not Reported |
| Cardiac Arrest; Coma;                                            | Clonazepam              |              |            | S           |              | 1 Mg               |                 | Not Reported |
| Depression;                                                      | Zanaflex                |              |            | S           | Oral         | 4 Mg, Oral         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                    |                               |   |        |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---|--------|--------------|
| Electrocardiogram Qt Prolonged;                                                                                                                                                    | Bupropion Hydrochloride       | S | 150 Mg | Not Reported |
| Electroencephalogram Abnormal; Heart Rate Increased; Miosis; Muscle Twitching; Mydriasis; Overdose; Posturing; Pupil Fixed; Respiratory Rate Decreased; Respiratory Rate Increased | Cyclobenzaprine Hydrochloride | S | 10 Mg  | Not Reported |
|                                                                                                                                                                                    | Amitriptyline Hydrochloride   | S | 50 Mg  | Not Reported |
|                                                                                                                                                                                    | Escitalopram                  | S |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2003              | 4031247       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04421-01     |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Emotional Distress; Feeling Abnormal; Self-Injurious Ideation | Ciprallex      |              |            | S           |              | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Nov-2003              | 4021515       | EXPEDITED (15-DAY) | Y                  | HO              | DE-GLAXOSMITHKLINE-D0042327A |                      | 46 YR      | Unknown    | DEU            |

| <u>Preferred Term</u>                 | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Intentional Overdose; Suicide Attempt | Lithium Carbonate |              |            | S           | Oral         | 25tab Single Dose  | 1 DAY           | Glaxosmithkline |
|                                       | Ciprallex         |              |            | S           | Oral         | 20tab Single Dose  | 1 DAY           | Not Reported    |
|                                       | Wine              |              |            | S           | Oral         |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2003              | 3871116       | EXPEDITED (15-DAY) | Y                  | DE              | S02-USA-02951-01     |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction      | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Celexa         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |           |   |              |
|--|-----------|---|--------------|
|  | Klonopin  | C | Not Reported |
|  | Diovan    | C | Not Reported |
|  | Duragesic | C | Not Reported |
|  | Actiq     | C | Not Reported |
|  | Duragesic | C | Not Reported |
|  | Flexeril  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2003              | 4008652       | EXPEDITED (15-DAY) | Y                  | DE              | S03-FRA-03812-01     |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram Oxalate      |              |            | S           | Oral         | 20 Mg Qd; Po       |                 | Not Reported |
|                       | Risperdal                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Levothyroxine Sodium      |              |            | C           |              |                    |                 | Not Reported |
|                       | Tenormin                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Tropatepine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Imovane (Zopiclone)       |              |            | C           |              |                    |                 | Not Reported |
|                       | Effexor                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Nov-2003              | 4025935       | DIRECT           | Y                  |                 |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|------------|
| Pregnancy Test Positive | Lexapro        |              |            | S           | Oral         | 20 Mg Daily (Taken Orally) |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Nov-2003              | 4026654       | DIRECT           | Y                  | CA, HO, LT, RI  |                      |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Syncope; Ventricular Fibrillation; Ventricular Tachycardia | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Forest       |
|                                                            | Premarin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2003              | 4024074       | NON-EXPEDITED    | Y                  |                 | US-                  |                      | 46 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

GLAXOSMITHKLINE-  
A0413937A

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Drug Interaction; Feeling Abnormal; Irritability | Wellbutrin     |              |            | S           | Oral         | 200mg Twice Per Day | 1 YR            | Glaxosmithkline |
|                                                  | Lexapro        |              |            | S           | Unknown      | 10mg Per Day        |                 | Not Reported    |
|                                                  | Ambien         |              |            | C           | Unknown      | 10mg At Night       |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2003              | 4025531       | DIRECT           | Y                  | RI              |                      |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section; Maternal Drugs Affecting Foetus; Neonatal Respiratory Arrest | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2003              | 4028326       | DIRECT           | Y                  | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Libido Decreased      | Lexapro        |              |            | S           | Oral         | 20 Mg Po Qd        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2003              | 4033644       | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04493-01     |                      | 35 YR      | Male       | GBR            |

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure; Vision Blurred | Ciprallex              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                         | Tramadol Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                        | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2003                                                     | 4033660                                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04499-01     |                      | 70 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                           | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Distress;<br>Hallucination, Visual                    | Ciprallex                                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                 | Stemetil "Aventis Pharma"<br>(Prochlorperazine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Ziimovane (Zopiclone)                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Innovace (Enalapril Maleate)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Losec (Omeprazole)                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Plendil                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Qvar (Beclometasone<br>Dipropionate)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Paramol-118                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Ventolin                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2003                                                     | 4000943                                         | EXPEDITED (15-DAY) | Y                  | HO, OT          | S03-BRA-03652-01     |                      | 30 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Blister;<br>Oropharyngeal Blistering;<br>Thrombocytopenia | Lexapro                                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                 | Lexapro                                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2003                                                     | 4014764                                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04018-01     |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                                    | Lexapro                                         |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                 | Lexapro                                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                 | Singulair                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Nasacort                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                 | Allegra                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 12-Nov-2003                                                                                                                   | 4035257                          | EXPEDITED (15-DAY) |                    | HO              | HQWYE542027OCT03     |                                           | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemoglobin; Intentional Overdose; Suicide Attempt                                                                            | Serax                            |                    |                    | S               | Oral                 | "Excessive Ingestion" (Dose Unknown) Oral |                 | Not Reported |                |
|                                                                                                                               | Unspecified Ingredient           |                    |                    | S               | Oral                 | Oral                                      |                 | Not Reported |                |
|                                                                                                                               | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg 1 X Per 1 Day Oral                  |                 | Not Reported |                |
|                                                                                                                               | Lexapro                          |                    |                    | S               |                      | 20 Mg 1x Per 1 Day                        |                 | Not Reported |                |
|                                                                                                                               | Neurontin                        |                    |                    | S               |                      | 300 Mg 3x Per 1 Day                       |                 | Not Reported |                |
|                                                                                                                               | Neurontin                        |                    |                    | S               |                      | 'Excessive Ingestion" (Dose Unknown)      |                 | Not Reported |                |
|                                                                                                                               | Corgard                          |                    |                    | C               |                      |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2003                                                                                                                   | 4035484                          | EXPEDITED (15-DAY) | Y                  | DS, HO, LT      | S03-SWI-04574-01     |                                           | 40 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Cachexia; Loss Of Consciousness; Miosis; Respiratory Rate Increased; Thrombocytopenia; Toxicologic Test Abnormal | Cipralext                        |                    |                    | S               | Oral                 | 20 Mg Qd Po                               |                 | Not Reported |                |
|                                                                                                                               | Valproate Sodium                 |                    |                    | S               | Oral                 | 500 Mg Qd Po                              |                 | Not Reported |                |
|                                                                                                                               | Imovane (Zopiclone)              |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                               | Kapanol (Morphine Sulfate)       |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                               | Seresta Forte (Oxazepam)         |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                               | Unspecified Ingredient           |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                               | Benerva (Thiamine Hydrochloride) |                    |                    | C               |                      |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2003                                                                                                                   | 4029739                          | DIRECT             | Y                  | DS, LT, RI      |                      |                                           | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;                                                                                                           | Lexapro                          |                    |                    | S               |                      |                                           |                 | Not Reported |                |

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|                                                                                           |          |   |              |
|-------------------------------------------------------------------------------------------|----------|---|--------------|
| Economic Problem; Loss Of Employment; Major Depression; Partner Stress; Suicidal Ideation | Adderall | C | Not Reported |
|-------------------------------------------------------------------------------------------|----------|---|--------------|

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Nov-2003                                           | 4033053        | DIRECT           | Y                  | HO              |                      |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased; Circulatory Collapse; Syncope | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Oral        |                 | Forest       |                |
|                                                       | Colace         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Senokot        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Abilify        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Multivitamins  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Citrucel       |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Nov-2003                                                                                                          | 4030478        | DIRECT           | N                  | DS              |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Asthenia; Depressed Mood; Drug Dependence; Drug Withdrawal Syndrome; Feeling Abnormal; Irritability; Pruritus | Lexapro        |                  |                    | S               |                      | 5 Mg 1 Time Dai      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Nov-2003                                                                                                      | 4036706        | EXPEDITED (15-DAY) | Y                  | OT              | SUSI-2003-00426      |                      | 11 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Delusional Disorder, Persecutory Type; Drug Interaction; Hallucination, Visual; Heart Rate Increased; | Adderall Xr    |                    |                    | S               |                      | 20 Mg, 1x/Day, Qd    |                 | Not Reported |                |
|                                                                                                                  | Lexapro        |                    |                    | S               |                      | 10 Mg, , 1x/Day, Qd  |                 | Not Reported |                |

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Social Avoidant Behaviour

| <u>FDA Received Date</u>              | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Nov-2003                           | 4032188                 | DIRECT           | Y                  | RI              |                      |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism; Spontaneous Penile Erection | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Oral        |                 | Not Reported |                |
|                                       | Trazodone Hydrochloride |                  |                    | S               | Oral                 | 50 Mg Hs-One T Oral  |                 | Not Reported |                |
|                                       | Mylanta                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Bisacodyl               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Nicorette               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Ibuoprofen              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Imitrex                 |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Nov-2003                                                                                                                             | 4032189        | DIRECT           | Y                  |                 |                      |                      | 47 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain; Aggression; Alcohol Use; Amnesia; Apathy; Back Pain; Drug Withdrawal Syndrome; Loss Of Consciousness; Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Nov-2003                                                                                                                    | 3905298                              | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-00415-01     |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anaemia; Asthenia; Balance Disorder; Coordination Abnormal; Dysphonia; Dyspnoea; Dyspnoea Exertional; Fatigue; Gait | Lexapro                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Acyclovir                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Cozaar                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Unspecified Ingredient               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Flomax Mr (Tamsulosin Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |



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|                                                                                                                                                                                                                         |                            |             |                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------|----------------------------------------------|
| Disturbance; Herpes Virus Infection; Hypersensitivity; Immunosuppression; Leukopenia; Liver Function Test Abnormal; Mental Status Changes; Neurotoxicity; Pyrexia; Toxicity To Various Agents; Tremor; Weight Decreased | Ambien<br>Xanax<br>Serzone | C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2003              | 4029579       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04440-01     |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrooesophageal Reflux Disease; Generalised Tonic-Clonic Seizure; Throat Irritation | Lexapro                              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                       | Wellbutrin (Bupropion Hydrochloride) |              |            | S           |              | 200 Mg Bid         |                 | Not Reported |
|                                                                                       | Wellbutrin (Bupropion Hydrochloride) |              |            | S           |              | 100 Mg Bid         |                 | Not Reported |
|                                                                                       | Wellbutrin (Bupropion Hydrochloride) |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |
|                                                                                       | Neurontin                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2003              | 4038109       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04559-01     |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation; Chest Pain; Dizziness; Headache; Hyperhidrosis; Throat Irritation | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                      | Nitroglycerin  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Toprol XL      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Calcium        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Vitamins       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Prempro        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Zocor          |              |            | C           |              |                    |                 | Not Reported |

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| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Nov-2003                                                        | 4038537                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S03-UKI-04745-01                                |                               |                          | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                  | Ciprallex               |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Nov-2003                                                        | 4038907                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-USA-04755-01                                |                               | 58 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Bilirubin Increased;<br>Hepatitis; Hepatomegaly;<br>Pruritus | Lexapro                 |                           |                             | S                        | Oral                                            | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Nov-2003                                                        | 4039042                 | EXPEDITED (15-DAY)        | N                           | HO                       | S03-USA-04754-01                                |                               | 78 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Failure<br>Congestive; Dry Mouth;<br>Polydipsia            | Lexapro                 |                           |                             | S                        | Oral                                            | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                    | Metoprolol              |                           |                             | C                        |                                                 |                               |                          | Not Reported        |                         |
|                                                                    | Tamoxifen Citrate       |                           |                             | C                        |                                                 |                               |                          | Not Reported        |                         |
|                                                                    | Diovan                  |                           |                             | C                        |                                                 |                               |                          | Not Reported        |                         |
|                                                                    | Aspirin                 |                           |                             | C                        |                                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Nov-2003                                                        | 4034004                 | NON-EXPEDITED             | Y                           | OT                       | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12416723 |                               | 2 YR                     | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Overdose                                                | Abilify                 |                           |                             | S                        | Oral                                            |                               |                          | Not Reported        |                         |
|                                                                    | Lexapro                 |                           |                             | S                        | Oral                                            |                               |                          | Not Reported        |                         |
|                                                                    | Seroquel                |                           |                             | S                        | Oral                                            |                               |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Nov-2003                                                                                                       | 4034441        | DIRECT           |                    | HO              |                      |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Hot; Heart Rate Increased                                                                                 | Lexapro        |                  |                    | S               | Oral                 | 10 Mg 1 Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2003                                                                                                       | 4034471        | DIRECT           | Y                  | HO              |                      |                      | 12 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory; Paranoia                                                                                 | Lexapro        |                  |                    | S               | Oral                 | 40 Mg Every Day Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2003                                                                                                       | 4035580        | DIRECT           | Y                  | HO, LT          |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Embolism                                                                                                | Lexapro        |                  |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2003                                                                                                       | 4036511        | DIRECT           | Y                  | DS              |                      |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Hypoaesthesia; Hypoaesthesia Oral; Paraesthesia; Polyneuropathy; Rash Maculo-Papular; Sensory Loss | Lexapro        |                  |                    | S               |                      | Once 10 Mg Am        | 4 WEEK          | Not Reported |                |

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| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2003                                                                                           | 3976614        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02912-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia; Mental Status Changes; Paraesthesia; Viral Infection; White Blood Cell Count Decreased | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2003                                                                                           | 3994061        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03538-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Diarrhoea; Hepatitis                                                                  | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2003                                                                                           | 4008955        | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-03768-01     |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound                                                                     | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Lisinopril     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Glucovance     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2003                                                                                           | 4035983        | DIRECT             | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error                                                                                      | Lexapro        |                    |                    | S               |                      | Tablet               |                 | Not Reported |                |
|                                                                                                       | Loxitane       |                    |                    | S               |                      | Capsules             |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2003                                                                   | 4041181                   | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-04763-01     |                      | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                             | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2003                                                                   | 4041198                   | EXPEDITED (15-DAY) | Y                  | HO, OT          | S03-USA-04762-01     |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Stenosis; Aortic Aneurysm; Arteriosclerosis                              | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Coronary Artery; Atrophy; Balance Disorder;                                   | Prevacid                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Cardiomegaly; Dysuria;                                                        | Lopressor                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Fall; Gait Disturbance;                                                       | Norvasc                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Gait Disturbance;                                                             | Lipitor                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hypochloroemia;                                                               | Acetaminophen\Hydrocodone |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Inappropriate Antidiuretic                                                    | Bitartrate                |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Hormone Secretion;                                                            | Ascriptin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Osteoarthritis; Pain;                                                         | Lidoderm(Lidocaine)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Physical Examination Abnormal; Spinal Osteoarthritis; Spinal Stenosis; Tremor |                           |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2003                                                                   | 4041200                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | S03-USA-04759-01     |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis; Hypercoagulation; Pelvic Pain; Thrombophlebitis         | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Superficial; Varicose Vein                                                    | Clonazepam                |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|------------------|----------------------|-----------------------------|-----------------|--------------------------------------------------------------|----------------|
| 28-Nov-2003                                                                                                          | 4036891                                             | DIRECT             | Y                  | DS               |                      |                             | 40 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hallucination;<br>Hypoaesthesia Oral;<br>Orgasm Abnormal;<br>Paraesthesia;<br>Polyneuropathy; Rash<br>Maculo-Papular | Lexapro                                             |                    |                    | S                |                      | Once 10 Mg Am               | 4 WEEK          | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 28-Nov-2003                                                                                                          | 4041804                                             | EXPEDITED (15-DAY) | Y                  | OT               | S03-UKI-04822-01     |                             | 44 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Colitis; Condition<br>Aggravated; Constipation;<br>Diarrhoea Haemorrhagic                                            | Ciprallex<br>Clotrimazole                           |                    |                    | S<br>C           | Oral                 | 10 Mg Qd Po                 |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 28-Nov-2003                                                                                                          | 4041805                                             | EXPEDITED (15-DAY) | Y                  | LT               | S03-UKI-04817-01     |                             | 53 YR           | Male                                                         | GBR            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Serotonin Syndrome                                                                                                   | Ciprallex<br>Buspirone<br>Mirtazapine<br>Nitrazepam |                    |                    | S<br>S<br>S<br>C | Oral<br><br>Oral     | 10 Mg Qd Po<br><br>15 Mg Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 28-Nov-2003                                                                                                          | 6035458                                             | EXPEDITED (15-DAY) | Y                  | OT               | S03-UKI-04827-01     |                             | 53 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Dermatitis; Sunburn                                                                                                  | Ciprallex                                           |                    |                    | S                | Oral                 | 1 Tablet Qd Po              |                 | Not Reported                                                 |                |

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|                                                                                                                                            |                         | Kliovance                 |                    | C               |                      |                      |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                            |                         | Propranolol Hydrochloride |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                            |                         | Olanzapine                |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                            |                         | Betnovate (Betamethasone) |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                            |                         | Unspecified Ingredient    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2003                                                                                                                                | 4038249                 | DIRECT                    | Y                  | OT              |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Maternal Drugs Affecting<br>Foetus; Maternal Drugs<br>Affecting Foetus                                            | Lexapro                 |                           |                    | S               | Oral                 | 1 Tablet Oral        |                 | Not Reported |                |
|                                                                                                                                            | Trazodone Hydrochloride |                           |                    | S               | Oral                 | 1 Tablet Oral        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2003                                                                                                                                | 4038781                 | EXPEDITED (15-DAY)        | Y                  | HO              | S03-BEL-04679-01     |                      | 82 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Fall;<br>General Physical Health<br>Deterioration;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram Oxalate    |                           |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                            | Tenormin                |                           |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Lorazepam               |                           |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Movicol                 |                           |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Omeprazole              |                           |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Risperidone             |                           |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Oxybutynin              |                           |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2003                                                                                                                                | 4040481                 | DIRECT                    | Y                  | OT              |                      |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ear Disorder; Sensory<br>Disturbance                                                                                                       | Lexapro                 |                           |                    | S               | Oral                 | 1 Tab Po Qd          |                 | Not Reported |                |
|                                                                                                                                            | Aciphex                 |                           |                    | C               |                      |                      |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------|-------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 04-Dec-2003                                                     | 3987985                             | EXPEDITED (15-DAY)        | Y                           | DE                       | S03-IRL-03292-01              |                               | 60 YR                    | Male                | IRL                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                               | Escitalopram Oxalate                |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2003                                                     | 3995655                             | EXPEDITED (15-DAY)        | Y                           | DE                       | S03-IRL-03508-01              |                               |                          | Male                | IRL                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                               | Lexapro                             |                           |                             | S                        | Oral                          | 40 Mg Qd Po                   |                          |                     | Not Reported            |
|                                                                 | Lexapro                             |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2003                                                     | 4027771                             | EXPEDITED (15-DAY)        | Y                           | HO                       | S03-GER-04340-01              |                               | 30 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Irritability; Restlessness;<br>Suicidal Ideation                | Cipralext                           |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |
|                                                                 | Cipralext                           |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          |                     | Not Reported            |
|                                                                 | Cipramil (Citalopram Hydrochloride) |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                 | Lorazepam                           |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                 | Zyprexa                             |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2003                                                     | 4043536                             | EXPEDITED (15-DAY)        | Y                           | CA                       | S03-UKI-04904-01              |                               | 34 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anembryonic Gestation;<br>Maternal Exposure During<br>Pregnancy | Cipralext                           |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2003                                         | 4014205                                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04011-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Ecchymosis; Somnolence | Lexapro                                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Adderall                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Xanax                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2003                                         | 4044642                                 | EXPEDITED (15-DAY) | Y                  | DS              | S03-SWI-04930-01     |                      | 34 YR           | Female       | CHE            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ageusia; Decreased<br>Appetite; Parosmia            | Ciprallex                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Xanax                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Zolpidem Tartrate                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2003                                         | 4044741                                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-04921-01     |                      | 59 YR           | Female       | GBR            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination                                       | Ciprallex                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Amitriptyline                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2003                                         | 4045303                                 | EXPEDITED (15-DAY) | Y                  | HO              | HQWYE311226NOV03     |                      | 83 YR           | Female       | AUT            |
| <u>Preferred Term</u>                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;<br>Depression;                    | Venlafaxine Hydrochloride               |                    |                    | S               | Oral                 | See Image Oral       |                 | Not Reported |                |
|                                                     |                                         |                    |                    |                 | Oral                 | See Image Oral       |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |                         |   |      |                    |                                     |                         |              |
|--------------------------------------------------------------------------|-------------------------|---|------|--------------------|-------------------------------------|-------------------------|--------------|
| Hyponatraemia; Urinary Tract Infection; White Blood Cell Count Increased | Ciprallex               | S | Oral | 2o Mg 1x Per 1 Day | See Image<br>See Image<br>See Image | 5 DAY<br>1 DAY<br>1 DAY | Not Reported |
|                                                                          | Trileptal               | S |      |                    |                                     |                         | Not Reported |
|                                                                          | Seroquel                | C |      |                    |                                     |                         | Not Reported |
|                                                                          | Memantine Hydrochloride | C |      |                    |                                     |                         | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 08-Dec-2003                       | 4041402                | DIRECT                    |                             | OT                       |                               |                               | 18 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Liver Function Test Abnormal   | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg 1/2 X 4 D 1 Oral      |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 09-Dec-2003                       | 4045601                | EXPEDITED (15-DAY)        | N                           | OT                       | S03-USA-04971-01              |                               | 21 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Agoraphobia; Claustrophobia; Dizziness; Loss Of Personal Independence In Daily Activities; Panic Attack; Somnambulism; Weight Increased | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                                                                                                                         | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 09-Dec-2003                       | 4045876                | EXPEDITED (15-DAY)        | Y                           | HO                       | HQWYE843007NOV03              |                               | 51 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|--------------------------------|--------------------------|---------------------|
| Drug Withdrawal Syndrome; Intentional Overdose; Loss Of Consciousness; Seizure; Suicide Attempt | Effexor Xr              |                       |                     | S                    | Oral                  | Overdose Amount, Unknown; Oral |                          | Not Reported        |
|                                                                                                 | Atenolol                |                       |                     | S                    |                       | Overdose Amount Unknown        |                          | Not Reported        |

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|                           |   |                         |              |
|---------------------------|---|-------------------------|--------------|
| Bactrim                   | S | Overdose Amount Unknown | Not Reported |
| Benzonatate               | S | Overdose Amount Unknown | Not Reported |
| Flavoxate Hydrochloride   | S | Overdose Amount Unknown | Not Reported |
| Indocin                   | S | Overdose Amount Unknown | Not Reported |
| Lexapro                   | S | Overdose Amount Unknown | Not Reported |
| Minocycline Hydrochloride | S | Overdose Amount Unknown | Not Reported |
| Naproxen                  | S | Overdose Amount Unknown | Not Reported |
| Wellbutrin                | S | Overdose Amount Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2003              | 4046829       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04356-01     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Sodium Decreased; Brain Stem Infarction; Confusional State; Coordination Abnormal; Encephalopathy; Extrapyrmidal Disorder; Haematocrit Decreased; Inappropriate Antidiuretic Hormone Secretion; Nystagmus; Pneumonia | Lexapro                     |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Lexapro                     |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Keppra                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Risperdal                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Abilify                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Nortriptyline Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Remeron                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                 | Metoprolol                  |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Dec-2003                       | 3990154                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-USA-03382-01              |                               | 36 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| No Adverse Event                  | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Dec-2003                                                                                                                                                                                                                                                                                                                                                                                           | 4024405                 | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | S03-USA-04275-01              |                               | 14 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anger; Atrioventricular Block First Degree; Atrioventricular Block Second Degree; Band Neutrophil Count Increased; Bronchitis; Bundle Branch Block Right; Dehydration; Diarrhoea; Gastritis Viral; Gastroesophageal Reflux Disease; Haematocrit Decreased; Hand Fracture; Headache; Injury; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Neutrophil Count Decreased; Tremor | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Dec-2003                       | 4047265                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-USA-03828-03              |                               | 37 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                                           |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Alopecia; Blood Potassium Decreased                                            |                                           | Lexapro            | S                  | Oral            | 20 Mg Qd Po          |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2003                                                                    | 4047429                                   | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-04848-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Fall;<br>Generalised Tonic-Clonic<br>Seizure; Tongue<br>Haemorrhage | Lexapro                                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                | Verelan (Verapamil Hydrochloride)         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Singulair                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Premarin                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2003                                                                    | 4047514                                   | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04961-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematemesis; Platelet Count Decreased                                         | Lexapro                                   |                    |                    | S               |                      | 10mg Pd Po           |                 | Not Reported |                |
|                                                                                | Trazodone Hydrochloride                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                | Prilosec                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Percocet                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Atenolol                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Clarinx                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Patanol                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Serevent Diskus                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Pulmicort Flexhaler                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Flexeril (Cloclobenzaprine Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2003                                                                    | 4047768                                   | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-05039-01     |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Alcohol<br>Interaction; Alcohol             | Lexapro                                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                | Alcohol                                   |                    |                    | S               |                      |                      |                 | Not Reported |                |

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Poisoning; Legal Problem;  
Road Traffic Accident

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Dec-2003              | 3991317                 | NON-EXPEDITED    | Y                  | HO              | S03-USA-01206-01     |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia              | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Trazodone Hydrochloride |                  |                    | S               |                      | 50 Mg Qhs            |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003              | 4076394                 | NON-EXPEDITED    | Y                  | OT              | S03-USA-03891-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Mania         | Lexapro                 |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003              | 4076397                 | NON-EXPEDITED    | Y                  | OT              | S03-USA-04012-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction    | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                          | Hydrochlorothiazide     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Hyzaar                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003              | 4076406                 | NON-EXPEDITED    | Y                  | HO              | S03-USA-04521-01     |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertension             | Lexapro                 |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>          | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Dec-2003                       | 4076408            | NON-EXPEDITED    | Y                  | HO              | S03-USA-04183-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>             | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                             | Lexapro            |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003                       | 4076410            | NON-EXPEDITED    | Y                  | HO              | S03-USA-04180-01     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                     | Lexapro            |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                   | Lexapro            |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                   | Lots Of Medication |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003                       | 4076412            | NON-EXPEDITED    | N                  | RI              | S03-USA-04146-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Vision Blurred | Lexapro            |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Celexa             |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003                       | 4076896            | NON-EXPEDITED    | Y                  | DE              | S03-USA-03784-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                             | Lexapro            |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                   | Lexapro            |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                   | Seroquel           |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003                       | 4076910            | NON-EXPEDITED    | N                  | OT              | S03-USA-03628-01     |                      | 25 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Feeling Abnormal;<br>Insomnia; Weight<br>Increased               | Lexapro             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                  | Remeron             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                  | Remeron             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2003                                                      | 4076926             | NON-EXPEDITED      | Y                  | HO              | S03-USA-03623-01     |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                    | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Atenolol            |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                  | Hydrochlorothiazide |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                  | Norvasc             |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                  | Synthroid           |                    |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                  | Premarin            |                    |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2003                                                      | 4048511             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05002-01     |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure<br>Fluctuation; Feeling Hot;<br>Muscular Weakness | Lexapro             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2003                                                      | 4048514             | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05065-01     |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                                                         | Lexapro             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Lexapro             |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2003                                                      | 4024949             | EXPEDITED (15-DAY) | Y                  | HO              | S03-GER-04322-01     |                      | 41 YR           | Male         | DEU            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysphagia;<br>Extrapyramidal Disorder;<br>Salivary Hypersecretion;<br>Sedation | Cipralext            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                | Lithium              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Solian (Amisulpride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2003              | 4024989       | EXPEDITED (15-DAY) | Y                  | HO              | S03-GER-04323-01     |                      | 77 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akinesia; Fall; Gait<br>Disturbance; General<br>Physical Health<br>Deterioration;<br>Pleurothotonus; Tremor | Cipralext                                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                             | Seroxat "Ciba-Geigy"<br>(Paroxetine Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Lithium                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Zeldox/Gfr/ (Ziprasidone<br>Mesilate)              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Omnice (Tamsulosin<br>Hydrochloride)               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Beloc Zoc (Metoprolol<br>Succinate)                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Acetylsalicylic Acid                               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2003              | 4049721       | EXPEDITED (15-DAY) | Y                  | OT              | S03-FRA-05101-01     |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis             | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Inipomp              |              |            | S           |              |                    |                 | Not Reported |
|                       | Milnacipran          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2003              | 4047864       | DIRECT           | Y                  |                 |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                |         |   |      |                  |              |
|----------------------------------------------------------------------------------------------------------------|---------|---|------|------------------|--------------|
| Abdominal Pain Upper;<br>Agitation; Hallucination;<br>Auditory; Headache;<br>Insomnia; Pollakiuria;<br>Trismus | Lexapro | S | Oral | 1 Tab Daily Oral | Not Reported |
|----------------------------------------------------------------------------------------------------------------|---------|---|------|------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2003              | 4052785       | EXPEDITED (15-DAY) | Y                  | DE              | S03-SWI-05165-01     |                      | 88 YR      | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anuria; Atrial Flutter;   | Ciprallex          |              |            | S           | Oral         | 10 Mg Qd; Po       |                 | Not Reported |
| Cardiac Failure; Cerebral | Aspirin            |              |            | S           | Oral         | 100 Mg Qd; Po      |                 | Not Reported |
| Haemorrhage; Depressed    | Ginkgo Extract     |              |            | S           | Oral         | 60 Mg Qd; Po       |                 | Not Reported |
| Level Of Consciousness;   | Torem (Torasemide) |              |            | C           |              |                    |                 | Not Reported |
| Dyskinesia; Feeling       |                    |              |            |             |              |                    |                 |              |
| Abnormal; Hypertension;   |                    |              |            |             |              |                    |                 |              |
| Nausea; Oxygen            |                    |              |            |             |              |                    |                 |              |
| Saturation Decreased;     |                    |              |            |             |              |                    |                 |              |
| Pyrexia; Tachycardia      |                    |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2003              | 4046864       | EXPEDITED (15-DAY) | Y                  | DE              | 200313742GDS         |                      | 88 YR      | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Anuria; Atrial Flutter;   | Aspirin        |              | Y          | S           | Oral         | 100 Mg, Qd, Oral         |                 | Not Reported |
| Blood Pressure Increased; | Ciprallex      |              |            | S           | Oral         | 10 Mg, Total Daily, Oral |                 | Not Reported |
| Cardiac Failure; Cerebral | Ginkgo Extract |              |            | S           | Oral         | 60 Mg, Total Daily, Oral |                 | Not Reported |
| Haemorrhage; General      | Torsemide      |              |            | C           |              |                          |                 | Not Reported |
| Physical Health           |                |              |            |             |              |                          |                 |              |
| Deterioration; Oxygen     |                |              |            |             |              |                          |                 |              |
| Saturation Decreased;     |                |              |            |             |              |                          |                 |              |
| Pyrexia; Tachycardia      |                |              |            |             |              |                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 23-Dec-2003              | 4047538       | EXPEDITED (15-DAY) | N                  | OT              | US-<br>GLAXOSMITHKLINE-<br>A0443376A |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                              |                                 |                    |                    |                 |                              |                      |                 |                 |                 |
|------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|-----------------|
| Agitation; Confusional State; Headache; Myalgia; Serotonin Syndrome                                                          |                                 | Wellbutrin         |                    | S               |                              |                      | 300mg Per Day   |                 | Glaxosmithkline |
|                                                                                                                              |                                 | Lexapro            |                    | S               |                              |                      |                 |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 23-Dec-2003                                                                                                                  | 4047539                         | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0443378A |                      |                 | Unknown         | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Agitation; Confusional State; Headache; Myalgia; Serotonin Syndrome                                                          | Wellbutrin                      |                    |                    | S               |                              | 300mg Per Day        |                 | Glaxosmithkline |                 |
|                                                                                                                              | Lexapro                         |                    |                    | S               |                              |                      |                 | Not Reported    |                 |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 23-Dec-2003                                                                                                                  | 4049495                         | DIRECT             | N                  | OT              |                              |                      | 45 YR           | Male            | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Medication Error                                                                                                             | Lexapro                         |                    |                    | S               |                              |                      |                 |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 23-Dec-2003                                                                                                                  | 4054524                         | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05194-01             |                      | 49 YR           | Female          | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Asthenia; Diarrhoea; Dizziness; Hallucination; Memory Impairment; Platelet Count Decreased; White Blood Cell Count Decreased | Lexapro                         |                    |                    | S               |                              |                      |                 |                 | Not Reported    |
|                                                                                                                              | Copegus                         |                    |                    | S               |                              |                      |                 |                 | Not Reported    |
|                                                                                                                              | Pegasys (Peginterferon Alfa-2a) |                    |                    | S               |                              |                      |                 |                 | Not Reported    |
|                                                                                                                              | Percocet                        |                    |                    | C               |                              |                      |                 |                 | Not Reported    |
|                                                                                                                              | Valtrex                         |                    |                    | C               |                              |                      |                 |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 23-Dec-2003                                                                                                                  | 4075817                         | NON-EXPEDITED      | Y                  | HO              | CEL-2003-03429-ROC           |                      | 67 YR           | Male            | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Hyponatraemia                                                                                                                | Zaroxolyn                       |                    |                    | S               |                              |                      |                 |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                           |                |                    |                    |                 |                      |                      |                       |              |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------------|--------------|------------------------------|
| Lasix<br>Lexapro                                                                                                                                                                                                                          |                |                    | S<br>S             |                 | Oral                 |                      | 10 Mg (10 Mg, Qd, Po) |              | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>            | <u>Sex</u>   | <u>Country</u>               |
| 24-Dec-2003                                                                                                                                                                                                                               | 4054776        | DIRECT             | Y                  | DE              |                      |                      | 37 YR                 | Female       | USA                          |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>       | <u>Mfr</u>   |                              |
| Drug Interaction; Drug Level Increased; Hepatic Steatosis                                                                                                                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg One Po         |                       | Not Reported |                              |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>            | <u>Sex</u>   | <u>Country</u>               |
| 26-Dec-2003                                                                                                                                                                                                                               | 4029258        | EXPEDITED (15-DAY) | Y                  | OT              | S03-IRL-04345-01     |                      | 25 YR                 | Male         | IRL                          |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>       | <u>Mfr</u>   |                              |
| Anxiety; Dizziness; Drug Withdrawal Syndrome; Headache; Insomnia; Thinking Abnormal                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                       | Not Reported |                              |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>            | <u>Sex</u>   | <u>Country</u>               |
| 26-Dec-2003                                                                                                                                                                                                                               | 4055703        | EXPEDITED (15-DAY) | Y                  | HO              | 8004818              |                      | 54 YR                 | Female       | USA                          |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>       | <u>Mfr</u>   |                              |
| Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebral Infarction; Confusional State; Coordination Abnormal; Cough; Encephalopathy; Extrapyramidal Disorder; Haematocrit Decreased; Hyponatraemia; | Keppra         |                    |                    | S               | Oral                 | Po                   |                       | Not Reported |                              |
|                                                                                                                                                                                                                                           | Lexapro        |                    |                    | S               | Oral                 | 50 Mg Po             |                       | Not Reported |                              |
|                                                                                                                                                                                                                                           | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Po             |                       | Not Reported |                              |
|                                                                                                                                                                                                                                           | Lithium        |                    |                    | C               |                      |                      |                       | Not Reported |                              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Inappropriate Antidiuretic  
Hormone Secretion;  
Nystagmus; Pneumonia;  
Shift To The Left

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Dec-2003                                                                                                         | 4055717                | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05196-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;                                                                                                | Lexapro                |                    |                    | S               | Oral                 | 40 Mg Once Po        |                 | Not Reported |                |
| Hypotension; Loss Of<br>Consciousness                                                                               | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2003                                                                                                         | 4055723                | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05222-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                             | Lexapro                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Ultram                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2003                                                                                                         | 4055933                | EXPEDITED (15-DAY) | Y                  | OT              | S03-UASA-04291-01    |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetic Retinal Oedema;                                                                                            | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Eye Haemorrhage;                                                                                                    | Lexapro                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hyperhidrosis; Intraocular<br>Pressure Increased; Open<br>Angle Glaucoma; Retinal<br>Haemorrhage; Vision<br>Blurred | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                     | Unspecified Ingredient |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Valium                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Neurontin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Insulin Nos            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2003                                                                                                         | 4055939                | EXPEDITED (15-DAY) | Y                  | OT              | S03-UKI-05258-01     |                      | 30 YR           | Female       | GBR            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Erythema Multiforme                                                                      | Ciprallex               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2003                                                                              | 4020691                 | EXPEDITED (15-DAY) | Y                  | DS, OT          | S03-USA-04165-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Carpal Tunnel Syndrome;<br>Condition Aggravated;<br>Muscle Spasms; Tardive<br>Dyskinesia | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Unspecified Ingredient  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2003                                                                              | 4041178                 | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-04761-01     |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound; Obsessive-<br>Compulsive Disorder                  | Lexapro                 |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Unspecified Ingredient  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Ambien                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2003                                                                              | 4059260                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05190-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased;<br>Confusional State;<br>Hyponatraemia; Urosepsis                | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Protonix                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Detrol                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Dilantin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Neurontin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Klonopin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Flexeril                |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                |                    |                    |                 |                              |                                  |                 |              |                |
|-------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Megace<br>Darvocet                                                                                    |                |                    | C<br>C             |                 | Not Reported<br>Not Reported |                                  |                 |              |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2003                                                                                           | 4059263        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05300-01             |                                  | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Antiphospholipid<br>Antibodies Positive;<br>Cardiolipin Antibody<br>Positive; Deep Vein<br>Thrombosis | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po                      |                 | Not Reported |                |
|                                                                                                       | Seroquel       |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2003                                                                                           | 4073674        | NON-EXPEDITED      | Y                  | HO              | HQWYE909629SEP03             |                                  | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness;<br>Intentional Overdose;<br>Serotonin Syndrome                   | Effexor Xr     |                    |                    | S               | Oral                         | Overdose Amount<br>Unknown, Oral |                 | Not Reported |                |
|                                                                                                       | Lexapro        |                    |                    | S               | Oral                         | Overdose Amount<br>Unknown, Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2003                                                                                           | 4059540        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05299-01             |                                  | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplastic Anaemia; Bone<br>Marrow Failure                                                              | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po                      |                 | Not Reported |                |
|                                                                                                       | Alesse 28      |                    |                    | S               |                              | 1 Tablet Qd                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2003                                                                                           | 4059557        | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-05295-01             |                                  | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                      |            |   |      |              |              |
|--------------------------------------------------------------------------------------|------------|---|------|--------------|--------------|
| Accident At Work; Drug Interaction; Drug Screen Positive; Injury; Loss Of Employment | Lexapro    | S | Oral | 10 Mg Qd Po  | Not Reported |
|                                                                                      | Valium     | S | Oral | 10 Mg Prn Po | Not Reported |
|                                                                                      | Lortab     | C |      |              | Not Reported |
|                                                                                      | Azulfidine | C |      |              | Not Reported |
|                                                                                      | Dyazide    | C |      |              | Not Reported |
|                                                                                      | Ibuprofen  | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2004              | 4048833       | EXPEDITED (15-DAY) | Y                  | OT              | S03-BRA-05171-01     |                      | 69 YR      | Male       | BRA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Hidantal (Phenytoin)          |              |            | C           |              |                    |                 | Not Reported |
|                       | Anlodipino (Amlodipine)       |              |            | C           |              |                    |                 | Not Reported |
|                       | Propranolol                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Clonazepam                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Clorana (Hydrochlorothiazide) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2004              | 4061557       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | S03-USA-00285-01     |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section; Condition Aggravated; Drug Ineffective; Hypertension; Hypoaesthesia; Maternal Drugs Affecting Foetus; Maternal Drugs Affecting Foetus; Pre-Eclampsia; Pregnancy; Premature Baby; Protein Urine Present | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                           | Aldomet        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                           | Nestabs        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2004              | 4062617       | DIRECT           | N                  | RI              |                      |                      |            | Male       | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| Anxiety; Condition Aggravated; Depression; Dissociation; Disturbance In Attention; Drug Ineffective; Drug Withdrawal Syndrome; Feeling Abnormal; Migraine; Nausea   | Zoloft                   |                    |                    | S               | Oral                 | Varied Per Mornin Oral    |                 | Not Reported |                |
|                                                                                                                                                                     | Paroxetine Hydrochloride |                    |                    | S               | Oral                 | 5-60 Mg"S Per Mornin Oral |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro                  |                    |                    | S               | Oral                 | Varied Per Morning Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2004                                                                                                                                                         | 4027543                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03493-01     |                           | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Blood Triglycerides Increased; Body Mass Index Increased; Cholelithiasis; High Density Lipoprotein Decreased; Type 2 Diabetes Mellitus | Lexapro                  |                    |                    | S               | Oral                 | 20 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                     | Klonopin                 |                    |                    | C               |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2004                                                                                                                                                         | 4045440                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04960-01     |                           | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                                                           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                     | Effexor                  |                    |                    | S               |                      | 75 Mg Qd                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2004                                                                                                                                                         | 4066359                  | DIRECT             | N                  | RI              |                      |                           | 10 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                   |                    |        |              |                                      |                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------|--------------|--------------------------------------|--------------------------------|
| Acne; Constipation;<br>Dyskinesia; Fear; Glucose<br>Tolerance Impaired;<br>Insulin Resistance; Morbid<br>Thoughts; Nightmare;<br>Polycystic Ovaries; Sleep<br>Disorder; Thinking<br>Abnormal; Weight<br>Increased | Abilify<br>Lexapro | S<br>S | Oral<br>Oral | 15 Mg Daily Oral<br>20 Mg Daily Oral | Bristol Myers Squibb<br>Forest |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------|--------------|--------------------------------------|--------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 09-Jan-2004              | 4057848        | NON-EXPEDITED    | Y                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0422162A |                      | 40 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nephrolithiasis          | Wellbutrin     |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Oral                                 | 10mg Unknown         |                 | Not Reported    |                |
|                          | Buspar         |                  |                    | C               |                                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 09-Jan-2004              | 4057859        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0422844A |                      | 11 YR           | Male            | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction         | Wellbutrin     |                  |                    | S               | Oral                                 | 100mg Twice Per Day  |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Unknown                              | 20mg Per Day         |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jan-2004                                                                                                          | 4059546                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05302-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium<br>Decreased; Diarrhoea;<br>Electrocardiogram Qt<br>Prolonged; Inappropriate<br>Antidiuretic Hormone | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Biaxin                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                      | Reglan (Metoclopramide) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                      | Cipro                   |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                          |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Secretion; Vomiting                                                   | Colchichine (Colchicine) |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                       | Amikacin                 |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2004                                                           | 4011272                  | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-03925-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Treatment                                 | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Noncompliance; Urine<br>Ketone Body Present                           | Insulin Nos              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2004                                                           | 4019386                  | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04093-01     |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis;<br>Pulmonary Embolism                           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                       | Lexapro                  |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                       | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                       | Risperdal                |                    |                    | S               |                      | 2.5 Mg Qd            |                 | Not Reported |                |
|                                                                       | Lithium                  |                    |                    | S               |                      | 1500 Mg Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2004                                                           | 4035103                  | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04545-01     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Disorientation;<br>Dizziness; Fall; Fatigue;<br>Hypersomnia; | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Hypoglycaemia; Loss Of<br>Consciousness; Seizure                      | Lexapro                  |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|------------------|------------------------------|----------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 14-Jan-2004                                                                          | 4054516                                    | EXPEDITED (15-DAY) | Y                  | HO               | S03-USA-05139-01             |                                  | 66 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Blood Pressure Decreased; Bradycardia; Cold Sweat; Fibrin D Dimer Increased; Syncope | Lexapro<br>Carafate<br>Fosamax<br>Protonix |                    |                    | S<br>C<br>C<br>C | Oral                         | 10 Mg Qd Po                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jan-2004                                                                          | 4062353                                    | NON-EXPEDITED      | N                  |                  | US-GLAXOSMITHKLINE-A0401802A |                                  |                 | Unknown                                                      | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Drug Interaction; Tremor                                                             | Wellbutrin<br>Lexapro                      |                    |                    | S<br>S           | Oral<br>Unknown              |                                  |                 | Glaxosmithkline<br>Not Reported                              |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jan-2004                                                                          | 4070279                                    | EXPEDITED (15-DAY) | Y                  | RI               | S04-USA-00022-01             |                                  |                 | Unknown                                                      | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Bradycardia; Condition Aggravated                                                    | Lexapro                                    |                    |                    | S                |                              |                                  |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jan-2004                                                                          | 4091655                                    | NON-EXPEDITED      | Y                  | OT               | A03200300177                 |                                  | 39 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Drug Interaction; Seizure                                                            | Demerol<br>Lexapro<br>Ativan<br>Vicodin    |                    |                    | S<br>S<br>S<br>S | Oral                         | 10 Mg Qd Oral<br>3 Mg Qd Unknown |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |                |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Nicotine                                                           |                |                    | S                  | Transdermal     | 14 Mg Qd Transdermal |                      |                 | Not Reported |                |
| Tylenol                                                            |                |                    | C                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2004                                                        | 4071781        | DIRECT             | N                  | OT              |                      |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Discomfort; Drug Ineffective; Pruritus Generalised                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg 1x Daily Oral  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2004                                                        | 4041202        | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04711-01     |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Crying; Delirium; Incoherent; Meningitis Viral; Nausea | Lexapro        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2004                                                        | 4074076        | EXPEDITED (15-DAY) | Y                  | HO              | HQWYE057005JAN04     |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplastic Anaemia; Bone Marrow Failure                              | Alesse 28      |                    |                    | S               | Oral                 | 1 Tablet Daily, Oral |                 | Not Reported |                |
|                                                                    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Daily, Oral    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2004                                                        | 4074631        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-00095-01     |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Self-Medication; Suicidal Ideation; Treatment    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |                        |   |      |             |              |
|---------------|------------------------|---|------|-------------|--------------|
| Noncompliance | Lexapro                | S | Oral | 10 Mg Qd Po | Not Reported |
|               | Alcohol                | S |      |             | Not Reported |
|               | Unspecified Ingredient | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2004              | 4034981       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04544-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anal Incontinence;      | Lexapro               |              |            | S           | Oral         | 10 Mg Once Po      |                 | Not Reported |
| Bruxism; Confusional    | Zoloft                |              |            | C           |              |                    |                 | Not Reported |
| State; Dizziness; Fall; | Xanax                 |              |            | C           |              |                    |                 | Not Reported |
| Feeling Abnormal; Focal | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
| Dyscognitive Seizures;  | Zyrtec                |              |            | C           |              |                    |                 | Not Reported |
| Nuclear Magnetic        | Tri-Levlen            |              |            | C           |              |                    |                 | Not Reported |
| Resonance Imaging       | Advil                 |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Panic Attack; | Aleve                 |              |            | C           |              |                    |                 | Not Reported |
| Paraesthesia;           |                       |              |            |             |              |                    |                 | Not Reported |
| Somnolence; Staring;    |                       |              |            |             |              |                    |                 | Not Reported |
| Vertigo                 |                       |              |            |             |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2004              | 4056658       | NON-EXPEDITED    | Y                  | HO              | A03200301838         |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased;    | Plavix                   |              |            | S           | Oral         | 75 Mg Qd - Oral    |                 | Not Reported |
| Gastritis; Gastrointestinal | Lexapro                  |              |            | S           | Oral         | 10 Mg Qd - Oral    |                 | Not Reported |
| Haemorrhage;                | Rosiglitazone Maleate    |              |            | C           |              |                    |                 | Not Reported |
| Hallucination, Visual; Iron | Glimepiride              |              |            | C           |              |                    |                 | Not Reported |
| Deficiency Anaemia;         | Acetylsalicylic Acid     |              |            | C           |              |                    |                 | Not Reported |
| Mental Status Changes;      | Simvastatin              |              |            | C           |              |                    |                 | Not Reported |
| Oesophagitis; Sleep         | Ramipril                 |              |            | C           |              |                    |                 | Not Reported |
| Disorder; Traumatic         | Alprazolam               |              |            | C           |              |                    |                 | Not Reported |
| Haematoma                   | Clonidine                |              |            | C           |              |                    |                 | Not Reported |
|                             | Sertraline Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                             | Clonazepam               |              |            | C           |              |                    |                 | Not Reported |
|                             | Nifedipine               |              |            | C           |              |                    |                 | Not Reported |
|                             | Metoprolol Succinate     |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 21-Jan-2004                                                                                                    | 4067466              | NON-EXPEDITED      | Y                  |                 | US-GLAXOSMITHKLINE-A0394874A |                      | 34 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Herpes Simplex                                                                               | Valtrex              |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                                                                | Valtrex              |                    |                    | S               | Oral                         | 500mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                                | Lexapro              |                    |                    | S               | Oral                         | 10mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Jan-2004                                                                                                    | 4024877              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04291-01             |                      | 26 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Diabetic Retinal Oedema; Hyperhidrosis; Open Angle Glaucoma; Post Procedural Complication; Retinal Haemorrhage | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                | Lexapro              |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                | Valium               |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                | Kenalog              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                | Neurontin            |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                | Insulin Nos          |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                | Triphasil-21         |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Jan-2004                                                                                                    | 4065720              | NON-EXPEDITED      | N                  | OT              | 2003039759                   |                      | 49 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Vision Blurred                                                                               | Relpax               |                    |                    | S               | Oral                         | 40 Mg (Prn), Oral    |                 | Not Reported    |                |
|                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                         | Oral                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Jan-2004                                                                                                    | 4078180              | DIRECT             | N                  | HO              |                              |                      | 58 YR           | Female          | USA            |

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| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hyperhidrosis; Nausea; Palpitations; Syncope; Vomiting                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                 | Effexor        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                 | Skelaxin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Prevacid       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Pepcid         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Premarin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Celebrex       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Ambien         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2004                                                                     | 4078541        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-00023-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Hot Flush; Hyperhidrosis; Hypertension; Hypoaesthesia; Stress | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Allegra        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Prilosec       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2004                                                                     | 4041184        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04764-01     |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Encephalomalacia; Optic Neuritis; Papilloedema                       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2004                                                                     | 4080378        | DIRECT             |                    | OT              |                      |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Twitching                                                                | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Once Daily Oral |                 | Forest       |                |
|                                                                                 | Benadryl       |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 27-Jan-2004                                                                                                                                                           | 4055934                     | EXPEDITED (15-DAY) | Y                  | DE, HO          | S03-UKI-05243-01     |                           | 83 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Myocardial Infarction;<br>Transient Ischaemic<br>Attack                                                                                                               | Ciprallex                   |                    |                    | S               | Oral                 | 20 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                       | Digoxin                     |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Warfarin Sodium             |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Paracetamol                 |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Tramadol Hydrochloride      |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Frusemide                   |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Candesartan                 |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Lansoprazole                |                    |                    | C               |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2004                                                                                                                                                           | 4081946                     | EXPEDITED (15-DAY) | Y                  | HO              | 04P-163-0247227-00   |                           | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium<br>Decreased; Diarrhoea;<br>Electrocardiogram Qt<br>Prolonged; Inappropriate<br>Antidiuretic Hormone<br>Secretion; Vomiting                           | Biaxin                      |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Per Oral |                 | Not Reported |                |
|                                                                                                                                                                       | Metoclopramide              |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Ciprofloxacin Hydrochloride |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Colchicine                  |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Amikacin                    |                    |                    | C               |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2004                                                                                                                                                           | 3962771                     | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-02049-01     |                           | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Systolic<br>Increased; Dysarthria;<br>Electroencephalogram<br>Abnormal; Gait<br>Disturbance; Injury;<br>Pulmonary Oedema;<br>Seizure; Syncope; Urinary | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                       | Detrol                      |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Advil                       |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Neurontin                   |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Valium                      |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Serzone                     |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Bextra                      |                    |                    | C               |                      |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                |                |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Incontinence                                                                                                                                                                                                   | Nicotine       |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2004                                                                                                                                                                                                    | 4008950        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03786-01     |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cardiac Disorder; Euphoric Mood; Fatigue; Hyperhidrosis; Loss Of Consciousness; Nausea; Seizure; Syncope                                                                                             | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                | Lithium        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Aleve          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Aspirin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Multi-Vitamin  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Calcium        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Vitamin E      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                | Vitamin D Nos  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2004                                                                                                                                                                                                    | 4017553        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04121-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                                                                                                                                                                   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jan-2004                                                                                                                                                                                                    | 4081711        | DIRECT             | N                  |                 |                      |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Abnormal Dreams; Anxiety; Decreased Appetite; Depression; Dizziness; Dysuria; Feeling Abnormal; Feeling Hot; Hallucination, Visual; Heart Rate Increased; Hypoacusis; Hypoaesthesia; Panic | Lexapro        |                    |                    | S               | Oral                 | 10 Mg 1 Tab Dai Oral |                 | Forest       |                |

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Reaction; Paranoia;  
Retching; Suicidal  
Ideation; Thinking  
Abnormal; Visual  
Impairment; Vomiting;  
Weight Decreased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2004              | 4083633       | EXPEDITED (15-DAY) | N                  | RI, OT          | S04-USA-00204-01     |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Bruxism; Fatigue;<br>Headache;<br>Hyperaesthesia Teeth;<br>Insomnia; Nausea; Tooth<br>Fracture | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                         | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                         | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                         | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                         | Clonazepam     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Ambien         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                         | Celebrex       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                         | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2004              | 4076100       | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12287124 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------------|---------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------------|-----------------|----------------------|
| Drug Withdrawal<br>Syndrome | Serzone             |              |            | S           | Oral         | D/C Serzone On 20-May-03,Restarted In Am Over Next Few Days, Then Restarted 150mg Bid On 27-May-03 | 3 YR            | Bristol Myers Squibb |
|                             | Lexapro             |              |            | S           |              |                                                                                                    |                 | Not Reported         |
|                             | Celebrex            |              |            | C           |              |                                                                                                    |                 | Not Reported         |
|                             | Evista              |              |            | C           |              |                                                                                                    |                 | Not Reported         |
|                             | Ranitidine Hcl Tabs |              |            | C           |              |                                                                                                    |                 | Not Reported         |

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|                                                             |                |                    |                    |                              |                      |                      |                 |              |                |
|-------------------------------------------------------------|----------------|--------------------|--------------------|------------------------------|----------------------|----------------------|-----------------|--------------|----------------|
| Multi-Vitamin<br>Calcium                                    |                | C<br>C             |                    | Not Reported<br>Not Reported |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2004                                                 | 4087521        | EXPEDITED (15-DAY) | Y                  | OT                           | S04-UK1-00235-01     |                      | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dizziness; Hypotension;<br>Malaise | Ciprallex      |                    |                    | S                            | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                             | Atorvastatin   |                    |                    | C                            |                      |                      |                 | Not Reported |                |
|                                                             | Atenolol       |                    |                    | C                            |                      |                      |                 | Not Reported |                |
|                                                             | Perindopril    |                    |                    | C                            |                      |                      |                 | Not Reported |                |
|                                                             | Aspirin        |                    |                    | C                            |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2004                                                 | 4087695        | EXPEDITED (15-DAY) | Y                  | LT                           | S04-USA-00311-01     |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Road Traffic Accident          | Lexapro        |                    |                    | S                            | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2004                                                 | 4087698        | EXPEDITED (15-DAY) | Y                  | OT                           | S04-USA-00277-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide                                                    | Lexapro        |                    |                    | S                            |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2004                                                 | 4088056        | EXPEDITED (15-DAY) | Y                  | HO                           | S04-GER-00302-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse                                        | Ciprallex      |                    |                    | S                            | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2004                                                                                                       | 4089215              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S04-UKI-00245-01     |                      | 82 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Orthostatic Hypotension                                                                                | Cipralext            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Nitrazepam           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Nasonex              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2004                                                                                                       | 4089833              | EXPEDITED (15-DAY) | Y                  | HO              | L04-USA-00370-01     |                      | 75 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2004                                                                                                       | 3995285              | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03512-01     |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Electroencephalogram Abnormal; Epilepsy; Haematocrit Decreased; Headache; Loss Of Consciousness; Seizure | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Risperdal            |                    |                    | S               |                      | 1 Mg Tid             |                 | Not Reported |                |
|                                                                                                                   | Risperdal            |                    |                    | S               |                      | 1 Mg Bid             |                 | Not Reported |                |
|                                                                                                                   | Trileptal            |                    |                    | S               |                      | 300 Mg Qam           |                 | Not Reported |                |
|                                                                                                                   | Trileptal            |                    |                    | S               |                      | 6 00 Mg Qhs          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2004                                                                                                       | 4022969              | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04218-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                       |   |      |             |              |
|-------------------------------------------------------------------|-----------------------|---|------|-------------|--------------|
| Anxiety Disorder; Aura;                                           | Lexapro               | S | Oral | 10 Mg Qd Po | Not Reported |
| Depressed Level Of Consciousness;                                 | Lexapro               | S | Oral | 5 Mg Qd Po  | Not Reported |
| Dysarthria; Dyspnoea;                                             | Singulair             | C |      |             | Not Reported |
| Fatigue; Focal                                                    | Micardis              | C |      |             | Not Reported |
| Dyscognitive Seizures;                                            | Nexium (Esomeprazole) | C |      |             | Not Reported |
| Gait Disturbance;                                                 | Demerol               | C |      |             | Not Reported |
| Hemiparesis; Idiosyncratic                                        | Phenergan             | C |      |             | Not Reported |
| Drug Reaction; Migraine;                                          | Xanax (Aqlprazolam)   | C |      |             | Not Reported |
| Palpitations; Speech Disorder; Toxicity To Various Agents; Tremor | Premarin              | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2004              | 4087860       | DIRECT           | N                  | DE              |                      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Condition Aggravated; Seizure | Lexapro        |              |            | S           | Oral         | 20 Mg Per Day Oral |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2004              | 4089549       | EXPEDITED (15-DAY) | N                  | LT              | S04-USA-00314-01     |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Impaired Driving Ability; Legal Problem; Loss Of Consciousness; Road Traffic Accident; Vision Blurred | Lexapro        |              |            | S           | Oral         | 10 Mg Qod Po       |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Prilosec       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2004              | 4089551       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-00279-01     |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                      |                      |   |      |             |              |
|----------------------|----------------------|---|------|-------------|--------------|
| Drug Screen Positive | Lexapro              | S | Oral | 10 Mg Qd Po | Not Reported |
|                      | Vicodin              | C |      |             | Not Reported |
|                      | Tylenol With Codeine | C |      |             | Not Reported |
|                      | Rhinocort            | C |      |             | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 09-Feb-2004                       | 4091472                | EXPEDITED (15-DAY)        | N                           | OT                       | 2004006440                    |                               | 64 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Blood Creatine Phosphokinase Increased; Chest Pain; Dyspnoea; Myalgia; Somnolence | Lipitor                 |                       |                     | S                    | Oral                  | 10 Mg (Daily), Oral         |                          | Not Reported        |
|                                                                                   | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | Oral                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Feb-2004                       | 4089306                | DIRECT                    | Y                           | OT                       |                               |                               | 82 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Memory Impairment              | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Daily Oral            |                          | Not Reported        |
|                                | Deseryl                 |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Aciphex                 |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Advair Diskus           |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Feb-2004                       | 4089425                | DIRECT                    | Y                           | OT                       |                               |                               | 31 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Rash Pruritic                  | Lexapro                 |                       |                     | S                    |                       | 10 Mg Qd                    |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Feb-2004                       | 4091874                | DIRECT                    | Y                           | OT                       |                               |                               | 36 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |                        |   |             |              |
|---------|------------------------|---|-------------|--------------|
| Bruxism | Lexapro                | S | 10 Mg Daily | Not Reported |
|         | Acetaminophen          | C |             | Not Reported |
|         | Unspecified Ingredient | C |             | Not Reported |
|         | Levothyroxine          | C |             | Not Reported |
|         | Esomeprazole           | C |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2004              | 4093238       | EXPEDITED (15-DAY) | Y                  | HO              | L04-USA-00436-01     |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Grandiosity; Insomnia; Mania; Psychomotor Hyperactivity; Psychotic Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2004              | 4093239       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00088-01     |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension; Abdominal Pain; Neoplasm Malignant | Lexapro          |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Morphine Sulfate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2004              | 4093240       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00336-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury   | Lexapro                              |              |            | S           |              |                    |                 | Not Reported |
|                       | Wellbutrin (Bupropion Hydrochloride) |              |            | S           |              |                    |                 | Not Reported |
|                       | Lipitor                              |              |            | C           |              |                    |                 | Not Reported |
|                       | Avapro                               |              |            | C           |              |                    |                 | Not Reported |
|                       | Tricor                               |              |            | C           |              |                    |                 | Not Reported |
|                       | Amiodarone                           |              |            | C           |              |                    |                 | Not Reported |
|                       | Androderm                            |              |            | C           |              |                    |                 | Not Reported |
|                       | Viagra                               |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                         |                    |                    |                 |                      |                              |                 |            |                |
|----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|------------|----------------|
| Multi-Vitamin<br>Saw Pallmetto                           |                         |                    | C<br>C             |                 |                      | Not Reported<br>Not Reported |                 |            |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Feb-2004                                              | 4093241                 | EXPEDITED (15-DAY) | Y                  | LT, RI          | S04-USA-00402-01     |                              | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction                                    | Lexapro                 |                    |                    | S               |                      |                              |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Feb-2004                                              | 4093525                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00414-01     |                              | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Impaired Driving Ability;<br>Legal Problem;<br>Nystagmus | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Feb-2004                                              | 4093527                 | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04963-01     |                              | 74 YR           | Female     | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Catatonia; Dementia                                      | Lexapro                 |                    |                    | S               |                      |                              |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Feb-2004                                              | 4107010                 | NON-EXPEDITED      | Y                  | HO              | A03200300326         |                              | 65 YR           | Male       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Overdose                                     | Ambien                  |                    |                    | S               | Oral                 | 75 Mg Qd -Oral               |                 |            | Not Reported   |
|                                                          | Ambien                  |                    |                    | S               | Oral                 | 5 Mg Hs - Oral               |                 |            | Not Reported   |
|                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg Qd - Oral              |                 |            | Not Reported   |
|                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd - Oral              |                 |            | Not Reported   |
|                                                          | Bupropion Hydrochloride |                    |                    | C               |                      |                              |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 13-Feb-2004                                                                                                       | 4091824                  | DIRECT             | Y                  | HO              |                      |                                | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue                                                                                                | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Po Qd Prior To Admission |                 | Not Reported |                |
|                                                                                                                   | Vicodin Es               |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                   | Soma                     |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                   | Benadryl                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2004                                                                                                       | 4094237                  | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00471-01     |                                | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Magnesium Decreased;                                                                                        | Lexapro                  |                    |                    | S               |                      |                                |                 | Not Reported |                |
| Bronchospasm; Chest Discomfort; Flushing; Loss Of Consciousness;                                                  | Premarin                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
| Myoclonus; Nausea; Oedema Peripheral; Restlessness; Swelling Face; Tremor                                         | Skelaxin                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                   | Tizanidine Hydrochloride |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                   | Percocet                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2004                                                                                                       | 4128248                  | NON-EXPEDITED      | Y                  | RI              | 345691               |                                | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Delusion; Depression; Hallucination;                                                                              | Pegasys                  |                    |                    | S               |                      |                                |                 | Not Reported |                |
| Hallucination, Auditory; Insomnia; Mental Disorder; Overdose; Platelet Count Decreased; Restlessness; White Blood | Lexapro                  |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cell Count Decreased

| <u>FDA Received Date</u>                                        | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 16-Feb-2004                                                     | 4088597                | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0412825A |                      | 31 YR           | Female          | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dry Mouth; Insomnia;<br>Rash; Sleep Disorder;<br>Vision Blurred | Lamictal               |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                 | Lexapro                |                  |                    | S               | Oral                                 |                      |                 | Not Reported    |                |
|                                                                 | Seroquel               |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                 | Unspecified Ingredient |                  |                    | C               |                                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 16-Feb-2004              | 4088737        | NON-EXPEDITED    | Y                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0431553A |                      | 22 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nystagmus                | Lamictal       |                  |                    | S               | Oral                                 | 100mg Per Day        |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Unknown                              |                      |                 | Not Reported    |                |
|                          | Depakote Er    |                  |                    | C               |                                      | 500mg Per Day        |                 | Not Reported    |                |
|                          | Lithobid       |                  |                    | C               | Unknown                              | 900mg Per Day        |                 | Glaxosmithkline |                |
|                          | Reopro         |                  |                    | C               | Unknown                              |                      | 3 MTH           | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 16-Feb-2004              | 4088776        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0432782A |                      | 44 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nystagmus                | Lamictal       |                  |                    | S               | Oral                                 | 100mg Per Day        |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Unknown                              | 10mg Per Day         |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2004              | 4081147       | EXPEDITED (15-DAY) | Y                  | OT              | S04-FRA-00165-01     |                      | 54 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hypokalaemia; Muscle Spasms; Polyuria                                                                                  | Escitalopram Oxalate |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                        | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                        | Aldactazine          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2004                                                                                                            | 4093305              | DIRECT           | Y                  | HO              |                      |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Heart Rate Increased                                                                                        | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2004                                                                                                            | 4093616              | DIRECT           | Y                  | OT              |                      |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia; Sensory Disturbance                                                                                     | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Qd Oral        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2004                                                                                                            | 4093632              | DIRECT           | Y                  | LT              |                      |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Anxiety; Drug Ineffective; Feeling Abnormal; Pain; Restlessness; Self-Injurious Ideation; Suicidal Ideation | Zoloft               |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                        | Paxil                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                        | Lexapro              |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                        | Prozac               |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                        | Risperidone          |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2004                                                                                                            | 5812608              | DIRECT           |                    |                 |                      |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |         |   |     |              |
|---------------------------|---------|---|-----|--------------|
| Medication Error; Product | Lexapro | S | Tab | Forest       |
| Dispensing Error          | Levoxyl | S | Tab | Not Reported |
|                           | Xanax   | S | Tab | Mylan        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2004              | 4095807       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00415-01     |                      | 72 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Lactate            | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Dehydrogenase            | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Increased; Fall;         |                |              |            |             |              |                    |                 |              |
| Haemolytic Uraemic       |                |              |            |             |              |                    |                 |              |
| Syndrome; Renal Failure; |                |              |            |             |              |                    |                 |              |
| Respiratory Failure;     |                |              |            |             |              |                    |                 |              |
| Sepsis; Spinal           |                |              |            |             |              |                    |                 |              |
| Compression Fracture;    |                |              |            |             |              |                    |                 |              |
| Thrombotic               |                |              |            |             |              |                    |                 |              |
| Thrombocytopenic         |                |              |            |             |              |                    |                 |              |
| Purpura                  |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2004              | 3959331       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-02425-01     |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Generalised Tonic- | Lexapro               |              |            | S           | Oral         | 10 Mg Qam Po       |                 | Not Reported |
| Clonic Seizure; Libido   | Wellbutrin Sr         |              |            | S           |              | 150 Mg Bid         |                 | Not Reported |
| Decreased; Tendon Injury | Wellbutrin (Bupropion |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |
|                          | Hydrochloride)        |              |            |             |              |                    |                 |              |
|                          | Dilantin              |              |            | C           |              |                    |                 | Not Reported |
|                          | Keppra                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2004              | 4015705       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-03938-01     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                        |         |   |      |               |              |
|----------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|---------------|--------------|
| Dizziness; Head Injury;<br>Hypoaesthesia; Loss Of<br>Consciousness; Nausea;<br>Paraesthesia; Road Traffic<br>Accident; Skin Laceration | Lexapro | S | Oral | 10 Mg Once Po | Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|---------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2004              | 4043583       | EXPEDITED (15-DAY) | Y                  | DE              | S03-USA-04792-01     |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest        | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lantus         |              |            | C           |              |                    |                 | Not Reported |
|                       | Lasix          |              |            | C           |              |                    |                 | Not Reported |
|                       | Zocor          |              |            | C           |              |                    |                 | Not Reported |
|                       | Diovan         |              |            | C           |              |                    |                 | Not Reported |
|                       | Vasotec        |              |            | C           |              |                    |                 | Not Reported |
|                       | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                       | Minoxidil      |              |            | C           |              |                    |                 | Not Reported |
|                       | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                       | Oxygen         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2004              | 4059264       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05301-01     |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;       | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
| Hyponatraemia; Lipase | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Increased;            | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Thrombocytopenia      | Coumadin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2004              | 4098603       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00533-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Alopecia                                                         | Lexapro                                  |                    | S                  | Oral            | 10 Mg Qd Po          |                      | Not Reported    |              |                |
|------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                  | Concerta                                 |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2004                                                      | 4095085                                  | DIRECT             | Y                  |                 |                      |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Insomnia; Tremor                        | Lexapro                                  |                    |                    | S               | Oral                 | 1 Tab Po Qd          |                 | Not Reported |                |
|                                                                  | Amaryl                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Calcuim                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Protonix                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Vit C                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2004                                                      | 4100256                                  | EXPEDITED (15-DAY) | Y                  | OT              | ZONI001325           |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Echocardiogram<br>Abnormal;<br>Electrocardiogram Qt<br>Prolonged | Zonegran                                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                  | Lexapro                                  |                    |                    | S               |                      | 20 Mg Daily          |                 | Not Reported |                |
|                                                                  | Klonopin                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Flexeril                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Bextra                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Nexium (Esomeprazole)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2004                                                      | 4049728                                  | EXPEDITED (15-DAY) | Y                  | OT              | T03-GER-05096-01     |                      | 60 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity Vasculitis                                      | Cipralext                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Celebrex                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Omeprazole                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Palladon(Hydromorphone<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Metoclopramide                           |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 25-Feb-2004              | 4101842        | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-00584-01             |                      |                 | Male            | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Homicidal Ideation       | Cipralext      |                    |                    | S               | Unknown                      | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Feb-2004              | 4095605        | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0494728A |                      | 37 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Menstrual Disorder       | Wellbutrin XI  |                    |                    | S               | Oral                         | 150mg Per Day        |                 | Glaxosmithkline |                |
|                          | Lexapro        |                    |                    | S               |                              | 20mg Per Day         |                 | Not Reported    |                |
|                          | Oxycontin      |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                          | Benadryl       |                    |                    | C               |                              |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Feb-2004              | 4095643        | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0496282A |                      | 44 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Tinnitus                 | Wellbutrin XI  |                    |                    | S               | Oral                         | 150mg Per Day        | 1 MTH           | Glaxosmithkline |                |
|                          | Lexapro        |                    |                    | S               |                              |                      | 1 MTH           | Not Reported    |                |
|                          | Advair Diskus  |                    |                    | C               | Respiratory (inhalation)     |                      |                 | Glaxosmithkline |                |
|                          | Flonase        |                    |                    | C               |                              |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Mar-2004              | 4035732        | EXPEDITED (15-DAY) | Y                  | LT              | T03-GER-04646-01             |                      | 38 YR           | Female          | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Food Allergy; | Cipralext      |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported    |                |



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|                        |                                   |   |              |
|------------------------|-----------------------------------|---|--------------|
| Heart Rate Increased;  | Ciprallex                         | S | Not Reported |
| Hypersensitivity;      | Accupril                          | C | Not Reported |
| Restlessness; Swelling | Nebilet (Nebivolol Hydrochloride) | C | Not Reported |
| Face; Swollen Tongue   |                                   |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2004              | 4044644       | EXPEDITED (15-DAY) | Y                  | LT              | T03-GER-04923-01     |                      | 43 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Emotional Distress; Epilepsy; Generalised Tonic-Clonic Seizure; Heart Rate Increased; Hypokalaemia; Hypoxia; Loss Of Consciousness; Nausea; Sinus Bradycardia; Syncope; Vertigo; Vomiting | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                      | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 01-Mar-2004              | 4099105       | EXPEDITED (15-DAY) | Y                  | OT              | GB-BRISTOL-MYERS SQUIBB COMPANY-12517025 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------|-----------------|----------------------|
| Depressed Level Of Consciousness; Hyponatraemia | Coaprovel Tabs 300mg/12.5mg |              |            | S           | Oral         |                                                                                              |                 | Bristol Myers Squibb |
|                                                 | Ciprallex                   |              |            | S           | Oral         |                                                                                              | 7 DAY           | Not Reported         |
|                                                 | Timolol Maleate             |              |            | C           | Ophthalmic   | Comment: "Other Drugs Listed Were Started Well Before 12/2003 And Are Continuing Therapies." |                 | Not Reported         |
|                                                 | Atenolol                    |              |            | C           |              | Comment: "Other Drugs Listed Were Started Well Before 12/2003 And Are Continuing Therapies." |                 | Not Reported         |
|                                                 | Latanoprost                 |              |            | C           |              | Comment: "Other Drugs Listed Were Started Well Before 12/2003 And Are Continuing Therapies." |                 | Not Reported         |

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Zopiclone C Before 12/2003 And Are Continuing Therapies." Not Reported  
Comment: "Other Drugs Listed Were Started Well Before 12/2003 And Are Continuing Therapies."

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 01-Mar-2004                                                                                        | 4102825                | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00724-01     |                            | 89 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pancreatitis; Pseudocyst | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2004                                                                                        | 4038617                | EXPEDITED (15-DAY) | Y                  | HO              | T03-GER-04806-01     |                            | 57 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Drug Ineffective; Hypertension; Hypertensive Crisis; Tachycardia; Weight Decreased      | Cipraxel               |                    |                    | S               | Oral                 | 10 Mg Qd Po                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2004                                                                                        | 4104759                | EXPEDITED (15-DAY) | N                  | OT              | 2004010841           |                            | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Delayed Recovery From Anaesthesia; Depressed Mood; Diplopia; Drug   | Neurontin              |                    |                    | S               | Oral                 | 1800 Mg (600 Mg Tid), Oral |                 | Not Reported |                |
|                                                                                                    | Topiramate             |                    |                    | S               | Oral                 | Oral                       |                 | Not Reported |                |
|                                                                                                    | Unspecified Ingredient |                    |                    | S               |                      |                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                              |                                                                                                                                                   |                            |                |                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------|----------------------------------------------------------------------------------------------|
| Ineffective; Dyspnoea;<br>Epileptic Aura;<br>Generalised Tonic-Clonic<br>Seizure; Hot Flush; Liver<br>Function Test Abnormal;<br>Loss Of Consciousness;<br>Nerve Injury; Vision<br>Blurred; Weight Increased | Escitalopram Oxalate<br>Citalopram Hydrobromide<br>Levothyroxine Sodium<br>Phenobarbital (Phenobarbital)<br>Alprazolam (Alprazolam)<br>Clonazepam | S<br>S<br>C<br>C<br>C<br>C | 10 Mg (Daily), | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2004              | 4102823       | DIRECT           | Y                  | DS              |                      |                      | 89 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Lexapro         |              |            | S           |              | Q Day              |                 | Not Reported |
|                       | Tums            |              |            | C           |              |                    |                 | Not Reported |
|                       | Colace          |              |            | C           |              |                    |                 | Not Reported |
|                       | Sinemet         |              |            | C           |              |                    |                 | Not Reported |
|                       | Vitamin B12     |              |            | C           |              |                    |                 | Not Reported |
|                       | Risperdal       |              |            | C           |              |                    |                 | Not Reported |
|                       | Enalapril       |              |            | C           |              |                    |                 | Not Reported |
|                       | Percocet        |              |            | C           |              |                    |                 | Not Reported |
|                       | Kcl             |              |            | C           |              |                    |                 | Not Reported |
|                       | Maxzide         |              |            | C           |              |                    |                 | Not Reported |
|                       | Celebrex        |              |            | C           |              |                    |                 | Not Reported |
|                       | Nitroglycerin   |              |            | C           |              |                    |                 | Not Reported |
|                       | Ferrous Sulfate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2004              | 4106177       | EXPEDITED (15-DAY) | Y                  | LT              | S03-UKI-05257-01     |                      | 56 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Cipralax       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                      | Cipralax       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                      | Metoclopramide |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Zopiclone      |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Esomeprazole   |              |            | C           |              |                    |                 | Not Reported |
|                                                      | Bisoprolol     |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |              |
|---------------------------|---|--------------|
| Gtn (Glyceryl Trinitrate) | C | Not Reported |
| Diazepam                  | C | Not Reported |
| Enoxaparin Sodium         | C | Not Reported |
| Simvastatin               | C | Not Reported |
| Pethidine                 | C | Not Reported |
| Diclofenac                | C | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Mar-2004                       | 4106569                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-00826-01              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Mar-2004                       | 4106573                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-00826-04              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Mar-2004                       | 4106576                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-00826-03              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-Mar-2004                       | 4106739                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-00826-02              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-Mar-2004                       | 4015866                | EXPEDITED (15-DAY)        | Y                           | OT                       | S03-TUR-04111-01              |                               |                     | Female              | TUR                     |

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| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| Aphasia; Lactic Acidosis                                                       | Cipralext           |                    |                    | S               | Oral                 | 10 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                | Liothyronine Sodium |                    |                    | C               |                      |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2004                                                                    | 4154131             | DIRECT             | Y                  | DE              |                      |                                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                                    | Adderall Xr         |                    |                    | S               | Oral                 | 20 Mg Q Day Oral                     |                 | Not Reported |                |
|                                                                                | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Q Day Oral                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2004                                                                    | 4106258             | DIRECT             | N                  |                 |                      |                                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Dizziness; Fatigue; Headache; Nervousness; Tinnitus; Weight Increased | Lexapro             |                    |                    | S               |                      | 10 Mg 1x Per Day<br>10 Mg 1x Per Day |                 | Forest       |                |
|                                                                                |                     |                    |                    |                 |                      |                                      |                 |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2004                                                                    | 4109252             | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-00592-01     |                                      | 62 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                             | Cipralext           |                    |                    | S               | Oral                 | 20 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                | Cipralext           |                    |                    | S               | Oral                 | 20 Mg Qd Po                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2004                                                                    | 4109265             | EXPEDITED (15-DAY) | Y                  | DE              | T04-GER-00858-01     |                                      | 64 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                          | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |                                                                                    |             |      |            |                                              |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------|------|------------|----------------------------------------------|
| Completed Suicide;<br>Condition Aggravated;<br>Depression; Restlessness | Ciprallex<br>Remergil (Mirtazapine)<br>Haldol Decanoate (Haloperidol<br>Decanoate) | S<br>C<br>C | Oral | 5 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------|------|------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2004              | 4106368       | DIRECT           | Y                  | OT              |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|------------|
| Alopecia              | Escitalopram Oxalate |              |            | S           | Oral         | 30mg Once Daily Oral |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2004              | 4106924       | DIRECT           | Y                  | OT              |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------|-------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|------------------------------|
| Anxiety; Dystonia;<br>Insomnia; Migraine; Tic | Lexapro<br>Relpax |              |            | S<br>S      | Oral<br>Oral | 20 Mg Qday Oral<br>40 Mg D2hx2dos Oral |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2004              | 4061592       | NON-EXPEDITED    | Y                  | HO              | S03-USA-03019-01     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|-----------------------|-------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------------|
| Anxiety               | Lexapro<br>Oxycontin<br>Lortab<br>Premarin<br>Levoxyl<br>Prilosec |              |            | S<br>C<br>C<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2004              | 4076400       | NON-EXPEDITED    | Y                  | HO              | S03-USA-04017-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                |                         |                    |                    |                 |                      |                      |                 |            |                |
|------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Hyponatraemia                                                                                  | Lexapro                 |                    | S                  | Oral            | 20 Mg Qd Po          |                      | Not Reported    |            |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                                                    | 4109974                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWE-00867-01     |                      | 78 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspepsia; Haemoglobin Decreased; Hiatus Hernia; Rectal Haemorrhage                            | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                | Plavix                  |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                | Terazosin Hydrochloride |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                | Pantoprazole Sodium     |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                                                    | 4110314                 | EXPEDITED (15-DAY) | Y                  | OT              | T04-GER-00879-01     |                      | 31 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition Aggravated; Conversion Disorder; Crying; Fear; Nausea; Restlessness; Tremor | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                                                    | 4110457                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01056-01     |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypoglycaemia                                                                                  | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                                                    | 4111776                 | NON-EXPEDITED      | Y                  | HO              | S04-USA-00313-01     |                      | 64 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Somnolence; Suicidal Ideation                                                                  | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |

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|  |           |   |      |             |              |
|--|-----------|---|------|-------------|--------------|
|  | Lexapro   | S | Oral | 15 Mg Qd Po | Not Reported |
|  | Lexapro   | S | Oral | 20 Mg Qd Po | Not Reported |
|  | Lexapro   | S | Oral | 30 Mg Qd Po | Not Reported |
|  | Risperdal | C |      |             | Not Reported |
|  | Klonopin  | C |      |             | Not Reported |
|  | Coumadin  | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2004              | 4112052       | NON-EXPEDITED    | Y                  | HO              | S03-USA-05315-01     |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Chloride Decreased; Blood Potassium Decreased; Confusional State; Depressed Mood; Disorientation; Hyponatraemia; Pco2 Increased | Lexapro                              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                       | Lexapro                              |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                       | Neurontin                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Alprazolam                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Effexor                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Wellbutrin (Bupropion Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2004              | 4112053       | NON-EXPEDITED    | Y                  | DE              | S03-USA-04790-01     |                      | 70 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Actos          |              |            | C           |              |                    |                 | Not Reported |
|                       | Glipizide      |              |            | C           |              |                    |                 | Not Reported |
|                       | Isosorbide     |              |            | C           |              |                    |                 | Not Reported |
|                       | Labetalol      |              |            | C           |              |                    |                 | Not Reported |
|                       | Neurontin      |              |            | C           |              |                    |                 | Not Reported |
|                       | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                       | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
|                       | Lotensin Hct   |              |            | C           |              |                    |                 | Not Reported |
|                       | Lasix          |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Mar-2004                       | 4112056                 | NON-EXPEDITED             | N                           | RI                       | S03-USA-04962-01              |                               | 44 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Menorrhagia                       | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Tenormin                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Mar-2004                       | 4113363                 | NON-EXPEDITED             | Y                           | HO                       | S03-USA-04556-01              |                               | 48 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                     | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Gabapentin              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Albuterol               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Mar-2004                       | 4113372                 | NON-EXPEDITED             | Y                           | HO                       | S04-USA-00601-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Mar-2004                       | 4113373                 | NON-EXPEDITED             | Y                           | LT, RI                   | S04-USA-00531-01              |                               | 51 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaphylactic Reaction             | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Mar-2004                       | 4113376                 | NON-EXPEDITED             | Y                           | HO                       | S04-USA-00278-01              |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                                                            |                |                    |                    |                 |                      |                      |                 |            |                |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Mania                                                      | Lexapro        | S                  | Oral               | 10 Mg Qd Po     | Not Reported         |                      |                 |            |                |
|                                                            | Lithium        | C                  |                    |                 | Not Reported         |                      |                 |            |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                | 4113380        | NON-EXPEDITED      | Y                  | HO              | S04-USA-00210-01     |                      | 43 YR           | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Syncope                                                    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                            | Atenolol       |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                | 4113381        | NON-EXPEDITED      | Y                  | HO              | S04-USA-00065-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia                                              | Lexapro        |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2004                                                | 4113383        | NON-EXPEDITED      | Y                  | HO              | S03-USA-05406-01     |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Tachycardia                                                | Lexapro        |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Mar-2004                                                | 4110645        | DIRECT             | Y                  |                 |                      |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Intolerance; Fatigue; Nausea; Nervous System Disorder | Lexapro        |                    |                    | S               |                      | 5 Mg Od Hs           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Mar-2004                                                | 4112620        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01062-01     |                      | 49 YR           | Female     | USA            |

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| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Ventricular Extrasystoles                                                                                                      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2004                                                                                                                    | 4059168        | EXPEDITED (15-DAY) | Y                  | OT              | S03-GER-05270-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Viral Load Increased; Viral Myocarditis                                                                                        | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2004                                                                                                                    | 4103721        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-00833-01     |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Antidepressant Drug Level Increased; Asphyxia; Completed Suicide; Food Interaction; Refusal Of Treatment By Patient | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2004                                                                                                                    | 4105180        | EXPEDITED (15-DAY) | Y                  | HO              | S04-NOR-00786-01     |                      | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Toxicity To Various Agents; Vomiting                                     | Ciprallex      |                    |                    | S               | Oral                 | 240 Tablet Once Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2004                                                                                                                    | 4113322        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-01210-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                      |         |   |      |               |              |
|--------------------------------------------------------------------------------------|---------|---|------|---------------|--------------|
| Attention-Seeking Behaviour; Emotional Distress; Family Stress; Intentional Overdose | Lexapro | S | Oral | 10 Mg Qd Po   | Not Reported |
|                                                                                      | Lexapro | S | Oral | 60 Mg Once Po | Not Reported |
|                                                                                      | Lexapro | S | Oral | 5 Mg Qd Po    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2004              | 4113333       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S04-USA-01209-01     |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ankle Fracture; Blood Pressure Increased; Fall; Injury; Self-Medication; Thyroid Neoplasm | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Maxzide        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Folic Acid     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Methotrexate   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2004              | 4112144       | DIRECT           | Y                  | DS, HO, LT, RI  |                      |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gun Shot Wound; Suicide Attempt | Lexapro                 |              |            | S           | Oral         | 10 Mg Orally Daily | 2 WEEK          | Not Reported |
|                                 | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                 | Norvasc                 |              |            | C           |              |                    |                 | Not Reported |
|                                 | Temazepam               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2004              | 4083639       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-00209-01     |                      | 13 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia              | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Strattera      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2004              | 4087700       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S04-USA-00264-01     |                      | 65 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Electrocardiogram Qt Prolonged; Ventricular Fibrillation; Ventricular Tachycardia                                                                                                | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                  | Amitriptyline        |                    |                    | S               |                              | 50 Mg Qd             |                 | Not Reported    |                |
|                                                                                                                                                                                  | Coumadin             |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                  | Digoxin              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Mar-2004                                                                                                                                                                      | 4113882              | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-01085-01             |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide; Drug Ineffective; Weight Increased                                                                                                                            | Lexapro              |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                  | Abilify              |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                  | Abilify              |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                  | Zyprexa              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 22-Mar-2004                                                                                                                                                                      | 4080650              | EXPEDITED (15-DAY) | Y                  | HO              | CH-GLAXOSMITHKLINE-B0320863A |                      | 80 YR           | Female          | CHE            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Decreased Activity; Depressed Level Of Consciousness; Fall; Gait Disturbance; Haemoglobin Decreased; Haemothorax; Rash; Rib Fracture; Sedation; White Blood Cell Count Decreased | Lamictal             |                    |                    | S               | Oral                         | 100mg Per Day        | 20 DAY          | Glaxosmithkline |                |
|                                                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                         | 15mg Per Day         | 77 DAY          | Not Reported    |                |
|                                                                                                                                                                                  | Lorazepam            |                    |                    | S               | Oral                         | 3mg Per Day          | 34 DAY          | Not Reported    |                |
|                                                                                                                                                                                  | Olanzapine           |                    |                    | S               | Oral                         | 5mg Per Day          | 24 DAY          | Not Reported    |                |
|                                                                                                                                                                                  | Mirtazapine          |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Mar-2004                                                                                                                                                                      | 4110317              | EXPEDITED (15-DAY) | Y                  | OT              | T04-GER-00940-01             |                      | 37 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Erythema; General Physical Health                                                                                                                                     | Ciprallex            |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                  | Simvastatin          |                    |                    | C               |                              |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Deterioration; Loss Of  
Consciousness; Petit Mal  
Epilepsy

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2004              | 4114298       | DIRECT           | N                  | HO, LT, RI      |                      |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Intentional Self-Injury;<br>Panic Attack; Suicide<br>Attempt | Lexapro            |              |            | S           | Oral         | 30 Mg 1x In Morn Oral |                 | Not Reported |
|                                                              | Aleve              |              |            | C           |              |                       |                 | Not Reported |
|                                                              | Nasal Decongestant |              |            | C           |              |                       |                 | Not Reported |
|                                                              | Cold Medicines     |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2004              | 4114541       | DIRECT           | N                  | DE              |                      |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression | Lexapro        |              |            | S           |              | Unknown            |                 | Not Reported |
|                                  | Xanax          |              |            | S           |              | Unknown When Neede |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2004              | 4114543       | DIRECT           | N                  | DE              |                      |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              | 2 Daily            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2004              | 4114580       | DIRECT           | N                  | HO              |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Confusional<br>State; Depression;<br>Dyskinesia; Feeling | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                   | Ambien         |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Indifference;  
Neck Pain; Night Sweats;  
Sleep Disorder; Suicide  
Attempt

| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|----------------------------------------------|----------------|
| 23-Mar-2004                                                                                                                                                                                                 | 4114712                        | DIRECT             | N                  | LT              |                      |                                             | 32 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abnormal Dreams;<br>Decreased Appetite;<br>Dizziness; Drug<br>Ineffective; Feeling<br>Abnormal; Indifference;<br>Insomnia; Marital Problem;<br>Suicidal Ideation; Thinking<br>Abnormal; Weight<br>Increased | Lexapro                        |                    |                    | S               | Oral                 | 10 Mg Daily Oral                            |                 | Forest                                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 23-Mar-2004                                                                                                                                                                                                 | 4115815                        | EXPEDITED (15-DAY) | Y                  | HO              | S04-AUS-01156-01     |                                             | 26 YR           | Unknown                                      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Blood Urea Decreased;<br>Electrocardiogram Qt<br>Prolonged; Overdose                                                                                                                                        | Lexapro<br>Alprazolam          |                    |                    | S<br>S          | Oral                 | 0.25 Mg Po                                  |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 24-Mar-2004                                                                                                                                                                                                 | 4114718                        | DIRECT             | N                  | RI, OT          |                      |                                             | 29 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abdominal Pain Upper;<br>Anger; Anxiety; Apathy;<br>Condition Aggravated;<br>Depression; Diarrhoea;<br>Disturbance In Attention;<br>Fatigue; Feeling                                                        | Lexapro<br>Lexapro<br>Adderall |                    |                    | S<br>S<br>C     | Oral<br>Oral         | 10 Mg Daily Oral<br>15 Mg, 20 Mg Daily Oral |                 | Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Irritability;  
Nausea; Stress

| <u>FDA Received Date</u>                                                 | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Mar-2004                                                              | 4114757                | DIRECT           | N                  | DE              |                      |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Irritability;<br>Suicide Attempt; Thinking<br>Abnormal | Lexapro                |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                          | Zoloft                 |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                          | Lexapro                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Unspecified Ingredient |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 24-Mar-2004                                                                                                                           | 4115113        | DIRECT           | N                  | LT              |                      |                       | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Apathy;<br>Condition Aggravated;<br>Depression; Drug<br>Ineffective; Indifference;<br>Sedation; Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Once Per D Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Mar-2004                                                                            | 4115214        | DIRECT           | N                  | HO              |                      |                      | 25 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Abnormal; Gait<br>Disturbance; Mania;<br>Movement Disorder;<br>Speech Disorder | Lexapro        |                  |                    | S               | Oral                 | 10 Mg 1 Time Oral    |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2004              | 4115403       | DIRECT           | N                  | OT              |                      |                      | 42 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>                                                   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|------------------|---------------------------|-----------------------|-----------------|--------------------------------------------------------------|----------------|
| Abnormal Behaviour;<br>Anxiety; Dissociation;<br>Dizziness; Dyspnoea;<br>Feeling Abnormal; Feeling<br>Cold; Flushing; Headache;<br>Impaired Work Ability;<br>Panic Attack;<br>Somnolence; Suicidal<br>Ideation; Tachycardia;<br>Thinking Abnormal | Lexapro                                          |                    |                    | S                | Oral                      | One Once Oral         |                 | Forest                                                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 25-Mar-2004                                                                                                                                                                                                                                       | 4119473                                          | EXPEDITED (15-DAY) | Y                  | DS               | S04-UKI-01087-01          |                       | 86 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Cerebral Ischaemia;<br>Dyskinesia; Hallucination,<br>Visual; Parkinsonism;<br>Somnolence                                                                                                                                                          | Cipralext<br>Aspirin<br>Ranitidine<br>Citalopram |                    |                    | S<br>C<br>C<br>C | Oral                      | 10 Mg Qd Po           |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 26-Mar-2004                                                                                                                                                                                                                                       | 4124335                                          | NON-EXPEDITED      | Y                  |                  | US-JNJFOC-<br>20040104233 |                       |                 | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Heart Rate Decreased                                                                                                                                                                                                                              | Reminyl                                          |                    |                    | S                | Oral                      | Oral                  |                 | Not Reported                                                 |                |
|                                                                                                                                                                                                                                                   | Lexapro                                          |                    |                    | S                | Oral                      | 10 Mg, 1 In Day, Oral |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 29-Mar-2004                                                                                                                                                                                                                                       | 4102883                                          | EXPEDITED (15-DAY) | Y                  | HO               | DSA_24006_2004            |                       | 80 YR           | Female                                                       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Antidepressant Drug Level<br>Increased; Asthenia;                                                                                                                                                                                                 | Lorazepam                                        |                    |                    | S                | Oral                      | 1.5 Mg Q Day Po       |                 | Not Reported                                                 |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                 |               |   |      |                 |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---|------|-----------------|--------------|
| Decreased Activity; Drug Interaction; Drug Level Increased; Fall; Gait Inability; Haemothorax; Hypophagia; Infection; Leukopenia; Normochromic Normocytic Anaemia; Pruritus; Rash; Rib Fracture | Lorazepam     | S | Oral | 3 Mg Q Day Po   | Not Reported |
|                                                                                                                                                                                                 | Lorazepam     | S | Oral | 0.5 Mg Q Day Po | Not Reported |
|                                                                                                                                                                                                 | Lorazepam     | S | Oral | 1 Mg Q Day Po   | Not Reported |
|                                                                                                                                                                                                 | Cipralext     | S |      |                 | Not Reported |
|                                                                                                                                                                                                 | Cipralext     | S |      |                 | Not Reported |
|                                                                                                                                                                                                 | Cipralext     | S |      |                 | Not Reported |
|                                                                                                                                                                                                 | Lamictal      | S |      | 100 Mg Q Day    | Not Reported |
|                                                                                                                                                                                                 | Lamictal      | S |      |                 | Not Reported |
|                                                                                                                                                                                                 | Zyprexa       | S |      | 5 Mg Q Day      | Not Reported |
|                                                                                                                                                                                                 | Zyprexa       | S |      | 2.5 Mg Q Day    | Not Reported |
|                                                                                                                                                                                                 | Remeron       | S |      |                 | Not Reported |
|                                                                                                                                                                                                 | Valproic Acid | C |      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2004              | 4118027       | DIRECT           | N                  | DE              |                      |                      | 89 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              | Daily              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2004              | 4120528       | DIRECT           | N                  |                 |                      |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urticaria             | Lexapro        |              |            | S           | Oral         | 20 Mg Po Qd        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2004              | 4122522       | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-01540-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Petit Mal Epilepsy; Tremor | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                            | Wellbutrin Sr  |              |            | S           |              | 150 Mg Qd          |                 | Not Reported |
|                            | Prozac         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2004                                                                                                                 | 4039039                | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04385-01     |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Blood Testosterone<br>Decreased;<br>Gynaecomastia; Pituitary<br>Tumour Benign; Sinus<br>Polyp | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                             | Ritalin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Ritalin Sr             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Wellbutrin Sr          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2004                                                                                                                 | 4120337                | DIRECT             | N                  | DE              |                      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Completed Suicide;<br>Intentional Self-Injury                                                        | Lexapro                |                    |                    | S               | Oral                 | Once A Day Oral      |                 | Not Reported |                |
|                                                                                                                             | Wellbutrin             |                    |                    | S               | Oral                 | Once A Day Oral      |                 | Not Reported |                |
|                                                                                                                             | Ambien                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Unspecified Ingredient |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Trazidone              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Maxalt                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                             | Flonase                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2004                                                                                                                 | 4120545                | DIRECT             | N                  | OT              |                      |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Dizziness;<br>Fatigue; Headache; Mood<br>Altered; Social Avoidant<br>Behaviour; Suicidal<br>Ideation; Tremor       | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Once Day Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2004                                                                                                                                                                                                                                                                         | 4123542                 | EXPEDITED (15-DAY) | N                  | RI, OT          | S04-USA-01551-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Heart Rate Increased; Weight Increased                                                                                                                                                                                                                                   | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2004                                                                                                                                                                                                                                                                         | 4091077                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWI-00443-01     |                      | 80 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| C-Reactive Protein Increased; Depressed Level Of Consciousness; Dermatitis Allergic; Drug Level Increased; Fall; Feeding Disorder; Haematocrit Decreased; Haemoglobin Decreased; Haemothorax; Leukopenia; Pruritus; Rash; Rib Fracture; Urinary Tract Infection; Walking Disability | Ciprallex               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Ciprallex               |                    |                    | S               | Oral                 | 15 M Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Lamictal                |                    |                    | S               | Oral                 | 100 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Lamictal                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Zyprexa                 |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Zyprexa                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Remeron                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Lorazepam               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2004                                                                                                                                                                                                                                                                         | 4121022                 | DIRECT             | Y                  | OT              |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysgeusia; Food Intolerance; Insomnia; Mania; Mydriasis; Olfactory Nerve Disorder; Palpitations; Parosmia; Sensory Disturbance; Skin                                                                                                                                                | Lexapro                 |                    |                    | S               | Oral                 | 1 Po Q Day           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Clonidine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Burning Sensation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2004              | 4121276       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01543-01     |                      | 12 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Myoclonus             | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Topamax        |              |            | C           |              |                    |                 | Not Reported |
|                       | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                       | Elavil         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2004              | 4121282       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01410-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2004              | 4035920       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S03-USA-04615-01     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Bone Marrow Transplant; Chronic Myelomonocytic Leukaemia; Ecchymosis; Fatigue; Myelodysplastic Syndrome; Nausea; Night Sweats; Oral Pain; Petechiae; Pyrexia; Refractory Anaemia With An Excess Of Blasts; Stomatitis; Thrombocytopenia; Trisomy 8 | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Fioricet       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Ibuprofen      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Keflex         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|----------------------|---------------------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| 01-Apr-2004                                                                                                                   | 4095767                                                                                | EXPEDITED (15-DAY) | Y                  | OT                         | S04-USA-00470-01     |                                       | 20 YR           | Female                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Blood Alcohol Increased;<br>Loss Of Consciousness;<br>Road Traffic Accident                                                   | Lexapro<br>Alcohol                                                                     |                    |                    | S<br>S                     |                      |                                       |                 | Not Reported<br>Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 01-Apr-2004                                                                                                                   | 4098612                                                                                | EXPEDITED (15-DAY) | Y                  | HO                         | S04-USA-00578-01     |                                       | 36 YR           | Female                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Blood Alkaline<br>Phosphatase Increased;<br>Hepatitis; Jaundice;<br>Protein Total Decreased                                   | Lexapro<br>Clozapine<br>Haldol<br>Prevacid<br>Ferrous Sulfate<br>Surfak Stool Softener |                    |                    | S<br>S<br>S<br>C<br>C<br>C | Oral                 | 20 Mg Qd Po<br>650 Mg Qd<br>2 Mg Q4hr |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 01-Apr-2004                                                                                                                   | 4107265                                                                                | EXPEDITED (15-DAY) | Y                  | OT                         | S04-USA-00917-01     |                                       | 38 YR           | Male                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Drug Hypersensitivity;<br>Generalised Tonic-Clonic<br>Seizure; Hypersomnia;<br>Status Epilepticus;<br>Treatment Noncompliance | Lexapro<br>Alcohol<br>Lotrel                                                           |                    |                    | S<br>S<br>C                | Oral                 | 10 Mg Qd Po                           |                 | Not Reported<br>Not Reported<br>Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 01-Apr-2004                                                                                                                   | 4113374                                                                                | EXPEDITED (15-DAY) | Y                  | HO                         | S04-USA-00400-01     |                                       | 18 YR           | Female                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                         |          |   |      |              |              |
|---------------------------------------------------------|----------|---|------|--------------|--------------|
| Depression Suicidal;<br>Homicidal Ideation;<br>Paranoia | Lexapro  | S | Oral | 40 Mg Qd Po  | Not Reported |
|                                                         | Lexapro  | S | Oral | 20 Mg Qd Po  | Not Reported |
|                                                         | Lexapro  | S | Oral | 80 Mg Prn Po | Not Reported |
|                                                         | Eskalith | C |      |              | Not Reported |
|                                                         | Abilify  | C |      |              | Not Reported |
|                                                         | Ativan   | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2004              | 4121034       | DIRECT           | Y                  | HO              |                      |                      | 78 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Decreased<br>Appetite; Hyponatraemia | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2004              | 4123747       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2004019987           |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hypoacusis; Tic | Relpax               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                      | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2004              | 4091327       | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWI-00374-01     |                      | 81 YR      | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Aggression; | Ciprallex           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Agitation; Crying;           | Ciprallex           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depression; Judgement        | Remeron             |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Impaired; Memory             | Remeron             |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
| Impairment; Psychomotor      |                     |              |            | C           |              |                    |                 | Not Reported |
| Hyperactivity;               | Zestoretic          |              |            | C           |              |                    |                 | Not Reported |
| Restlessness; Suicidal       | Fursol (Furosemide) |              |            | C           |              |                    |                 | Not Reported |
| Ideation                     | Norvasc             |              |            | C           |              |                    |                 | Not Reported |
|                              | Digoxin             |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2004                | 4116901                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01369-01     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Mania; Maternal Drugs      | Albuterol               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Affecting Foetus; Maternal | Topical Cortisone Cream |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Drugs Affecting Foetus;    |                         |                    |                    |                 |                      |                      |                 |              |                |
| Pregnancy                  |                         |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2004                | 4124420                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01534-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bacterial Infection; Body  | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Temperature Increased;     | Celexa                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Dehydration; Nausea;       |                         |                    |                    |                 |                      |                      |                 |              |                |
| Vertigo; Vomiting; White   |                         |                    |                    |                 |                      |                      |                 |              |                |
| Blood Cell Count           |                         |                    |                    |                 |                      |                      |                 |              |                |
| Decreased                  |                         |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2004                | 4124764                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01556-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage                | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2004                | 4128568                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-GER-01375-01     |                      | 21 YR           | Male         | DEU            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase   | Ciprallex               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Increased; Apathy;         | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Aspartate                  |                         |                    |                    |                 |                      |                      |                 |              |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |           |   |      |             |              |
|---------------------------------------------------------------------|-----------|---|------|-------------|--------------|
| Aminotransferase Increased; Blood Creatine Phosphokinase Increased; | Ciprallex | S | Oral | 20 Mg Qd Po | Not Reported |
| Blood Creatine Phosphokinase Mb                                     | Ciprallex | S | Oral | 15 Mg Qd Po | Not Reported |
| Abnormal; Nausea; Polydipsia; Restlessness                          | Ciprallex | S | Oral | 20 Mg Qd Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2004              | 4123393       | DIRECT           | N                  | OT              |                      |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome; Gastrointestinal Disorder; Irritability; Pruritus; Tinnitus | Lexapro        |              |            | S           | Oral         | Once Day Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2004              | 4124564       | DIRECT           | Y                  | OT              |                      |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation; Diarrhoea; Muscular Weakness; Nausea; Throat Tightness | Lexapro        |              |            | S           | Oral         | 5 Mg Po            |                 | Not Reported |
|                                                                           | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Tenonmin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Vistaril       |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Prilosec       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2004              | 4115007       | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-00950-01     |                      | 57 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Erectile Dysfunction; Leukopenia; Neutropenia; Somnolence; | Ciprallex            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                        | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |             |   |      |             |              |
|-----------------------------------------|-------------|---|------|-------------|--------------|
| Therapeutic Product Effect<br>Decreased | Ciprallex   | S | Oral | 10 Mg Qd Po | Not Reported |
|                                         | Allopurinol | S |      | 300 Mg Od   | Not Reported |
|                                         | Allopurinol | S |      | 300 Mg Qd   | Not Reported |
|                                         | Captopril   | S |      | 100 Mg Qd   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2004              | 4126027       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01409-01     |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Fall;<br>Hypotension; Loss Of<br>Consciousness;<br>Orthostatic Hypotension;<br>Syncope | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                   | Neurontin      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2004              | 4113341       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01203-01     |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose;<br>Blood Creatinine<br>Increased; Blood<br>Potassium Increased;<br>Chills; Confusional State;<br>Disorientation; Drug<br>Interaction; Influenza Like<br>Illness; International<br>Normalised Ratio<br>Increased; Laboratory<br>Test Interference;<br>Lethargy; Medication<br>Error; Nausea; Pain;<br>Serotonin Syndrome;<br>Urinary Retention | Lexapro        |              |            | S           | Oral         | 30 Mg Bid Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Maxzide        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Enalapril      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Coumadin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Famotidine     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Metformin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Propoxy-N/Apap |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Vitamin C      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                    | Zinc           |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |   |              |
|----------------------------------|---|--------------|
| Acetaminophen                    | C | Not Reported |
| Simethicone                      | C | Not Reported |
| Diphenhydramine                  | C | Not Reported |
| Diphenoxylate W/Atropine Sulfate | C | Not Reported |
| Lidocaine                        | C | Not Reported |
| Morphine                         | C | Not Reported |
| Morphine                         | C | Not Reported |
| Promethazine                     | C | Not Reported |
| Barriere Cream                   | C | Not Reported |
| Bag Balm                         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2004              | 4125430       | DIRECT           | Y                  | OT              |                      |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Confusional State;<br>Delirium;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram T Wave<br>Abnormal | Lexapro<br>Oxycontin<br>Neurontin<br>Xanax<br>Soma |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg Po Daily     |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2004              | 4128222       | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-01374-01     |                      | 29 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-----------------------|--------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Angioedema; Dyspnoea  | Ciprallex<br>Zyprexa<br>Risperdal<br>Tavor (Lorazepam) |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2004              | 4127951       | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-01444-01     |                      | 42 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                              |                 |                    |                    |                 |                      |                               |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Leukopenia; Neutropenia                                                                                                                                                      | Ciprallex       |                    | S                  | Oral            | 5 Mg Qd Po           |                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2004                                                                                                                                                                  | 4128109         | EXPEDITED (15-DAY) | Y                  | RI              | 2004PK00586          |                               | 82 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebrovascular Accident; Hepatic Enzyme Increased; Hepatocellular Injury; Urinary Tract Infection | Nexium          |                    |                    | S               | Oral                 | 20 Mg Daily                   |                 | Not Reported |                |
|                                                                                                                                                                              | Ciprallex       |                    |                    | S               | Oral                 | 20 Mg Daily                   |                 | Not Reported |                |
|                                                                                                                                                                              | Augmentin       |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                              | Morphin Streuli |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                              | Dafalgan        |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2004                                                                                                                                                                  | 4131863         | NON-EXPEDITED      | Y                  | RI              | 03I-163-0235748-00   |                               | 44 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anticonvulsant Drug Level Below Therapeutic; Seizure                                                                                                                         | Depakote        |                    |                    | S               | Oral                 | See Image                     |                 | Not Reported |                |
|                                                                                                                                                                              |                 |                    |                    |                 | Oral                 | See Image                     |                 |              |                |
|                                                                                                                                                                              |                 |                    |                    |                 | Oral                 | See Image                     |                 |              |                |
|                                                                                                                                                                              |                 |                    |                    |                 | Oral                 | See Image                     |                 |              |                |
|                                                                                                                                                                              | Lexapro         |                    |                    | S               | Oral                 | 20; 10 Mg, 1 In 1 D, Per Oral |                 | Not Reported |                |
|                                                                                                                                                                              |                 |                    |                    |                 | Oral                 | 20; 10 Mg, 1 In 1 D, Per Oral |                 |              |                |
|                                                                                                                                                                              | Carbamazepine   |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2004                                                                                                                                                                  | 4128692         | EXPEDITED (15-DAY) | Y                  | DS              | S04-SWI-01446-01     |                               | 82 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholelithiasis;                                                                                                                                                              | Ciprallex       |                    |                    | S               | Oral                 | 20 Mg Qd Po                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                            |   |      |             |              |
|-----------------------------------------------------------------|----------------------------|---|------|-------------|--------------|
| Hepatocellular Injury;<br>Parotitis; Urinary Tract<br>Infection | Nexium (Esomeprazole)      | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                                 | Augmentin                  | C |      |             | Not Reported |
|                                                                 | Morphin Streuli (Morphine) | C |      |             | Not Reported |
|                                                                 | Acetaminophen              | C |      |             | Not Reported |
|                                                                 | Prednisone                 | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2004              | 4131240       | EXPEDITED (15-DAY) | Y                  | OT              | T04-GER-01460-01     |                      | 43 YR      | Female     | DEU            |

| <u>Preferred Term</u>                          | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Restlessness;<br>Serotonin Syndrome | Cipralex                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                | Maxalt                          |              |            | C           |              |                    |                 | Not Reported |
|                                                | Foradil P (Formoterol Fumurate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2004              | 4101335       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00722-01     |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness Transient   | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Prilosec              |              |            | C           |              |                    |                 | Not Reported |
|                       | Tylenol (Paracetamol) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2004              | 4128964       | EXPEDITED (15-DAY) | Y                  | OT              | A03200400979         |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Pain;<br>Procedural Complication;<br>Therapy Non-Responder | Demerol        |              |            | S           | Unknown      | 50 Mg Once Unknown | 1 DAY           | Not Reported |
|                                                                              | Lexapro        |              |            | S           | Oral         | 5 Mg Qd - Oral     |                 | Not Reported |
|                                                                              | Versed         |              |            | S           | Unknown      | 7 Mg Once Unknown  | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2004              | 4129429       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-01687-01     |                      | 22 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Asphyxia; Completed Suicide; Family Stress                                                                                                                            | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                       | Unspecified Ingredient      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2004                                                                                                                                                           | 4129887                     | EXPEDITED (15-DAY) | Y                  | HO              |                      | T04-GER-01528-01     | 44 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Addison'S Disease; Alanine Aminotransferase Increased; Blood Cholesterol Increased; Depression; Medication Error; Refusal Of Treatment By Patient; Serotonin Syndrome | Ciprallex                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                       | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                       | Tryptophan (Tryptophan, L-) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2004                                                                                                                                                           | 4130383                     | EXPEDITED (15-DAY) | Y                  | OT              |                      | S04-UKI-01520-01     | 22 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                                      | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                       | Albuterol Sulfate           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2004                                                                                                                                                           | 4094434                     | EXPEDITED (15-DAY) | Y                  | DE              |                      | 2004UW02477          | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriosclerosis Coronary Artery; Coma; Toxicity To Various Agents                                                                                                    | Seroquel                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Neurontin                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Clonazepam                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Oxycontin                   |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 16-Apr-2004               | 4128526        | DIRECT             | Y                  | RI              |                              |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Decreased   | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Day Oral       |                 | Forest       |                |
|                           | Lantus         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Humalog        |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2004               | 4130788        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-01895-01             |                      |                 | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide         | Lexapro        |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2004               | 4132323        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-01887-01             |                      |                 | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Increased Appetite;       | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
| Insomnia; Seizure; Weight | Xanax          |                    |                    | C               |                              |                      |                 | Not Reported |                |
| Increased                 | Toprol XL      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Altace         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Plavix         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Aspirin        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Potassium      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Water Pills    |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                           | Phenobarbital  |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2004               | 4127695        | EXPEDITED (15-DAY) | Y                  | OT              | DE-GLAXOSMITHKLINE-D0043604A |                      | 39 YR           | Female       | DEU            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                          |               |   |        |                          |                 |
|--------------------------|---------------|---|--------|--------------------------|-----------------|
| Alanine Aminotransferase | Lamictal      | S | Oral   | 3tab Three Times Per Day | Glaxosmithkline |
| Abnormal; Blood Creatine | Acetaminophen | S | Rectal | 1sup Unknown             | Glaxosmithkline |
| Phosphokinase Increased; | Trileptal     | S | Oral   | 3tab Three Times Per Day | Not Reported    |
| Hepatic Function         | Cipralext     | S | Oral   | 1.5tab Per Day           | Not Reported    |
| Abnormal; Prothrombin    | Folic Acid    | S | Oral   | 1tab Per Day             | Not Reported    |
| Time Prolonged           |               |   |        |                          |                 |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 20-Apr-2004                 | 4130136        | DIRECT           | N                  | LT              |                      |                       | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Conversion         | Lexapro        |                  |                    | S               | Oral                 | 10 Mgs 1 X Daily Oral |                 | Not Reported |                |
| Disorder; Impaired Work     | Lexapro        |                  |                    | S               | Oral                 | 05 Mgs 1 X Daily Oral |                 | Not Reported |                |
| Ability; Suicidal Ideation; |                |                  |                    |                 |                      |                       |                 |              |                |
| Yawning                     |                |                  |                    |                 |                      |                       |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 20-Apr-2004              | 4130783        | DIRECT           | Y                  | DE              |                      |                       | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;       | Lexapro        |                  |                    | S               |                      | Lexapro 15 Qd, Over 1 |                 | Not Reported |                |
| Overdose                 | Seroquel       |                  |                    | S               |                      | Year                  |                 | Not Reported |                |
|                          | Carbamazepine  |                  |                    | S               |                      | Carbamazepine 800 Qd  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Apr-2004              | 4124418        | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-01533-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Seizure                  | Glyburide      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lisinopril     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Clarinet       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Topamax        |                    |                    | C               |                      |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Apr-2004                                                                                          | 4132210                 | DIRECT             | N                  | DE              |                      |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Completed Suicide; Fear                                                                   | Lexapro                 |                    |                    | S               | Oral                 | 1 Pill Daily Oral    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2004                                                                                          | 4134542                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-01670-01     |                      | 35 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy | Ciprallex               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2004                                                                                          | 4134796                 | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-00541-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coeliac Disease                                                                                      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                      | Insulin Nos             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                      | Levoxyl                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                      | Fosamax                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                      | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2004                                                                                          | 4094951                 | EXPEDITED (15-DAY) | Y                  | HO, RI          | S04-USA-00559-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Disease Recurrence; Ovarian Cyst; Pain                                               | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 26-Apr-2004                                                           | 4133224                          | DIRECT             | Y                  | OT              |                      |                          | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Irregular;<br>Palpitations                                 | Lexapro                          |                    |                    | S               | Oral                 | 20 Milligram Oral        |                 | Not Reported |                |
|                                                                       | Multi-Vitamin                    |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Vit C                            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Vitamin E                        |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Magnesium                        |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Soya Lecithin                    |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Prostate-Vitamin/Herb Supplement |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                       | Baby Aspirin                     |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2004                                                           | 4133573                          | DIRECT             | Y                  | OT              |                      |                          | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Diarrhoea; Nausea;<br>Vomiting               | Lexapro                          |                    |                    | S               | Oral                 | 20 Mg Po Daily           |                 | Forest       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2004                                                           | 4133622                          | DIRECT             | N                  | OT              |                      |                          | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Fatigue;<br>Nausea; Suicidal Ideation;<br>Tension Headache | Lexapro                          |                    |                    | S               |                      | 5 Mg Daily<br>5 Mg Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2004                                                           | 4123513                          | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-01403-01     |                          | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                                      |   |      |             |              |
|------------------------------------------------------------------|--------------------------------------|---|------|-------------|--------------|
| Dyskinesia; Nuclear Magnetic Resonance Imaging Abnormal; Syncope | Lexapro                              | S | Oral | 5 Mg Qd Po  | Not Reported |
|                                                                  | Lexapro                              | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                  | Wellbutrin (Bupropion Hydrochloride) | C |      |             | Not Reported |
|                                                                  | Flomax                               | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2004              | 4133710       | DIRECT           |                    |                 |                      |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension; Abdominal Pain; Back Pain; Chills; Dyskinesia; Eye Burns; Eye Irritation; Flatulence; Gastroesophageal Reflux Disease; Hallucination; Headache; Hyperhidrosis; Hypoaesthesia; Oedema Peripheral; Pain; Palpitations; Pruritus; Raynaud'S Phenomenon; Restless Legs Syndrome; Serotonin Syndrome; Vision Blurred | Lexapro        |              |            | S           |              | 10 Mg , Daily      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2004              | 4137086       | EXPEDITED (15-DAY) | Y                  | OT              | 2004209512US         |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation; Chest Discomfort; Diarrhoea; Drug Interaction; Dysgeusia; Hyperhidrosis; Hypertension; Hypophagia; Muscle Rigidity; Myalgia; Mydriasis; Parosmia; | Zyvox          |              |            | S           |              | 600 M G, Qd        |                 | Not Reported |
|                                                                                                                                                                      | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd, Oral    |                 | Not Reported |
|                                                                                                                                                                      | Vancomycin     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                      | Lortab         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                      | Catapres-Tts   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyrexia; Serotonin  
Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2004              | 4137398       | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05001-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eosinophil Count Increased;                                                                                                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qhs Po       |                 | Not Reported |
| Hypothyroidism;                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Leukopenia; Lymphocyte Count Increased; Muscle Spasms; Neutrophil Count Increased; Normochromic Normocytic Anaemia; Platelet Count Decreased; Purpura; Somnolence | Duragesic      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Stadol         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Premarin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2004              | 4137092       | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-02239-01     |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;                                                                                                           | Lexapro        |              |            | S           | Oral         | 30 Mg Prn Po       |                 | Not Reported |
| Amnesia; Cardiac Failure Congestive; Confusional State; Heart Valve Incompetence; Sleep Apnoea Syndrome; Thrombosis; Wheezing | Lexapro        |              |            | S           | Oral         | 40 Mg Prn Po       |                 | Not Reported |
|                                                                                                                               | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                               | Lorcet         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                               | Soma           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2004              | 4137862       | EXPEDITED (15-DAY) | Y                  | HO              | S04-UKI-01735-01     |                      | 39 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonic Convulsion     | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Zolpidem       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                             |                       |                    |                    |                 |                       |                      |                 |              |                |
|-----------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Oxazepam                    |                       |                    | C                  |                 |                       | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2004                 | 4139417               | NON-EXPEDITED      | Y                  | OT              | US-JNJFOC-20031205539 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure   | Ultram                |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
|                             | Lexapro               |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2004                 | 4122524               | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-01407-01      |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Fatigue;           | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qam Po         |                 | Not Reported |                |
| Hyperhidrosis; Loss Of      | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| Consciousness;              |                       |                    |                    |                 |                       |                      |                 |              |                |
| Medication Error; Nausea;   | Seroquel              |                    |                    | C               |                       |                      |                 | Not Reported |                |
| Seizure; Tongue Biting;     | Wellbutrin (Bupropion |                    |                    | C               |                       |                      |                 | Not Reported |                |
| Vomiting                    | Hydrochloride)        |                    |                    |                 |                       |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2004                 | 4138335               | EXPEDITED (15-DAY) | Y                  | OT              | 2004S1001092          |                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;        | Lexapro               |                    |                    | S               | Oral                  | 30mg Bid, Oral       |                 | Not Reported |                |
| Blood Creatinine            | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd, Oral       |                 | Not Reported |                |
| Increased; Blood            | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| Potassium Increased;        | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| Blood Urea Increased;       | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| Confusional State;          | Lexapro               |                    |                    | S               | Oral                  | 20 Mg Qd Po          |                 | Not Reported |                |
| Disorientation; Drug        | Lexapro               |                    |                    | S               | Oral                  | 30 Mg Qd Po          |                 | Not Reported |                |
| Interaction; Influenza Like | Lexapro               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| Illness; International      | Maxzide               |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Normalised Ratio            | Enalapril             |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| Increased; Lethargy;        |                       |                    |                    |                 |                       |                      |                 |              |                |
| Medication Error; Nausea;   | Warfarin Sodium       |                    |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                                                                                                                                                                                                                                                                                  |                                                                                   |                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oropharyngeal Pain; Pain;<br>Serotonin Syndrome;<br>Urinary Retention | Famotidine<br>Metformin Hydrochloride<br>Amlodipine<br>Propoxyphene Napsylate &<br>Apap<br>Vitamin C<br>Morphine Sulfate\Zinc<br>Acetaminophen<br>Simethicone<br>Diphenhydramine<br>Diphenoxylate And Atropine<br>Sulfate<br>Lidocaine<br>Morphine<br>Promethazine<br>Barriere Cream<br>Bag Balm | C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2004              | 4093517       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00532-01     |                      | 13 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                       | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Acne; Blood Glucose<br>Increased; Condition<br>Aggravated; Eyelid<br>Oedema; Headache; High<br>Density Lipoprotein<br>Decreased;<br>Hypertriglyceridaemia;<br>Oliguria; Renal<br>Impairment; Urinary Tract<br>Disorder; Weight<br>Increased | Lexapro<br>Seroquel<br>Risperdal<br>Abilify |              |            | S<br>C<br>C<br>C | Oral         | 20 Mg Qhs Po       |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2004              | 4138499       | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-01736-01     |                      | 45 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hypersomnia; Syncope                                                   |                | Ciprallex          |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2004                                                            | 4138622        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-02243-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                             | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Oxycontin      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                        | Oxycontin      |                    |                    | S               | Oral                 | 50 Mg Po             |                 | Not Reported |                |
|                                                                        | Oxycodone      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                        | Elavil         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Seroquel       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Neurontin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Prevacid       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2004                                                            | 4136819        | DIRECT             | N                  | OT              |                      |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Condition Aggravated;<br>Depression; Somnolence | Lexapro        |                    |                    | S               |                      | 10 Mg Daily At Night | 1 YR            | Not Reported |                |
|                                                                        | Seroquel       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2004                                                            | 4136957        | DIRECT             | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error                                                       | Lexapro        |                    |                    | S               |                      | Tablet               |                 | Forest       |                |
|                                                                        | Loxapine       |                    |                    | S               |                      | Capsule              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2004                                                            | 4138963        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02246-01     |                      | 28 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Agitation; Dizziness;                                                                                                                                                | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Dyskinesia; Feeling Jittery;                                                                                                                                         | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Intentional Overdose;                                                                                                                                                | Flexeril       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Muscle Twitching;                                                                                                                                                    | Flexeril       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Restlessness; Serotonin Syndrome; Suicide Attempt                                                                                                                    |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2004                                                                                                                                                          | 4131360        | EXPEDITED (15-DAY) | Y                  | DS              | S04-PRT-01661-01     |                      | 57 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Glucose Increased; Gamma-Glutamyltransferase Increased; Liver Function Test Abnormal | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                      | Lorezepam      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2004                                                                                                                                                          | 4139714        | EXPEDITED (15-DAY) | Y                  | HO              | HQWYE571722APR04     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Anal Incontinence; Drug Ineffective; Hepatotoxicity; Nausea; Oedema                                                                            | Effexor Xr     |                    |                    | S               | Oral                 | See Image Oral       |                 | Not Reported |                |
| Peripheral; Rash; Sunburn; Urinary Incontinence                                                                                                                      | Lexapro        |                    |                    | S               | Oral                 | See Image Oral       |                 | Not Reported |                |
|                                                                                                                                                                      | Buspar         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2004                                                                                                                                                          | 4140292        | EXPEDITED (15-DAY) | Y                  | OT              | SO4-USA-02247-01     |                      | 50 YR           | Male         | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Fluctuation | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                           | Insulin Nos    |              |            | C           |              |                    |                 | Not Reported |
|                           | Ativan         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2004              | 4139328       | DIRECT           | N                  | HO, LT          |                      |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Anxiety; Crying;<br>Dysphonia; Euphoric<br>Mood; Feeling Abnormal;<br>Impaired Work Ability;<br>Irritability; Jaw Disorder;<br>Loss Of Consciousness;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Mental Disorder;<br>Mydriasis; Nervousness;<br>Paraesthesia;<br>Photosensitivity Reaction;<br>Respiratory Arrest;<br>Suicidal Ideation; Suicide<br>Attempt; Tremor; Vision<br>Blurred | Lexapro                |              |            | S           | Oral         | 10 ,20 Mg Day Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                | Unspecified Ingredient |              |            | C           | Oral         | 10 ,20 Mg Day Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2004              | 4092616       | EXPEDITED (15-DAY) | Y                  | HO              | T04-USA-00435-01     |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Agitation; Bipolar Disorder;<br>Blood Glucose Increased;<br>Blood Thyroid Stimulating<br>Hormone Increased; | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Placebo              |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |
|                                                                                                                                    | Placebo              |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Extrapyramidal Disorder;  
Family Stress; Insomnia;  
Intentional Self-Injury;  
Irritability; Logorrhoea;  
Mood Altered; Mood  
Swings; Muscle Tightness;  
Paranoia; Psychomotor  
Hyperactivity; Psychotic  
Disorder; Sleep Disorder;  
Somnolence; Speech  
Disorder

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2004              | 4131254       | EXPEDITED (15-DAY) | Y                  | HO              | S04-GER-01521-01     |                      | 34 YR      | Female     | DEU            |

| <u>Preferred Term</u>                  | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Akathisia;<br>Hypoaesthesia | Ciprallex                     |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                        | Ofloxacin                     |              |            | S           | Oral         | 500 Mg Bid Po      |                 | Not Reported |
|                                        | Metoclopramide                |              |            | C           |              |                    |                 | Not Reported |
|                                        | Novalglin (Metamizole Sodium) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2004              | 4139684       | DIRECT           | Y                  | LT, RI          |                      |                      | 45 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Agitation; Anger;<br>Discomfort; Dissociation;<br>Dry Mouth; Feeling<br>Abnormal; Hostility;<br>Impatience; Insomnia;<br>Intentional Self-Injury;<br>Irritability; Medication<br>Error; Nausea; Suicidal<br>Ideation; Terminal<br>Insomnia | Lexapro                 |              |            | S           | Oral         | 25 Mg Daily In A Oral |                 | Forest       |
|                                                                                                                                                                                                                                            | Effexor Xr              |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Wellbutrin Sr           |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Aricept                 |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Trazodone Hydrochloride |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Klonopin                |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Dexadrine               |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Celebrex                |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Nexium                  |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Lipitor                 |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Singulair               |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Rhinocort               |              |            | C           |              |                       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                          |                                            |                    |                    |                 |                      |                      |                 |            |                |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Cpap                                                                                                                                     |                                            |                    | C                  |                 |                      | Not Reported         |                 |            |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-May-2004                                                                                                                              | 4141317                                    | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02275-01     |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Delirium                                                                                                                                 | Lexapro                                    |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-May-2004                                                                                                                              | 7136022                                    | NON-EXPEDITED      | N                  | HO              | PHEH2003US09932      |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased;<br>Blood Sodium Decreased;<br>Cardiac Disorder;<br>Dysarthria; Gait<br>Disturbance; Seizure;<br>Vision Blurred | Tegretol                                   |                    |                    | S               | Oral                 | Oral                 |                 |            | Not Reported   |
|                                                                                                                                          | Atacand (Candesartan Cilexetil)            |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Lexapro                                    |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Tiazac                                     |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Seroquel                                   |                    |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Synthroid                                  |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Klonopin                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Multiple Psychiatric Medications           |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-May-2004                                                                                                                              | 4070488                                    | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05404-01     |                      | 77 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Electrocardiogram Qt<br>Prolonged; Ventricular<br>Tachycardia                                                                            | Lexapro                                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                                          | Zestril                                    |                    |                    | S               |                      | 25 Mg Qd             |                 |            | Not Reported   |
|                                                                                                                                          | Dobutrex                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Lovenox (Heparin-Fructose,<br>Sodium Salt) |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Lopresor                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Darvocet                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Morphine                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Percocet                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          | Ventolin                                   |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                          |                                            |                    |                    |                 |                      |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-May-2004                | 4089548        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00316-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Dyspnoea       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Exertional;                | Lipitor        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Electrocardiogram Qt       | Lopid          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Prolonged;                 | Evista         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Electrocardiogram Qt       | Synthroid      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Prolonged; Heart Rate      |                |                    |                    |                 |                      |                      |                 |              |                |
| Decreased                  |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-May-2004                | 4139817        | DIRECT             | Y                  | DE              |                      |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acidosis; Cardio-          | Lexapro        |                    |                    | S               | Oral                 | One Daily Orally     |                 | Not Reported |                |
| Respiratory Arrest; Chest  |                |                    |                    |                 |                      |                      |                 |              |                |
| Injury; Completed Suicide; |                |                    |                    |                 |                      |                      |                 |              |                |
| Craniocerebral Injury;     |                |                    |                    |                 |                      |                      |                 |              |                |
| Disorder Of Orbit;         |                |                    |                    |                 |                      |                      |                 |              |                |
| Haemothorax; Hypoxia;      |                |                    |                    |                 |                      |                      |                 |              |                |
| Intentional Overdose; Jaw  |                |                    |                    |                 |                      |                      |                 |              |                |
| Fracture; Oxygen           |                |                    |                    |                 |                      |                      |                 |              |                |
| Saturation Decreased;      |                |                    |                    |                 |                      |                      |                 |              |                |
| Pneumothorax; Road         |                |                    |                    |                 |                      |                      |                 |              |                |
| Traffic Accident           |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2004                | 4113117        | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWI-01001-01     |                      | 39 YR           | Female       | CHE            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Oedema; Delirium;    | Ciprallex      |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Fluid Retention;           | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Inappropriate Antidiuretic |                |                    |                    |                 |                      |                      |                 |              |                |
| Hormone Secretion;         |                |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Polydipsia; Staring

| <u>FDA Received Date</u>                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-May-2004                                     | 4142493           | EXPEDITED (15-DAY) | N                  | HO              | A0509409A            |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Bleeding<br>Time Prolonged | Calcium Carbonate |                    |                    | S               | Oral                 | Oral                 | 4 YR            | Not Reported |                |
|                                                 | Lexapro           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Potassium Salt    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Omeprazole        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Alprazolam        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Methylcellulose   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Simvastatin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2004                                     | 4143395           | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-01868-01     |                      | 24 YR           | Male         | GBR            |
| <u>Preferred Term</u>                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Overdose            | Ciprallex         |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Ciprallex         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Co-Codamol        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2004                                     | 4140428           | DIRECT             | N                  | DE              |                      |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Pain                         | Lexapro           |                    |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
|                                                 | Flexeril          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2004                                     | 4122438           | EXPEDITED (15-DAY) | N                  | OT              | 2004017393           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |           |   |      |      |              |  |  |  |  |
|--------------------------------------|-----------|---|------|------|--------------|--|--|--|--|
| Nausea; Somnolence;<br>Uterine Polyp | Nardil    | S | Oral | Oral | Not Reported |  |  |  |  |
|                                      | Lexapro   | S | Oral | Oral | Not Reported |  |  |  |  |
|                                      | Estrogens | C |      |      | Not Reported |  |  |  |  |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2004                       | 4143427                | EXPEDITED (15-DAY)        | Y                           | DE                       | S04-UKI-01943-01              |                               | 59 YR               | Unknown             | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Completed Suicide              | Ciprallex               |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                | Atenolol                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Dyazide                 |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Amlodipine              |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2004                       | 4143442                | DIRECT                    | N                           |                          |                               |                               | 31 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Abdominal Discomfort;<br>Dizziness; Headache;<br>Hyperhidrosis; Influenza<br>Like Illness; Insomnia;<br>Paraesthesia | Lexapro                 |                       |                     | S                    | Oral                  | 1 Daily Oral                |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2004                       | 4145898                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-UKI-01949-01              |                               |                     | Female              | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Trismus                        | Ciprallex               |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2004                       | 4145900                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-UKI-01946-01              |                               | 48 YR               | Female              | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |           |   |      |                |              |
|-------------------------|-----------|---|------|----------------|--------------|
| Anxiety; Rebound Effect | Ciprallex | S | Oral | 1 Tablet Qd Po | Not Reported |
|-------------------------|-----------|---|------|----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2004              | 4119552       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01397-01     |                      | 79 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia;                  | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Cytomegalovirus Test      | Norvasc             |              |            | C           |              |                    |                 | Not Reported |
| Positive; Dupuytren'S     | Triamterene And     |              |            | C           |              |                    |                 | Not Reported |
| Contracture; Dyspnoea     | Hydrochlorothiazide |              |            |             |              |                    |                 |              |
| Exertional; Epstein-Barr  | Advair Diskus       |              |            | C           |              |                    |                 | Not Reported |
| Virus Antibody Positive;  | Prednisone          |              |            | C           |              |                    |                 | Not Reported |
| Gait Inability; Guillain- | Lipitor             |              |            | C           |              |                    |                 | Not Reported |
| Barre Syndrome; Human     | Lupron              |              |            | C           |              |                    |                 | Not Reported |
| Herpes Virus 6 Serology   | Casodex             |              |            | C           |              |                    |                 | Not Reported |
| Positive; Mononeuropathy  |                     |              |            |             |              |                    |                 |              |
| Multiplex; Rectal         |                     |              |            |             |              |                    |                 |              |
| Haemorrhage               |                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2004              | 4121265       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01552-01     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Automatism; Condition   | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
| Aggravated; Depressed   |                |              |            |             |              |                    |                 |              |
| Level Of Consciousness; |                |              |            |             |              |                    |                 |              |
| Dysphonia; Seizure      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2004              | 4129433       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01832-01     |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Seizure                  |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-May-2004                                                                                           | 4143597        | DIRECT             |                    | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Divorced; Family Stress; Medication Error; Mid-Life Crisis; Partner Stress; Personality Change | Lexapro        |                    |                    | S               | Oral                 | 15mg Daily Oral      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2004                                                                                           | 4147432        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02686-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Suicidal Ideation                                                            | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Risperidone    |                    |                    | S               | Oral                 | 0.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                       | Risperidone    |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                       | Risperidone    |                    |                    | S               | Oral                 | 1.5 Mg Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2004                                                                                           | 4147434        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02760-01     |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Psychosis; Obsessive Thoughts; Suicidal Ideation                                                | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2004                                                                                           | 4147544        | EXPEDITED (15-DAY) | Y                  | HO              | S04-UKI-02072-01     |                      | 79 YR           | Female       | GBR            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Discomfort;<br>Circulatory Collapse;<br>Diarrhoea; Hyponatraemia                         | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                    | Perindopril    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Calcichew-D3   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2004                                                                                        | 4127402        | EXPEDITED (15-DAY) | Y                  | HO              | S04-AUS-01383-01     |                      | 43 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Legal Problem; Mania;<br>Paranoia; Persecutory<br>Delusion; Psychotic<br>Disorder; Self-Medication | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                    | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                    | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2004                                                                                        | 4148611        | EXPEDITED (15-DAY) | Y                  | HO              | 2004UW09432          |                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Ventricular<br>Tachycardia                                      | Zestril        |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                    | Lexapro        |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                    | Diflucan       |                    |                    | S               |                      | 8 Puff Daily         |                 | Not Reported |                |
|                                                                                                    | Ventolin       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Dobutrex       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Lovenox        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Lopresor       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Darvocet-N 100 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Morphine       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                    | Percocet       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-May-2004                                                                                        | 4148848        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05111-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |              |   |      |             |              |
|---------------------------|--------------|---|------|-------------|--------------|
| Metastases To Liver;      | Lexapro      | S | Oral | 10 Mg Qd Po | Not Reported |
| Neoplasm Malignant;       | Lexapro      | S | Oral | 20 Mg Qd Po | Not Reported |
| Platelet Count Decreased; | Ativan       | C |      |             | Not Reported |
| White Blood Cell Count    | Fluorouracil | C |      |             | Not Reported |
| Decreased                 | Leucovorin   | C |      |             | Not Reported |
|                           | Camptosar    | C |      |             | Not Reported |
|                           | Avastatin    | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-May-2004              | 4080439       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-00185-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Infarction   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 21-May-2004              | 4142978       | NON-EXPEDITED    | Y                  |                 | US-GLAXOSMITHKLINE-A0501211A |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|-----------------|
| Lymphadenopathy; Pain | Wellbutrin XI  |              |            | S           | Oral         | 300mg In The Morning |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Oral         | 10mg In The Morning  |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 21-May-2004              | 4143009       | NON-EXPEDITED    | N                  |                 | US-GLAXOSMITHKLINE-A0502356A |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Crying; Depression;   | Wellbutrin XI  |              |            | S           | Oral         | 300mg Per Day      |                 | Glaxosmithkline |
| Hangover; Nausea;     | Lexapro        |              |            | S           | Oral         | 20mg Per Day       | 5 YR            | Not Reported    |
| Vertigo               |                |              |            |             |              |                    |                 |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2004              | 4144799       | DIRECT           | N                  | RI              |                      |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                               |                      |        |      |                  |                        |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------|------|------------------|------------------------|
| Arthralgia; Drug Withdrawal Syndrome; Hypersensitivity; Plantar Fasciitis; Weight Increased; Weight Loss Poor | Lexapro<br>Synthroid | S<br>C | Oral | 10mg 1x Day Oral | Forest<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------|------|------------------|------------------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-May-2004                       | 4148828                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-UKI-02080-01              |                               | 37 YR               | Female              | GBR                     |

| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Confusional State; Dysarthria; Somnolence | Ciprallex               |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-May-2004                       | 4148833                | EXPEDITED (15-DAY)        | Y                           | DS                       | S04-FRA-02223-01              |                               | 56 YR               | Male                | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>          | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>          |
|--------------------------------|----------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|------------------------------|
| Dyspnoea Exertional            | Escitalopram Oxalate<br>Preterax |                       |                     | S<br>C               | Oral                  | 10 Mg Qd Po                 |                          | Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-May-2004                       | 4148838                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-UKI-02076-01              |                               | 77 YR               | Male                | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>             | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |
|--------------------------------|-------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|----------------------------------------------|
| Epilepsy                       | Ciprallex<br>Atenolol<br>Amlodipine |                       |                     | S<br>C<br>C          | Oral                  | 10 Mg Qd Po                 |                          | Not Reported<br>Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-May-2004                       | 4147010                | DIRECT                    |                             | OT                       |                               |                               | 78 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                    |                                                     |                    |                    |                 |                      |                                   |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| Rash                                                                                                               | Lexapro                                             |                    | S                  | Oral            | Oral                 |                                   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2004                                                                                                        | 4147868                                             | DIRECT             | Y                  | DE              |                      |                                   | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Fatigue;<br>Insomnia; Mood Swings                                                | Lexapro                                             |                    |                    | S               |                      | 5 Mg X 11 Days; 10 Mg X<br>5 Days |                 | Not Reported |                |
|                                                                                                                    | Paxil                                               |                    |                    | S               |                      | Paxil 12.5 X 3 Days               |                 | Not Reported |                |
|                                                                                                                    | Elavil                                              |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2004                                                                                                        | 4150369                                             | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-02146-01     |                                   | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Dyskinesia; Memory<br>Impairment; Personality<br>Change; Social Avoidant<br>Behaviour | Ciprallex                                           |                    |                    | S               | Oral                 | 5 Mg Qd Po                        |                 | Not Reported |                |
|                                                                                                                    | Seroxat "Ciba-Geigy"<br>(Paroxetine Hydrohchloride) |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2004                                                                                                        | 4150371                                             | EXPEDITED (15-DAY) | Y                  | OT              | S04-IRL-02153-01     |                                   | 44 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Seizure;<br>Syncope                                                                                     | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | 10 Mg Qd Po                       |                 | Not Reported |                |
|                                                                                                                    | Xanax                                               |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                    | Mefac(Mefenamic Acid)                               |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2004                                                                                                        | 4123515                                             | EXPEDITED (15-DAY) | Y                  | LT              | S04-USA-01411-01     |                                   | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                                             |                  |      |            |                                                              |
|---------------------------------------------------------------|---------------------------------------------|------------------|------|------------|--------------------------------------------------------------|
| Disease Progression;<br>Hepatic Cirrhosis; Hepatic<br>Failure | Lexapro<br>Aldactone<br>Protonix<br>Procrit | S<br>C<br>C<br>C | Oral | 5 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------|---------------------------------------------|------------------|------|------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2004              | 4147947       | DIRECT           | N                  | OT              |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour;<br>Anger; Marital Problem;<br>Personality Change | Lexapro        |              |            | S           | Oral         | 15 Mg Daily Orally |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2004              | 4149738       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02795-01     |                      | 7 YR       | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mania                 | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2004              | 4153767       | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-02151-01     |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Maternal Drugs Affecting<br>Foetus; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2004              | 4148557       | DIRECT           | N                  | DE              |                      |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|----------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Completed Suicide                      | Lexapro                 | S                         |                             |                          |                               | 1 Per Day                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-May-2004                            | 4127401                 | EXPEDITED (15-DAY)        | Y                           | DS                       | S04-AUS-01448-01              |                               | 36 YR                    | Female              | AUS                     |
| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hallucination, Visual                  | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |
|                                        | Diazepam                |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2004                            | 4132311                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-02050-01              |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatitis                              | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          |                     | Not Reported            |
|                                        | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          |                     | Not Reported            |
|                                        | Ambien                  |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                        | Lopresor                |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                        | Zetia                   |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                        | Zyrtec                  |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                        | Aspirin                 |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2004                            | 4140951                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-TUR-01932-01              |                               | 34 YR                    | Female              | TUR                     |
| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amenorrhoea; Blood Prolactin Increased | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2004                            | 4150224                 | DIRECT                    | N                           | LT, RI                   |                               |                               | 22 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                           |                         |   |      |                  |              |
|---------------------------------------------------------------------------|-------------------------|---|------|------------------|--------------|
| Depression; Psychiatric Symptom; Self-Injurious Ideation; Suicide Attempt | Lexapro                 | S | Oral | 10 Mg Daily Oral | Not Reported |
|                                                                           | Trazodone Hydrochloride | S | Oral | Nightly Oral     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2004              | 4150521       | DIRECT           | N                  | DE              |                      |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 1/2 Dose Ea Mornin Oral |                 | Not Reported |
|                       | Adderall Xr    |              |            | S           | Oral         | 1 Dose Ea. Mornin Oral  |                 | Not Reported |
|                       | Adderall Xr    |              |            | S           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2004              | 4150981       | DIRECT           | N                  | HO, LT          |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Diarrhoea; Insomnia; Intentional Overdose; Muscle Contractions Involuntary; Restlessness; Stress; Suicidal Ideation; Suicide Attempt | Paxil          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Prozac         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Effexor        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Celexa         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Remeron        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Serzone        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Wellbutrin     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Zoloft         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Sleep Pills    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2004              | 4152924       | EXPEDITED (15-DAY) | Y                  | DE              | 2004-116341-NL       |                      | 37 YR      | Male       | CHE            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound | Mirtazapine    |              |            | S           |              | 15 Mg              | 24 DAY          | Not Reported |
|                                   | Lorazepam      |              |            | S           |              | See Image          | 1 DAY           | Not Reported |
|                                   |                |              |            |             |              | See Image          | 21 DAY          |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram Oxalate

S

See Image  
See Image1 DAY  
24 DAY

Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-Jun-2004                       | 4153296                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-02799-01              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Petit Mal Epilepsy             | Lexapro                 |                       |                     | S                    | Oral                  | 40 Mg Qd Po                 |                          | Not Reported        |
|                                | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 02-Jun-2004                       | 4137087                | EXPEDITED (15-DAY)        | Y                           | HO                       | S04-USA-02240-01              |                               | 20 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Blood Potassium Decreased; Serotonin Syndrome; Vision Blurred; Visual Impairment | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                                                                  | Unspecified Ingredient  |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 02-Jun-2004                       | 4146036                | EXPEDITED (15-DAY)        | Y                           | HO                       | 04P-163-0259510-00            |                               | 38 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coma; Depressed Level Of Consciousness; Electrocardiogram St Segment; Intentional Overdose; Self-Medication | Depakote                |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                             | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg, Unknown Amount, Oral |                          | Not Reported        |
|                                                                                                             | Olanzapine              |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                             | Alcohol                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                             | Cocaine                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 02-Jun-2004                       | 4153381                | EXPEDITED (15-DAY)        | Y                           | DS                       | S04-UKI-02284-01              |                               | 34 YR               | Male                | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                                   |             |      |             |                                              |
|----------------------------------------------------------|-----------------------------------|-------------|------|-------------|----------------------------------------------|
| Dyskinesia; Gait<br>Disturbance;<br>Restlessness; Tremor | Ciprallex<br>Aspirin<br>Ibuprofen | S<br>C<br>C | Oral | 10 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------|-----------------------------------|-------------|------|-------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2004              | 3939698       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-USA-01380-01     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Cardiac Arrest;<br>Palpitations; Torsade De<br>Pointes; Treatment<br>Noncompliance;<br>Ventricular Fibrillation | Lexapro<br>Zestril<br>Klonopin |              |            | S<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2004              | 4132342       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S04-USA-01892-01     |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>            | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------|-------------------------------|--------------|------------|-------------|-------------------------|------------------------------------|-----------------|----------------------------------------------|
| Atrial Fibrillation   | Lexapro<br>Lexapro<br>Lexapro |              |            | S<br>S<br>S | Oral<br>Oral<br>Unknown | 10 Mg Qd; Po<br>5 Mg Qd; Po<br>Unk |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2004              | 4147393       | EXPEDITED (15-DAY) | Y                  | OT              | T04-USA-02082-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>                                                                                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|----------------------------|----------------------|----------------------------------------------|-----------------|----------------------------------------------------------------------------------------------|
| Akathisia; Restlessness | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Escitalopram Oxalate<br>Triamterene<br>Atenolol<br>Cenestin (Estrogens<br>Conjugated) |              |            | S<br>S<br>S<br>C<br>C<br>C | Oral<br>Oral<br>Oral | 2.5 Mg Qd; Po<br>5 Mg Qd; Po<br>10 Mg Qd; Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 03-Jun-2004                                                                               | 4149781              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02794-01     |                         | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Alcoholism; Anxiety; Drug<br>Interaction; Road Traffic<br>Accident | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                           | Strattera            |                    |                    | S               |                      | 60 Mg Qd                |                 | Not Reported |                |
|                                                                                           | Strattera            |                    |                    | S               |                      | 40 Mg Qd                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2004                                                                               | 4152165              | DIRECT             |                    | OT              |                      |                         | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Drug<br>Withdrawal Syndrome;<br>Epistaxis; Myalgia;<br>Vomiting               | Lexapro              |                    |                    | S               | Buccal               | 10 Mg Once A Day Buccal |                 | Forest       |                |
|                                                                                           | Tylenol With Codeine |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2004                                                                               | 4154865              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02956-01     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                   | Lexapro              |                    |                    | S               | Unknown              | Unk                     |                 | Not Reported |                |
|                                                                                           | Birth Control Pills  |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2004                                                                               | 4154872              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02969-01     |                         |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Nausea;<br>Photopsia; Seizure;<br>Somnolence; Visual<br>Impairment; Vomiting     | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd; Po            |                 | Not Reported |                |
|                                                                                           | Accutane             |                    |                    | S               |                      | 20 Mg Qd                |                 | Not Reported |                |
|                                                                                           | Accutane             |                    |                    | S               | Oral                 | 30 Mg Qd; Po            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 04-Jun-2004                                                                                    | 4149977        | EXPEDITED (15-DAY) | Y                  | OT              | US-ROCHE-369062      |                       | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged                                                                 | Klonopin       |                    |                    | S               | Unknown              |                       |                 | Roche        |                |
|                                                                                                | Lexapro        |                    |                    | S               | Oral                 |                       | 22 DAY          | Not Reported |                |
|                                                                                                | Lexapro        |                    |                    | S               | Oral                 |                       | 21 DAY          | Not Reported |                |
|                                                                                                | Lasix          |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                | Kcl            |                    |                    | C               |                      |                       |                 | Not Reported |                |
|                                                                                                | Multi-Vitamin  |                    |                    | C               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2004                                                                                    | 4153119        | DIRECT             | N                  | DE              |                      |                       | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                              | Lexapro        |                    |                    | S               | Oral                 | Once Daily Oral       |                 | Not Reported |                |
|                                                                                                | Remeron        |                    |                    | S               | Oral                 | 30 Mg Once Daily Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2004                                                                                    | 4153629        | DIRECT             | N                  |                 |                      |                       | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Feeling Abnormal; Mood Swings; Personality Change; Suicidal Ideation | Lexapro        |                    |                    | S               | Oral                 | 1 Daily Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2004                                                                                    | 4157030        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02584-01     |                       | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                           |                                |             |      |             |                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------|------|-------------|----------------------------------------------|
| Abdominal Distension;<br>Discomfort; Fluid<br>Retention; Treatment<br>Noncompliance; Varicose<br>Vein; Vascular Pain;<br>Weight Increased | Lexapro<br>Remeron<br>Klonopin | S<br>C<br>C | Oral | 10 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------|------|-------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4136806       | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-02237-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------|------------|---------------------------------|----------------------|-------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Alcohol Use; Completed<br>Suicide; Gun Shot Wound;<br>Treatment Noncompliance | Lexapro<br>Lexapro<br>Lexapro<br>Xanax<br>Valium<br>Vicodin<br>Spinal Epidermal Injections |              |            | S<br>S<br>S<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral | 10 Mg Qd Po<br>10 Mg Qd Po<br>10 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4153873       | DIRECT           | N                  | DE, OT          |                      |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                             |
|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------|
| Completed Suicide;<br>Condition Aggravated;<br>Depression; Feeling<br>Abnormal; Gun Shot<br>Wound | Lexapro<br>Simvastatin<br>Famotidine<br>Potassium Chloride<br>Verapamil Hydrochloride<br>Prednisone |              |            | S<br>C<br>C<br>C<br>C<br>C | Oral         | 10 Mg Daily / Oral |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4155158       | DIRECT           | Y                  | HO, OT          |                      |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |         |   |                              |              |
|--------------------------------|---------|---|------------------------------|--------------|
| Erythema; Oedema<br>Peripheral | Lexapro | S | 2 Doses Only<br>2 Doses Only | Not Reported |
|--------------------------------|---------|---|------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4157594       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-03007-01     |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Seizure     | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                       | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
|                       | Trileptal      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4157597       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-03003-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Completed<br>Suicide; Insomnia | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                           | Prozac         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2004              | 4157895       | EXPEDITED (15-DAY) | Y                  | OT              | T04-GER-02370-01     |                      | 73 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Ciprallex                    |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |
|                       | Voltaren                     |              |            | C           |              |                    |                 | Not Reported |
|                       | Allopurinol                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Lorzaar (Losartan Potassium) |              |            | C           |              |                    |                 | Not Reported |
|                       | Metoprolol                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Valoron N                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Zolpidem Tartrate            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2004              | 4153104       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2004006851           |                      | 39 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|-----------------|----------------|
| Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Abnormal; Blood Creatine Phosphokinase Increased; Blood Lactic Acid Increased; Coma; Hepatic Function Abnormal; Pneumonia; Prothrombin Time Prolonged; Pyrexia; Sepsis | Lamictal                             |                    |                    | S               | Oral                 | 3tab Three Times Per Day |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                      | Trileptal                            |                    |                    | S               | Oral                 | 3tab Three Times Per Day |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Cipralext                            |                    |                    | S               | Oral                 | 1.5tab Per Day           |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Folic Acid                           |                    |                    | S               | Oral                 | 1tab Per Day             |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      |                                      |                    |                    |                 |                      |                          |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Jun-2004                                                                                                                                                                                                                          | 4048501                              | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | S03-USA-05064-02     |                          | < 1 DAY         | Female          | USA            |
|                                                                                                                                                                                                                                      |                                      |                    |                    |                 |                      |                          |                 |                 |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Breech Delivery; Caesarean Section; Jaundice Neonatal; Maternal Exposure During Pregnancy; Neonatal Aspiration; Premature Baby                                                                                                       | Lexapro                              |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental  |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Lexapro                              |                    |                    | S               | Transplacental       | 10 Mg Qd Po              |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Prenatal Vitamins                    |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Effexor                              |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Wellbutrin Sr                        |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Insulin Insulatard Nph Nordisk       |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Humalog                              |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      |                                      |                    |                    |                 |                      |                          |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Jun-2004                                                                                                                                                                                                                          | 4070262                              | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00021-01     |                          | 41 YR           | Male            | USA            |
|                                                                                                                                                                                                                                      |                                      |                    |                    |                 |                      |                          |                 |                 |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Bruxism; Depression; Diarrhoea; Headache; Hyperhidrosis; Hyperphagia; Insomnia; Pain; Restlessness; Somnolence; Suicidal                                                                                                      | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Bid Po             |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Lexapro                              |                    |                    | S               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Buspar                               |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Seroquel                             |                    |                    | C               |                      |                          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                      | Paxil                                |                    |                    | C               |                      |                          |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ideation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4120495       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-GER-01225-01     |                      | 82 YR      | Female     | DEU            |

| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;       | Ciprallex                   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Duodenitis; Gastric Ulcer | Aspirin                     |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |
| Haemorrhage; General      | Beloc [Metoprolol Tartrate] |              |            | C           |              |                    |                 | Not Reported |
| Physical Health           | Ovestin (Estriol)           |              |            | C           |              |                    |                 | Not Reported |
| Deterioration;            | Unat (Torasemide)           |              |            | C           |              |                    |                 | Not Reported |
| Haematemesis;             |                             |              |            |             |              |                    |                 |              |
| Haematocrit Decreased;    |                             |              |            |             |              |                    |                 |              |
| Haemoglobin Decreased;    |                             |              |            |             |              |                    |                 |              |
| International Normalised  |                             |              |            |             |              |                    |                 |              |
| Ratio Decreased; Platelet |                             |              |            |             |              |                    |                 |              |
| Count Increased;          |                             |              |            |             |              |                    |                 |              |
| Prothrombin Time          |                             |              |            |             |              |                    |                 |              |
| Shortened; Vertigo;       |                             |              |            |             |              |                    |                 |              |
| Vomiting                  |                             |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4151290       | EXPEDITED (15-DAY) | Y                  | HO, OT          | T04-GER-02281-01     |                      | 82 YR      | Female     | DEU            |

| <u>Preferred Term</u>     | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;       | Ciprallex                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Duodenitis; Gastric Ulcer | Aspirin                          |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |
| Haemorrhage; General      | Beloc Zok (Metoprolol Succinate) |              |            | C           |              |                    |                 | Not Reported |
| Physical Health           | Ovestin (Estriol)                |              |            | C           |              |                    |                 | Not Reported |
| Deterioration;            | Unat (Torasemide)                |              |            | C           |              |                    |                 | Not Reported |
| Haematemesis;             |                                  |              |            |             |              |                    |                 |              |
| Haematocrit Decreased;    |                                  |              |            |             |              |                    |                 |              |
| Haemoglobin Decreased;    |                                  |              |            |             |              |                    |                 |              |
| International Normalised  |                                  |              |            |             |              |                    |                 |              |
| Ratio Decreased; Platelet |                                  |              |            |             |              |                    |                 |              |
| Count Increased;          |                                  |              |            |             |              |                    |                 |              |
| Prothrombin Time          |                                  |              |            |             |              |                    |                 |              |
| Shortened; Vertigo        |                                  |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2004                                                                                                                                                | 4154133                          | EXPEDITED (15-DAY) | Y                  | HO              | S04-DEN-02358-01     |                      | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Emotional Disorder;<br>Gastroenteritis; Hepatitis<br>Toxic; International<br>Normalised Ratio<br>Decreased; International<br>Normalised Ratio<br>Increased | Cipralext                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                            | Cipralext                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                            | Bendroflumethiazide              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Warfarin Sodium                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                                                                                | 4159006                          | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-03103-01     |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Hypoaesthesia;<br>Paraesthesia; Seizure                                                                                                          | Lexapro                          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                            | Gabitril                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Phenobarb (Phenobarbital Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Lisinopril                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Allopurinol                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Pepcid                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                            | Dantrum (Dantrolene Sodium)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                                                                                | 4159008                          | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-03104-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                          | Lexapro                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                                                                                | 4159089                          | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-03132-01     |                      |                 | Unknown      | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Sodium Decreased;<br>Seizure                                                          | Lexapro                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                 | 4159538                                 | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | S03-USA-05064-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Premature Labour | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qam Po         |                 | Not Reported |                |
|                                                                                             | Effexor Xr                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Wellbutrin Sr                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Prenatal Vitamins                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Nph Insulin                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Humalog                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                 | 4160395                                 | NON-EXPEDITED      | Y                  | HO              | S04-USA-01536-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                               | Lexapro                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                 | 4160397                                 | NON-EXPEDITED      | Y                  | HO              | S04-USA-01536-02     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                               | Lexapro                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2004                                                                                 | 4160399                                 | NON-EXPEDITED      | N                  | RI              | S04-USA-01368-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |         |   |      |              |              |
|------------------|---------|---|------|--------------|--------------|
| Hypersensitivity | Lexapro | S | Oral | 10 Mg Qod Po | Not Reported |
|                  | Lexapro | S | Oral | 10 Mg Qd Po  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4160402       | NON-EXPEDITED    | Y                  | HO              | S04-USA-01404-01     |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |
|                       | Toprol XL           |              |            | C           |              |                    |                 | Not Reported |
|                       | Lisinopril          |              |            | C           |              |                    |                 | Not Reported |
|                       | Prevacid            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4160403       | NON-EXPEDITED    | Y                  | HO              | S04-USA-01207-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4162862       | NON-EXPEDITED    | Y                  | HO              | S04-USA-02761-01     |                      | 54 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis; Somnolence | Lexapro        |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                          |                |              |            |             | Oral         | See Image          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2004              | 4162870       | NON-EXPEDITED    | Y                  | DE              | S04-USA-02676-01     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Benadryl       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                                           | Skelaxin         |                    | C                |                      |                                     |                 |                                                              | Not Reported   |
|----------------------------------------------------------------------|-------------------------------------------|------------------|--------------------|------------------|----------------------|-------------------------------------|-----------------|--------------------------------------------------------------|----------------|
|                                                                      |                                           | Ambien           |                    | C                |                      |                                     |                 |                                                              | Not Reported   |
|                                                                      |                                           | Ritalin          |                    | C                |                      |                                     |                 |                                                              | Not Reported   |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jun-2004                                                          | 4162880                                   | NON-EXPEDITED    | Y                  | HO               | S04-USA-02242-01     |                                     | 60 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Depersonalisation/Derealisation Disorder                             | Lexapro<br>Lithium                        |                  |                    | S<br>C           |                      |                                     |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jun-2004                                                          | 4162883                                   | NON-EXPEDITED    | N                  | HO               | S04-USA-02273-01     |                                     | 17 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Depression; Suicidal Ideation                                        | Lexapro                                   |                  |                    | S                | Oral<br>Oral<br>Oral | See Image<br>See Image<br>See Image |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jun-2004                                                          | 4162886                                   | NON-EXPEDITED    | Y                  | HO               | S04-USA-02274-01     |                                     | 20 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Intentional Overdose; Somnolence; Suicidal Ideation; Suicide Attempt | Lexapro<br>Ambien<br>Ritalin<br>Albuterol |                  |                    | S<br>C<br>C<br>C | Oral                 | See Image                           |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 14-Jun-2004                                                          | 4162903                                   | NON-EXPEDITED    | Y                  | HO               | S04-USA-01684-01     |                                     |                 | Unknown                                                      | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hyponatraemia                                                        | Lexapro                                   |                  |                    | S                |                      |                                     |                 | Not Reported                                                 |                |

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| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2004                                                                                                                                       | 4162923               | NON-EXPEDITED      | Y                  | HO              | S04-USA-01893-01     |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                                                | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Zyvox                 |                    |                    | S               |                      | 600 Mg Qd            |                 | Not Reported |                |
|                                                                                                                                                   | Vancomycin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Lortab                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Catapres-Tts          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2004                                                                                                                                       | 4123206               | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-01406-01     |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Decreased Appetite; Dehydration; Diarrhoea; Dizziness; Fall; Loss Of Consciousness; Mitral Valve Incompetence; Nausea; Weight Decreased | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Synthroid             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Klonopin (Clonazepma) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2004                                                                                                                                       | 4126030               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01682-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                                                                                                      | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                   | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2004                                                                                                                                       | 4132306               | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01885-01     |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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| Intentional Overdose;<br>Suicide Attempt;<br>Treatment Noncompliance                                                                                         | Lexapro                                |                           | S                           | Oral                     | 400 Mg Once Po                |                               | Not Reported             |                     |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
|                                                                                                                                                              | Lexapro                                |                           | S                           | Oral                     | 20 Mg Qd Po                   |                               | Not Reported             |                     |                         |
| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Jun-2004                                                                                                                                                  | 4157107                                | DIRECT                    | N                           | OT                       |                               |                               | 30 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Disturbance In Attention;<br>Influenza Like Illness;<br>Irritability; Nausea;<br>Tremor; Trismus                                                             | Lexapro                                |                           |                             | S                        | Oral                          | 10 Mg Daily Oral              |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Jun-2004                                                                                                                                                  | 4157116                                | DIRECT                    | Y                           | DE                       |                               |                               | 61 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                                                                                                            | Fluoxetine                             |                           |                             | S                        | Oral                          | 20 Mg Daily Oral              |                          | Not Reported        |                         |
|                                                                                                                                                              | Lexapro                                |                           |                             | S                        | Oral                          | 10 Mg Daily Oral              |                          | Not Reported        |                         |
|                                                                                                                                                              | Nadolol                                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Triamterene And<br>Hydrochlorothiazide |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Allegra                                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                            | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Jun-2004                                                                                                                                                  | 4161051                                | EXPEDITED (15-DAY)        | Y                           | HO                       | S04-USA-03152-01              |                               | 88 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                               | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Chloride<br>Decreased; Blood<br>Potassium Decreased;<br>Confusional State;<br>Depression;<br>Hyponatraemia;<br>Therapeutic Product Effect<br>Decreased | Lexapro                                |                           |                             | S                        | Oral                          | 10 Mg Po                      |                          | Not Reported        |                         |
|                                                                                                                                                              | Norvasc                                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Protonix                               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Warfarin Sodium                        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                              | Lorazepam                              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2004                                                                                                                                                                                                          | 4161414          | EXPEDITED (15-DAY) | Y                  | RI, OT          | S04-USA-03109-01     |                      | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tooth Disorder                                                                                                                                                                                                       | Lexapro          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Norvasc          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Plavix           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Flomax           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Aspirin          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2004                                                                                                                                                                                                          | 4070040          | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-04750-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bleeding Time Prolonged;<br>Coagulation Factor VIII<br>Level Increased; Condition<br>Aggravated; Educational<br>Problem; Iron Deficiency<br>Anaemia; Leukopenia;<br>Menorrhagia                                      | Lexapro          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Celexa           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Ortho Tri Cyclen |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Levlite          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2004                                                                                                                                                                                                          | 4158712          | DIRECT             | N                  |                 |                      |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Aggression; Arthralgia;<br>Crying; Disturbance In<br>Attention; Drug Withdrawal<br>Syndrome; Influenza Like<br>Illness; Memory<br>Impairment; Myalgia;<br>Nightmare; Pain; Pruritus;<br>Tinnitus | Lexapro          |                    |                    | S               | Oral                 | Once Day Oral        |                 | Not Reported |                |
|                                                                                                                                                                                                                      | Wellbutrin Sr    |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                     | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------------------------|----------------|
| 16-Jun-2004                                                                                                                                                                                              | 4159218             | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWE-02566-01     |                                     | 79 YR           | Female                         | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                     |                |
| Asthenia; Balance Disorder; Cerebral Haemorrhage; Headache; Vomiting                                                                                                                                     | Cipralext<br>Plavix |                    |                    | S<br>S          | Oral<br>Oral         | 10 Mg Qd Po<br>10 Mg Qd Po          |                 | Not Reported<br>Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                     | <u>Country</u> |
| 17-Jun-2004                                                                                                                                                                                              | 4157447             | DIRECT             |                    |                 |                      |                                     |                 | Female                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                     |                |
| Medication Error                                                                                                                                                                                         | Celexa<br>Lexapro   |                    |                    | S<br>S          |                      |                                     |                 | Not Reported<br>Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                     | <u>Country</u> |
| 17-Jun-2004                                                                                                                                                                                              | 4159168             | DIRECT             | N                  | HO              |                      |                                     | 12 YR           | Female                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                     |                |
| Abnormal Behaviour; Acne; Affective Disorder; Blood Glucose Abnormal; Condition Aggravated; Depression; Hair Growth Abnormal; Polycystic Ovaries; Suicidal Ideation; Thinking Abnormal; Weight Increased | Abilify<br>Lexapro  |                    |                    | S<br>S          | Oral<br>Oral         | 15mg Daily Oral<br>30 Mg Daily Oral |                 | Bristol Myers Squibb<br>Forest |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>                     | <u>Country</u> |
| 18-Jun-2004                                                                                                                                                                                              | 4146409             | EXPEDITED (15-DAY) | Y                  | CA, DE          | S04-USA-02755-01     |                                     | 19 YR           | Female                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>                     |                |

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|                                                                                                                                 |         |   |      |             |              |
|---------------------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Abortion Induced; Limb Malformation; Maternal Drugs Affecting Foetus; Oligohydramnios; Potter'S Syndrome; Pregnancy; Stillbirth | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                                                 | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2004              | 4159712       | DIRECT           | N                  |                 |                      |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Agitation; Decreased Appetite; Dizziness; Headache; Irritability; Medication Error; Mobility Decreased; Nausea | Lexapro        |              |            | S           | Oral         | 10 Mg 1 Time A D Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2004              | 4161929       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S04-SWI-02501-01     |                      | 35 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia;              | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Thrombocytopenia      | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2004              | 4163143       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S04-BEL-02509-01     |                      | 55 YR      | Female     | BEL            |

| <u>Preferred Term</u>                                           | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident; Completed Suicide; Serotonin Syndrome | Escitalopram Oxalate               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                 | Trazolan (Trazodone Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Buroniil (Melperone Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Zyprexa                            |              |            | C           |              |                    |                 | Not Reported |



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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                                                                                                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                                    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------------------------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 22-Jun-2004                                                                                                                                                                                                                                                                                         | 4093519                                                                                                                                                                                                                                 | EXPEDITED (15-DAY) | Y                  | HO                                                                 | S04-USA-00532-02     |                      | 28 YR           | Female                                                                                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                                                                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                                        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                   |                |
| Alanine Aminotransferase Increased; Blood Calcium Increased; Blood Osmolarity Increased; Blood Potassium Increased; Blood Thyroid Stimulating Hormone Decreased; Body Temperature Increased; Condition Aggravated; Nephropathy; Rash; Renal Failure; Tubulointerstitial Nephritis; Weight Increased | Lexapro<br>Concerta<br>Ambien<br>Buspar<br>Wellbutrin (Bupropion Hydrochloride)<br>Methylphenidate Hydrochloride<br>Seroquel<br>Omeprazole<br>Topamax<br>Risperdal<br>Ativan<br>Synthroid<br>Mirtazapine<br>Abilify /Usa/ (Aripirazole) |                    |                    | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral                 | 30 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                                                                                                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                                    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                                   | <u>Country</u> |
| 22-Jun-2004                                                                                                                                                                                                                                                                                         | 4140232                                                                                                                                                                                                                                 | EXPEDITED (15-DAY) | Y                  | HO                                                                 | S04-USA-02172-01     |                      | 38 YR           | Male                                                                                                                                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                                                                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                                        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                   |                |
| Alcohol Use; Coma; Depressed Level Of Consciousness; Drug Abuser; Electrocardiogram St Segment; Medication Error; Overdose; Self-Medication                                                                                                                                                         | Lexapro<br>Lexapro<br>Depakote<br>Zyprexa<br>Alcohol<br>Cocaine                                                                                                                                                                         |                    |                    | S<br>S<br>S<br>S<br>S<br>S                                         | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                                                                                                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                                    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                                   | <u>Country</u> |
| 22-Jun-2004                                                                                                                                                                                                                                                                                         | 4164025                                                                                                                                                                                                                                 | EXPEDITED (15-DAY) | Y                  | HO                                                                 | S04-EST-02356-01     |                      | 13 YR           | Female                                                                                                                                                                                                       | EST            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                                                                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                                        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                       |   |      |             |              |
|----------------------------|-----------------------|---|------|-------------|--------------|
| Agitation; Anxiety;        | Cipralext             | S | Oral | 10 Mg Qd Po | Not Reported |
| Arthropathy; Circulatory   | Cipralext             | S | Oral | 5 Mg Qd Po  | Not Reported |
| Collapse; Conversion       |                       |   |      |             |              |
| Disorder; Coordination     | Trexan (Methotrexate) | C |      |             | Not Reported |
| Abnormal; Cyanosis;        | Antrex (Folic Acid)   | C |      |             | Not Reported |
| Dysarthria; Dyspnoea;      |                       |   |      |             |              |
| Hyperventilation; Muscular |                       |   |      |             |              |
| Weakness; Panic Attack;    |                       |   |      |             |              |
| Psychotic Disorder;        |                       |   |      |             |              |
| Respiratory Disorder;      |                       |   |      |             |              |
| Tremor                     |                       |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2004              | 4196800       | NON-EXPEDITED    | Y                  | OT              | US-JNJFOC-20030604021 |                      | 88 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Haldol                                   |              |            | S           |              | 5 Mg, 1 In 4 Hour  |                 | Not Reported |
|                       | Haldol                                   |              |            | S           |              | 3 Mg, 1 In 1 Day   |                 | Not Reported |
|                       | Lexapro                                  |              |            | S           |              | 10 Mg, 1 In 1 Day  |                 | Not Reported |
|                       | Ativan                                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Risperdal                                |              |            | C           |              |                    |                 | Not Reported |
|                       | Vasotec                                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Lopresor                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Nitroglycerin                            |              |            | C           |              |                    |                 | Not Reported |
|                       | Hydrodiuril                              |              |            | C           |              |                    |                 | Not Reported |
|                       | Potassium                                |              |            | C           |              |                    |                 | Not Reported |
|                       | Slow-Mag (Magnesiukm Chloride Anhydrous) |              |            | C           |              |                    |                 | Not Reported |
|                       | Premarin                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Synthroid                                |              |            | C           |              |                    |                 | Not Reported |
|                       | Alphagan P                               |              |            | C           |              |                    |                 | Not Reported |
|                       | Levaquin                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Lidex                                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Aspirin (Acetylsalicylic Acid)           |              |            | C           |              |                    |                 | Not Reported |
|                       | Tylenol (Paracetamol)                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Vicodin                                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Protonix                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Prilosec                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Gaviscon                                 |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |              |
|-----------------------|---|--------------|
| Maalox (Maalox)       | C | Not Reported |
| Milk Of Magnesia      | C | Not Reported |
| Theragram (Theragran) | C | Not Reported |
| Vitamin E             | C | Not Reported |
| Ensure (Ensure)       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2004              | 4093521       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00532-03     |                      | 76 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Bruit; Acute      | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Kidney Injury; Asthenia;    | Celexa                 |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
| Blood Calcium Decreased;    | Lisinopril             |              |            | S           |              | 2.5 Mg Bid         |                 | Not Reported |
| Blood Magnesium             | Lasix                  |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Increased; Cardiac Failure  | Kayexalate             |              |            | C           |              |                    |                 | Not Reported |
| Congestive; Cardiac         | Coreg                  |              |            | C           |              |                    |                 | Not Reported |
| Murmur; Chronic Kidney      | Protonix               |              |            | C           |              |                    |                 | Not Reported |
| Disease; Chronic            | Ativan                 |              |            | C           |              |                    |                 | Not Reported |
| Obstructive Pulmonary       | Tylenol (Paracetamol)  |              |            | C           |              |                    |                 | Not Reported |
| Disease; Communication      | Vitamin B12            |              |            | C           |              |                    |                 | Not Reported |
| Disorder; Diastolic         | Colace                 |              |            | C           |              |                    |                 | Not Reported |
| Dysfunction; Gastritis;     | Ferrous Sulfate        |              |            | C           |              |                    |                 | Not Reported |
| Kidney Small; Mitral Valve  | Maalox                 |              | Y          | C           |              |                    |                 | Not Reported |
| Incompetence;               | Milk Of Magnesia       |              |            | C           |              |                    |                 | Not Reported |
| Musculoskeletal Chest       | Norvasc                |              |            | C           |              |                    |                 | Not Reported |
| Pain; Pneumonia; Protein    | Aspirin                |              |            | C           |              |                    |                 | Not Reported |
| Urine Present; Pulmonary    | Isosorbide Mononitrate |              |            | C           |              |                    |                 | Not Reported |
| Hypertension; Red Blood     | Avelox                 |              |            | C           |              |                    |                 | Not Reported |
| Cells Urine Positive; Renal | Albuterol              |              |            | C           |              |                    |                 | Not Reported |
| Artery Stenosis;            | Xanax                  |              |            | C           |              |                    |                 | Not Reported |
| Respiratory Distress;       | Combivent              |              |            | C           |              |                    |                 | Not Reported |
| Respiratory Rate            |                        |              |            |             |              |                    |                 |              |
| Increased; Tachycardia;     |                        |              |            |             |              |                    |                 |              |
| White Blood Cells Urine     |                        |              |            |             |              |                    |                 |              |
| Positive                    |                        |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2004              | 3959067       | EXPEDITED (15-DAY) | Y                  | OT              | US-SHR-03-008382     |                      | 43 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------------------|------------------------|-----------------|--------------|
| Alopecia; Anxiety;<br>Depression; Disturbance<br>In Attention; Dizziness;<br>Feeling Abnormal;<br>Irritability; Menopause;<br>Mood Swings; Sinus<br>Tachycardia | Climara        |              |            | S           | Transdermal<br>Transdermal | See Image<br>See Image |                 | Not Reported |
|                                                                                                                                                                 | Lexapro        |              |            | S           |                            |                        |                 | Not Reported |
|                                                                                                                                                                 | Vitamins       |              |            | C           |                            |                        |                 | Not Reported |
|                                                                                                                                                                 | Testosterone   |              |            | C           |                            |                        |                 | Not Reported |
|                                                                                                                                                                 | Remeron        |              |            | C           |                            |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2004              | 4139685       | EXPEDITED (15-DAY) | Y                  | HO              | 2004UW08247          |                      | 83 YR      | Female     | ARE            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood<br>Potassium Decreased;<br>Blood Pressure Systolic<br>Increased; Body<br>Temperature Increased;<br>Cardiac Murmur;<br>Depression; Eating<br>Disorder; Fatigue;<br>Helicobacter Infection;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Myositis; Nausea; Pco2<br>Decreased; Pedal Pulse<br>Decreased; Respiratory<br>Rate Increased; Vomiting | Crestor                |              |            | S           | Oral         | 10 Mg Po           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Lexapro                |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Diovan Hct             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Cardizem               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Xanax                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Protonix               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Biaxin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Prinivil               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Dextra                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Theosol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Nitroglycerin          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                         | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2004              | 4156434       | EXPEDITED (15-DAY) | Y                  | OT              | S04-IRL-02365-01     |                      | 59 YR      | Male       | IRL            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deep Vein Thrombosis;<br>Disease Recurrence;<br>Overdose | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                          | Zyprexa        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2004                                                                                                                                 | 4166386             | DIRECT             | N                  | OT              |                       |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                                                                                                    | Zoloft              |                    |                    | S               |                       | 100mg Once A Day     |                 | Pfizer       |                |
|                                                                                                                                             | Lexapro             |                    |                    | S               |                       | 15mg Once A Day      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2004                                                                                                                                 | 4139458             | EXPEDITED (15-DAY) | Y                  | HO              | DE-MERCK-0405DEU00077 |                      | 42 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Creatine Phosphokinase Increased; Central Nervous System Inflammation; Exhibitionism; Myopathy; Overdose; Personality Change | Maxalt-Mlt          |                    |                    | S               | Oral                  |                      |                 | Merck        |                |
|                                                                                                                                             | Ciprallex           |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                             | Domperidone         |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Ergotamine Tartrate |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                             | Metoclopramide      |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                             | Petasites           |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2004                                                                                                                                 | 4141327             | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02268-01      |                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Dry Mouth; Extrapyramidal Disorder; Fear; Neck Pain; Sedation; Vomiting                                                   | Lexapro             |                    |                    | S               | Oral                  | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                                                             | Allegra             |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                             | Protopik            |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2004                                                                                                                                 | 4167452             | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-03273-01      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                          |         |   |              |
|------------------------------------------------------------------------------------------|---------|---|--------------|
| Altered Visual Depth Perception; Depressed Level Of Consciousness; Road Traffic Accident | Lexapro | S | Not Reported |
|------------------------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2004              | 4167519       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-03513-01     |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Decreased Appetite; Depression; Drug Ineffective; Emotional Distress; Insomnia; Near Drowning; Restlessness; Schizoaffective Disorder; Seizure; Thinking Abnormal | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                | Risperdal      |              |            | S           |              | 3 Mg Qd            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2004              | 4182830       | NON-EXPEDITED    | Y                  | DE              | 2003013970           |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Condition Aggravated; Depression; Erectile Dysfunction; Gastric Disorder; Homicide; Insomnia; Mood Swings; Sexual Dysfunction | Zoloft                  |              |            | S           | Oral         | 150 Mg (Daily), Oral |                 | Not Reported |
|                                                                                                                               | Escitalopram Oxalate    |              |            | S           | Oral         | Oral                 |                 | Not Reported |
|                                                                                                                               | Alprazolam (Alprazolam) |              |            | C           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2004              | 4182896       | NON-EXPEDITED    | Y                  | OT              | 2004026989           |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Abdominal Pain Upper; Alanine Aminotransferase | Zoloft               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                            |              |   |              |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|--------------|
| Increased; Aspartate Amino transferase<br>Increased; Blood Alkaline Phosphatase Increased;<br>Diarrhoea; Urinary Tract Infection; Vomiting | Lansoprazole | C | Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2004              | 4038107       | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-04702-01     |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Lexapro                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                              | Multiple Medications (Nos) |              |            | C           |              |                    |                 | Not Reported |
|                                              | Zoloft                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2004              | 4106583       | EXPEDITED (15-DAY) | Y                  | DE              | T04-USA-00730-01     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia;                                                                | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
| Arteriosclerosis Coronary Artery; Arteriospasm                             | Celexa                  |              |            | S           |              |                    |                 | Not Reported |
| Coronary; Coronary Artery Stenosis; Pulmonary Oedema; Sudden Cardiac Death | Alcohol                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Methadone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2004              | 4145737       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S04-USA-02757-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Seizure     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2004              | 4167206       | DIRECT           | N                  | LT              |                      |                      | 17 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
|----------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
| Hostility; Personality Change; Social Avoidant Behaviour; Suicide Attempt                          | Lexapro<br>Fluvoxamine  |                    |                    | S<br>S          |                      |                      |                 | Forest<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 01-Jul-2004                                                                                        | 4167988                 | EXPEDITED (15-DAY) | Y                  | DE              | T04-USA-03454-01     |                      | 52 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Arrhythmia;                                                                                        | Celexa                  |                    |                    | S               |                      |                      |                 | Not Reported           |                |
| Arteriosclerosis Coronary Artery; Coronary Artery Stenosis; Pulmonary Oedema; Sudden Cardiac Death | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Alcohol                 |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Methadone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 02-Jul-2004                                                                                        | 4168072                 | DIRECT             | Y                  | OT              |                      |                      | 52 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Pruritus; Rash                                                                                     | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Q Day Oral     |                 | Forest                 |                |
|                                                                                                    | Benzotropine Mesylate   |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Clonazepam              |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Risperidone             |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Valproic Acid           |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Vitamin E               |                    |                    | C               |                      |                      |                 | Not Reported           |                |
|                                                                                                    | Ibuprofen               |                    |                    | C               |                      |                      |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 02-Jul-2004                                                                                        | 6035461                 | EXPEDITED (15-DAY) | Y                  | OT              | TOR-2004-0001        |                      | 63 YR           | Female                 | GBR            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Coordination Abnormal; Depression; Gait                                                            | Fareston                |                    |                    | S               | Oral                 |                      | 4 YR            | Not Reported           |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |              |   |      |                        |        |              |
|-----------------------------------------------------------------------------|--------------|---|------|------------------------|--------|--------------|
| Disturbance; Lower Respiratory Tract Infection; Nystagmus; Overdose; Tremor | Ciprallex    | S | Oral | 20 Mg (20 Mg, 1 In 1d) | 10 MTH | Not Reported |
|                                                                             | Diazepam     | S |      |                        |        | Not Reported |
|                                                                             | Anadin Extra | S |      |                        |        | Not Reported |
|                                                                             | Ketoprofen   | C |      |                        |        | Not Reported |
|                                                                             | Misoprostol  | C |      |                        |        | Not Reported |
|                                                                             | Fibrogel     | C |      |                        |        | Not Reported |
|                                                                             | Venlafaxin   | C |      |                        |        | Not Reported |
|                                                                             | Olanzapine   | C |      |                        |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2004              | 4153953       | EXPEDITED (15-DAY) | Y                  | HO              | T04-USA-02228-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams; Benign Laryngeal Neoplasm; Coma; Conversion Disorder; Fall; Gaze Palsy; Generalised Tonic-Clonic Seizure; Headache; Hemiplegia; Leukoplakia; Musculoskeletal Chest Pain; Panic Reaction; Paraesthesia; Post Procedural Complication; Somnolence; Vision Blurred | Escitalopram Oxalate                |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Escitalopram Oxalate                |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Fentanyl                            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Isoflurane                          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Ativan                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Omeprazole                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Benzoyl Peroxide (Benzoyl Peroxide) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Calcium With Vitamin D              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Cetirizine Hydrochloride            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Vitamins Nos                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Acetaminophen W/Oxycodone           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Sodium Chloride                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Dermophil Indien Sun Screen         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Tretonoin                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                  | Triamcinolone Acetinide             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2004              | 4169851       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02247-01     |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Fluctuation; Hyperglycaemia; | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                            | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |           |   |              |
|--------------------------------|-----------|---|--------------|
| Hypoglycaemia; Self-Medication | Ativan    | C | Not Reported |
|                                | Captopril | C | Not Reported |
|                                | Lipitor   | C | Not Reported |
|                                | Aspirin   | C | Not Reported |
|                                | Buspar    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2004              | 4169855       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-03701-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aphasia; Conversion Disorder; Gait Disturbance; Headache; Paralysis; Seizure; Tendonitis | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2004              | 6511307       | DIRECT           | Y                  | HO, LT          |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psychotic Disorder; Serotonin Syndrome | Zyvox          |              |            | S           |              | 600 Mg IV/Po Q12h  |                 | Not Reported |
|                                        | Lexapro        |              |            | S           | Oral         | 10 Mg Po Bid       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2004              | 4158587       | EXPEDITED (15-DAY) | Y                  | DS              | T04-AUT-02502-01     |                      | 38 YR      | Female     | AUT            |

| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased; Metabolic Disorder | Escitalopram Oxalate                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                | Escitalopram Oxalate                 |              |            | S           | Oral         | 10 Mg Qdpo         |                 | Not Reported |
|                                                                                                                                                                                                | Mianserin Hydrochloride              |              |            | S           | Oral         | 120 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                                                                | Oxazepam                             |              |            | S           | Oral         | 150 Mg Qd Po       |                 | Pliva        |
|                                                                                                                                                                                                | Panthenol                            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Dominal (Prothipendyl Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------|-----------------|----------------------|----------------|
| 07-Jul-2004                                                                                                        | 4171109                              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-03697-01                         |                       | 42 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Aspartate Amino transferase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased                  | Lexapro                              |                    |                    | S               | Oral                                     | 10 Mg Qd Po           |                 | Not Reported         |                |
|                                                                                                                    | Diovan Hct                           |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Alprazolam                           |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Viagra                               |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Toprol XL                            |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jul-2004                                                                                                        | 4169848                              | DIRECT             | N                  | RI, OT          |                                          |                       | 38 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Disturbance In Attention; Fear; Feeling Abnormal; Feeling Of Despair; Headache; Insomnia; Morbid Thoughts | Lexapro                              |                    |                    | S               | Oral                                     | 1/2 Tablet Daily Oral |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 09-Jul-2004                                                                                                        | 4169959                              | NON-EXPEDITED      | Y                  | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-12302923 |                       | 65 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Hypotension; Toxicity To Various Agents                                                          | Coumadin                             |                    |                    | S               |                                          |                       |                 | Bristol Myers Squibb |                |
|                                                                                                                    | Lovenox                              |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Protonix                             |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Zetia                                |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Carafate                             |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Ferrous Sulfate                      |                    |                    | C               |                                          |                       |                 | Not Reported         |                |
|                                                                                                                    | Elavil                               |                    |                    | C               |                                          |                       |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |      |                        |              |
|--|-----------------|---|------|------------------------|--------------|
|  | Peri-Colace     | C |      | Dose 2 Capsules Daily. | Not Reported |
|  | Robaxin         | C |      |                        | Not Reported |
|  | Reglan          | C |      |                        | Not Reported |
|  | Lortab          | C |      |                        | Not Reported |
|  | Multi-Vitamin   | C |      |                        | Not Reported |
|  | Nystatin        | C |      |                        | Apothecon    |
|  | Sodium Chloride | C |      | Dose: "100 Units".     | Not Reported |
|  | Toprol XL       | C |      |                        | Not Reported |
|  | Diovan          | C |      |                        | Not Reported |
|  | Lexapro         | S | Oral |                        | Not Reported |

| <u>FDA Received Date</u>                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------------------|-----------------|----------------------|----------------|
| 09-Jul-2004                                 | 4170130        | NON-EXPEDITED    | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12374955 |                                                                    | 68 YR           | Female               | USA            |
| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>           |                |
| International Normalised<br>Ratio Increased | Coumadin       |                  |                    | S               |                                                 | Dose: 5 Mg Alternated<br>With 2.5 Mg/Day.<br>Expected To Re-Start. |                 | Bristol Myers Squibb |                |
|                                             | Lexapro        |                  |                    | S               | Oral                                            |                                                                    | 8 DAY           | Not Reported         |                |
|                                             | Insulin Nos    |                  |                    | C               |                                                 |                                                                    |                 | Not Reported         |                |
|                                             | Colchicine     |                  |                    | C               |                                                 |                                                                    |                 | Not Reported         |                |
|                                             | Prinivil       |                  |                    | C               |                                                 |                                                                    |                 | Not Reported         |                |
|                                             | Furosemide     |                  |                    | C               |                                                 |                                                                    |                 | Not Reported         |                |
|                                             | Ranitidine     |                  |                    | C               |                                                 |                                                                    |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Jul-2004                                                                                  | 4061534                        | EXPEDITED (15-DAY) | Y                  | OT              | S03-USA-05298-02     |                      | 91 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Transient<br>Ischaemic Attack | Lexapro                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                              | Megace                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Lopresor                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Nitrotab (Glyceryl Trinitrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Norvasc                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Plavix                         |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 13-Jul-2004                                                                    | 4152032                       | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0513591A |                      | 75 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Eye Haemorrhage; Macular Degeneration; Visual Acuity Reduced | Advair Diskus                 |                    |                    | S               | Respiratory (inhalation)     |                      | 2 MTH           | Glaxosmithkline |                |
|                                                                                | Lexapro                       |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                | Vitamins                      |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                | Hypericum                     |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                | Carotenoids                   |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jul-2004                                                                    | 4172743                       | DIRECT             | Y                  |                 |                              |                      | 69 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthralgia; Back Pain; Feeling Abnormal; Muscle Spasms                         | Lexapro                       |                    |                    | S               |                              | Qd                   |                 | Not Reported    |                |
|                                                                                | Unisom                        |                    |                    | C               |                              | Qd                   |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jul-2004                                                                    | 4175380                       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-03834-01             |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Monoplegia                                                                     | Lexapro                       |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                | Calcium Channel Blocker (Nos) |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                | Unspecified Ingredient        |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Jul-2004                                                                    | 4168150                       | DIRECT             | N                  | HO, RI          |                              |                      | 56 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Kidney Injury;                                                           | Zelnorm                       |                    |                    | S               |                              | 1 Daily By Mouth     |                 | Novartis        |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                             |         |   |                  |        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------------------|--------|
| Constipation; Diarrhoea;<br>Drug Ineffective;<br>Hydronephrosis;<br>Hypertension; Nausea;<br>Rectal Haemorrhage;<br>Retroperitoneal Fibrosis;<br>Therapeutic Product Effect<br>Decreased; Ureteric<br>Obstruction; Vomiting | Lexapro | S | 1 Daily By Mouth | Forest |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2004              | 4176120       | EXPEDITED (15-DAY) | Y                  | HO              | T04-GER-02230-01     |                      | 72 YR      | Male       | DEU            |

  

| <u>Preferred Term</u>      | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;        | CipraleX                   |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Apathy; Bladder            | CipraleX                   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Diverticulum; Condition    | Hydrochlorothiazide        |              |            | S           |              |                    |                 | Not Reported |
| Aggravated; Cystitis;      | Ramipril                   |              |            | C           |              |                    |                 | Not Reported |
| Cystoscopy Abnormal;       | Carvedilol                 |              |            | C           |              |                    |                 | Not Reported |
| Dehydration; Dementia;     | Amiodarone                 |              |            | C           |              |                    |                 | Not Reported |
| Depression; Drug           | Triamterene (Triamterene)  |              |            | C           |              |                    |                 | Not Reported |
| Ineffective; Feeling       | Allopurinol                |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Haematuria;      | Allopurinol                |              |            | C           |              |                    |                 | Not Reported |
| Haemoglobin Decreased;     | Zocor                      |              |            | C           |              |                    |                 | Not Reported |
| Irritability; Memory       | Ass (Acetylsalicylic Acid) |              |            | C           |              |                    |                 | Not Reported |
| Impairment; Pyelonephritis | (Acetylsalicylic Acid)     |              |            |             |              |                    |                 | Not Reported |
| Acute; Stupor;             |                            |              |            |             |              |                    |                 |              |
| Vasodilatation             |                            |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2004              | 4177136       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-03937-01     |                      | 13 YR      | Male       | USA            |

  

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Bipolar Disorder;<br>Depression; Family<br>Stress; Irritability; Memory<br>Impairment; Psychomotor<br>Hyperactivity; Refusal Of | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment By Relative

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 15-Jul-2004                                                                                                                                                                                                                  | 4173642                   | DIRECT             | Y                  | HO              |                      |                      | 42 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anhedonia; Asthenia;<br>Decreased Appetite;<br>Feeling Abnormal;<br>Irritability; Libido<br>Decreased; Self Esteem<br>Decreased; Social<br>Avoidant Behaviour;<br>Suicidal Ideation; Suicide<br>Attempt; Weight<br>Decreased | Interferon Nos<br>Lexapro |                    |                    | S<br>S          | Oral                 | 10 Mg Daily Oral     |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Jul-2004                                                                                                                                                                                                                  | 4177665                   | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04010-01     |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Pericarditis                                                                                                                                                                                                                 | Lexapro                   |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Jul-2004                                                                                                                                                                                                                  | 4178335                   | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-02984-01     |                      | 47 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Flushing; White Blood Cell<br>Count Decreased                                                                                                                                                                                | Cipralex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 15-Jul-2004                                                                                                                                                                                                                  | 4178339                   | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-02987-01     |                      | 28 YR           | Female                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Monocyte Count                                                                                                                                                                                                               | Cipralex                  |                    |                    | S               |                      |                      |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Increased; Paraesthesia;  
Photosensitivity Reaction;  
Pruritus Generalised; Skin  
Abrasion

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Jul-2004              | 5823357                | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-04007-01                                |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;           | Lexapro                |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
| Pneumonia                | Benicar Hct            |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2004              | 4177624                | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04076-01                                |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                  | Lexapro                |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2004              | 4116255                | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-01170-01                                |                      |                 | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Allergic;     | Ciprallex              |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
| Epidermolysis;           | Unspecified Ingredient |                    |                    | S               | Oral                                            | 50 Mg Qd Po          |                 | Not Reported |                |
| Pemphigoid               | Unspecified Ingredient |                    |                    | S               |                                                 | 150 Mg Qd            |                 | Not Reported |                |
|                          | Omeprazole             |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                          | Tegretol               |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2004              | 4169815                | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12487039 |                      | 10 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |         |   |      |              |
|---------------------------|---------|---|------|--------------|
| Acne; Constipation;       | Abilify | S | Oral | Not Reported |
| Dyskinesia; Fear; Glucose | Lexapro | S | Oral | Not Reported |
| Tolerance Impaired;       |         |   |      |              |
| Insulin Resistance;       |         |   |      |              |
| Nightmare; Polycystic     |         |   |      |              |
| Ovaries; Sleep Disorder;  |         |   |      |              |
| Weight Increased          |         |   |      |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2004              | 4173227       | EXPEDITED (15-DAY) | Y                  | HO              | T04-SWE-02787-01     |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuser; Generalised<br>Tonic-Clonic Seizure | Ciprallex              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                  | Ciprallex              |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                                                  | Actos (Pioglitazone)   |              |            | C           |              |                    |                 | Not Reported |
|                                                  | (Pioglitazone)         |              |            |             |              |                    |                 |              |
|                                                  | Novonorm (Repaglinide) |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Allopurinol            |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Ramipril               |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Warfarin Sodium        |              |            | C           |              |                    |                 | Not Reported |
| Norvasc                                          |                        |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2004              | 4136926       | EXPEDITED (15-DAY) | N                  | HO              | US-JNJFOC-20040405349 |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Alcohol<br>Poisoning; Apathy;<br>Depression; Impulse-<br>Control Disorder; Weight<br>Increased | Concerta       |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                                                                                                                   |                |              |            |             | Oral         | See Image          |                 |              |
|                                                                                                                                   |                |              |            |             | Oral         | See Image          |                 |              |
|                                                                                                                                   | Lexapro        |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                                                                                                                   |                |              |            |             | Oral         | See Image          |                 |              |
|                                                                                                                                   |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2004              | 4147438       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-02762-01     |                      | 30 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Completed Suicide;         | Lexapro                |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Craniocerebral Injury;     | Ambien                 |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Family Stress; Gun Shot    | Valium                 |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Wound; Insomnia; Marital   | Wellbutrin             |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Problem; Medication Error; | Unspecified Ingredient |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Treatment Noncompliance    |                        |                    |                    |                 |                      |                          |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2004                | 4152332                | EXPEDITED (15-DAY) | Y                  | DE              | 2004032706           |                          | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                      | Geodon                 |                    |                    | S               |                      | 240 Mg (80 Mg, 3 In 1 D) |                 | Not Reported |                |
|                            | Lorazepam              |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                            | Escitalopram Oxalate   |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                            | Topiramate             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                            | Diazepam (Diazepam)    |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2004                | 4176687                | DIRECT             | Y                  | HO              |                      |                          | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Lethargy    | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Daily Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2004                | 4129416                | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-01686-01     |                          | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
| Diabetes Mellitus          | Ativan                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Inadequate Control;        | Insulin Nos            |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Family Stress; Feeling     | Prozac                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Abnormal; Hyperhidrosis;   |                        |                    |                    |                 |                      |                          |                 |              |                |
| Prostate Cancer; Sleep     |                        |                    |                    |                 |                      |                          |                 |              |                |
| Disorder                   |                        |                    |                    |                 |                      |                          |                 |              |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 21-Jul-2004                                                                                                                                                                                                                                       | 4177339              | DIRECT             | N                  | OT              |                           |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Fatigue;<br>Headache; Loss Of<br>Personal Independence In<br>Daily Activities;<br>Photosensitivity Reaction;<br>Weight Increased                                                                                                       | Celexa               |                    |                    | S               | Oral                      | 40 Mg Daily Oral     |                 | Forest       |                |
|                                                                                                                                                                                                                                                   | Lexapro              |                    |                    | S               | Oral                      | 10 Mg Daily Oral     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2004                                                                                                                                                                                                                                       | 6747123              | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-<br>20040703092 |                      | 28 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Bradycardia; Decreased<br>Appetite; Depression;<br>Disease Recurrence; Drug<br>Ineffective; Emotional<br>Distress; Insomnia;<br>Medication Error;<br>Restlessness;<br>Schizoaffective Disorder;<br>Treatment Noncompliance | Risperdal            |                    |                    | S               | Oral                      | 3 Mg, In 1 Day, Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               |                           | See Image            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   |                      |                    |                    |                 |                           | See Image            |                 |              |                |
|                                                                                                                                                                                                                                                   |                      |                    |                    |                 |                           | See Image            |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2004                                                                                                                                                                                                                                       | 4177772              | DIRECT             | N                  | DE              |                           |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Circulatory Collapse;<br>Completed Suicide;<br>Constipation; Diarrhoea;<br>Dizziness                                                                                                                                         | Lexapro              |                    |                    | S               |                           | 1 A Day              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Zyrex                |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Atenolol             |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Lorazepam            |                    |                    | C               |                           |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 22-Jul-2004                                                                                                                                                                                                                                                                                                                         | 4181230                                           | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-02859-01     |                                                   | 38 YR           | Female                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Decreased Appetite;<br>Hyperhidrosis;<br>Hypoaesthesia; Lethargy                                                                                                                                                                                                                                                                    | Cipralext<br>Zopiclone                            |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po                                       |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 22-Jul-2004                                                                                                                                                                                                                                                                                                                         | 4181542                                           | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-02985-01     |                                                   | 32 YR           | Female                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Blood Creatine<br>Phosphokinase Increased                                                                                                                                                                                                                                                                                           | Cipralext<br>Acetylsalicylic Acid<br>Trimipramine |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po                                       |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 23-Jul-2004                                                                                                                                                                                                                                                                                                                         | 4180332                                           | DIRECT             | N                  | LT              |                      |                                                   | 32 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Autoimmune<br>Thyroiditis; Chest<br>Discomfort; Crying;<br>Depression; Drug<br>Withdrawal Syndrome;<br>Fear; Feeling Abnormal;<br>Gastrooesophageal Reflux<br>Disease; Influenza Like<br>Illness; Mental Disorder;<br>Migraine; Muscle Spasms;<br>Nightmare; Pain; Panic<br>Attack; Suicidal Ideation;<br>Weight Increased | Paxil Cr<br>Lexapro                               |                    |                    | S<br>S          | Oral<br>Oral         | 1 Pill Once Daily Oral<br>1 Pill Twice Daily Oral |                 | Not Reported<br>Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jul-2004                                                                                                                                                                                                                                                     | 4176345              | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2004US07790      |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oropharyngeal Swelling                                                                                                                                                                                                                                          | Zelnorm              |                    |                    | S               | Oral                 | 20 Mg, Qd            |                 | Novartis     |                |
|                                                                                                                                                                                                                                                                 | Senokot              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Seroquel             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Risperdal            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Klonopin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Dulcolax (Bisacodyl) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2004                                                                                                                                                                                                                                                     | 4177621              | EXPEDITED (15-DAY) | Y                  | HO              | 04H-163-0266755-00   |                      | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Aggression; Alcohol Use;<br>Anaesthetic Complication;<br>Coma; Conversion<br>Disorder; Fall; Gaze Palsy;<br>Head Injury; Headache;<br>Hemiplegia;<br>Musculoskeletal Chest<br>Pain; Paraesthesia;<br>Seizure; Somnolence;<br>Vision Blurred | Fentanyl Citrate     |                    |                    | S               | Oral                 | Per Oral             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Isoflurane           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 |                      |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2004                                                                                                                                                                                                                                                     | 4180966              | DIRECT             | Y                  |                 |                      |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Medication Error                                                                                                                                                                                                                        | Lexapro              |                    |                    | S               |                      |                      |                 | Forest       |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jul-2004                                                                                                                                                                                                                                                                                             | 4181725        | DIRECT             | N                  | OT              |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysgeusia; Nausea; Parosmia                                                                                                                                                                                                                                                                             | Lexapro        |                    |                    | S               | Oral                 | 10 Mg 1 A Day Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2004                                                                                                                                                                                                                                                                                             | 4184920        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-04303-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Road Traffic Accident; Toxicity To Various Agents                                                                                                                                                                                                                                                       | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2004                                                                                                                                                                                                                                                                                             | 4175403        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-03833-01     |                      | 28 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Cachexia; Chorea; Choreoathetosis; Conversion Disorder; Depressed Level Of Consciousness; Dizziness; Dystonia; Gait Disturbance; Gait Disturbance; Gait Inability; Hypoaesthesia; Insomnia; Intentional Overdose; Memory Impairment; Mental Status Changes; Suicide Attempt; Wheelchair User | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 270 Mg Once Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                         | Excedrin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2004                                                                                                                                                                                                                                                                                             | 4183485        | DIRECT             | N                  | OT              |                      |                      | 47 YR           | Female       | USA            |

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| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|---------------------------------------|--------------------------|---------------------|-------------------------|
| Abnormal Sensation In Eye; Diplopia; Vision Blurred; Visual Brightness; Visual Field Defect; Visual Impairment | Lexapro                 |                           |                             | S                        | Oral                          | 1 Tablet Per Day Oral                 |                          | Walgreen            |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Jul-2004                                                                                                    | 4187669                 | EXPEDITED (15-DAY)        | Y                           | LT                       | S04-GER-03130-01              |                                       | 35 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Morbid Thoughts; Nervousness; Obsessive Thoughts; Suicidal Ideation                                            | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                           |                          | Not Reported        |                         |
|                                                                                                                | Remergil (Mirtazapine)  |                           |                             | C                        |                               |                                       |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Jul-2004                                                                                                    | 4164950                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 2004219679GB                  |                                       | 19 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cholangitis; Contusion; Hepatitis Chronic Active                                                               | Depo-Provera            |                           |                             | S                        | Intramuscular                 | 150 Mg, Last Injection, Intramuscular |                          | Not Reported        |                         |
|                                                                                                                |                         |                           |                             |                          | Intramuscular                 | 150 Mg, Last Injection, Intramuscular |                          |                     |                         |
|                                                                                                                | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Oral                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Jul-2004                                                                                                    | 4187328                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S04-BRA-03329-01              |                                       | 83 YR                    | Female              | BRA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Non-Cardiogenic Pulmonary Oedema; Therapy Non-Responder; Urinary Tract Infection                               | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                           |                          | Not Reported        |                         |
|                                                                                                                | Levothyroxine Sodium    |                           |                             | C                        |                               |                                       |                          | Not Reported        |                         |
|                                                                                                                | Insulin Nos             |                           |                             | C                        |                               |                                       |                          | Not Reported        |                         |
|                                                                                                                | Amlodipine              |                           |                             | C                        |                               |                                       |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

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### Detailed Report

|             |   |              |
|-------------|---|--------------|
| Captopril   | C | Not Reported |
| Phenytoin   | C | Not Reported |
| Pravastatin | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2004              | 4188585       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04386-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombocytopenia      | Lexapro                              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                       | Topamax                              |              |            | S           |              | 100 Mg Qam         |                 | Not Reported |
|                       | Topamax                              |              |            | S           |              | 200 Mg Qhs         |                 | Not Reported |
|                       | Wellbutrin (Bupropion Hydrochloride) |              |            | S           |              | 200 Mg Bid         |                 | Not Reported |
|                       | Topamax                              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2004              | 4188606       | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-02797-01     |                      | 3 YR       | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound; Mood Swings | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2004              | 4188619       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04368-01     |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eye Haemorrhage; Macular Degeneration; Visual Impairment | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Advair                 |              |            | S           | Oral         | 1 Puff Bid Po      |                 | Not Reported |
|                                                          | Advair                 |              |            | S           | Oral         | 1 Puff Qd Po       |                 | Not Reported |
|                                                          | Advair                 |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Lutein                 |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Vitamins               |              |            | C           |              |                    |                 | Not Reported |



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| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------------|------------------|--------------------|-----------------|-----------------------|----------------------------------------------------------------------------|-----------------|--------------|----------------|
| 29-Jul-2004                                   | 4207673              | NON-EXPEDITED    | Y                  | HO              | US-JNJFOC-20030906650 |                                                                            | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis;<br>Pulmonary Embolism   | Risperdal            |                  |                    | S               | Oral                  | 2.5 Mg, 1 In 1 Day, Oral                                                   |                 | Not Reported |                |
|                                               | Lithium (Lithium)    |                  |                    | S               |                       | 1500 Mg, 1 In 1 Day                                                        |                 | Not Reported |                |
|                                               | Escitalopram Oxalate |                  |                    | S               |                       | 10 Mg, 1 In 1 Day                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2004                                   | 4207716              | NON-EXPEDITED    | N                  | HO              | US-JNJFOC-20040305938 |                                                                            | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Suicidal Ideation | Risperdal            |                  |                    | S               | Oral                  | 0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, 1 In 1 Day, Oral |                 | Not Reported |                |
|                                               |                      |                  |                    |                 | Oral                  | 0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, 1 In 1 Day, Oral |                 |              |                |
|                                               |                      |                  |                    |                 | Oral                  | 0.5 Mg, 1 In 1 Day, Oral; 1 Mg, 1 In 1 Day, Oral; 1.5 Mg, 1 In 1 Day, Oral |                 |              |                |
|                                               | Lexapro              |                  |                    | S               | Oral                  | 10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral  |                 | Not Reported |                |
|                                               |                      |                  |                    |                 | Oral                  | 10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral  |                 |              |                |
|                                               |                      |                  |                    |                 | Oral                  | 10 Mg, 1 In 1 Day, Oral; 20 Mg, 1 In 1 Day, Oral; 30 Mg, 1 In 1 Day, Oral  |                 |              |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2004                                   | 4208438              | NON-EXPEDITED    | Y                  | OT              | US-JNJFOC-20030900220 |                                                                            | 29 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Seizure                                                                                                                                      | Risperdal              |                    |                    | S               | Oral                 | 1 Mg, 3 In 1 Day; Oral  |                 | Not Reported |                |
|                                                                                                                                              | Lexapro                |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 Day,Oral  |                 | Not Reported |                |
|                                                                                                                                              | Trileptal              |                    |                    | S               | Oral                 | 900 Mg 1 In 1 Day; Oral |                 | Not Reported |                |
|                                                                                                                                              | Oxcarbazepine          |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2004                                                                                                                                  | 4189191                | EXPEDITED (15-DAY) | Y                  | DE              |                      | S04-NOR-03402-01        | 23 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                            | Ciprallex              |                    |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                              | Zyprexa                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2004                                                                                                                                  | 4189500                | EXPEDITED (15-DAY) | N                  | HO              |                      | S04-USA-04401-01        | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Burns<br>Second Degree; Euphoric<br>Mood; Feeling Drunk;<br>Hypophagia; Memory<br>Impairment; Overdose;<br>Speech Disorder | Lexapro                |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Unspecified Ingredient |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Celebrex               |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Oil Of Oregano         |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Inderal                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2004                                                                                                                                  | 3910218                | EXPEDITED (15-DAY) | Y                  | OT              |                      | S03-FRA-00523-01        | 23 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Glycosuria;<br>Hyperglycaemia;<br>Ketonuria                                                                                                  | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                              | Xanax                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Zolpidem Tartrate      |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                              | Imovane (Zopiclone)    |                    |                    | C               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Aug-2004                                                                                                                                                                               | 4190490                    | EXPEDITED (15-DAY) | Y                  | DS              | S04-FRA-03409-01     |                      | 57 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Haemorrhagic Disorder; Pain; Pain In Extremity; Swelling                                                                                                                      | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexomil (Bromazepam)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Zolpidem Tartrate          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2004                                                                                                                                                                               | 4192591                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-USA-04485-01     |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Alcoholism; Apathy; Belligerence; Depression; Disinhibition; Legal Problem; Personality Change; Physical Assault; School Refusal; Thinking Abnormal; Weight Increased | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro                    |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Concerta                   |                    |                    | S               |                      | 135 Mg Qd            |                 | Not Reported |                |
|                                                                                                                                                                                           | Alcohol                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2004                                                                                                                                                                               | 4192599                    | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-04403-01     |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis; Hyponatraemia                                                                                                                                                              | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qod Po         |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qod Po         |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Multiple Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Aug-2004                                                                                                                                                                               | 4086860                    | EXPEDITED (15-DAY) | Y                  | DE, DS, HO      | T03-GER-05233-01     |                      | 82 YR           | Female       | DEU            |

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| <u>Preferred Term</u>                    | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Cardiac Failure;               | Cipralext                       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Cerebral Ischaemia;                      | Cipralext                       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Depression; Diabetes Mellitus Inadequate | Actos                           |              |            | S           |              | 30 Mg Qd           |                 | Not Reported |
| Control; Diet Refusal;                   | Amaryl                          |              |            | C           |              |                    |                 | Not Reported |
| Disturbance In Attention;                | Unat (Torasemide)               |              |            | C           |              |                    |                 | Not Reported |
| Feeling Abnormal; Gait                   | Glucobay                        |              |            | C           |              |                    |                 | Not Reported |
| Inability; Mental Disorder;              | Godamed                         |              |            | C           |              |                    |                 | Not Reported |
| Multiple Organ                           | Enahexal (Enalapril Maleate)    |              |            | C           |              |                    |                 | Not Reported |
| Dysfunction Syndrome;                    | Glucophage                      |              |            | C           |              |                    |                 | Not Reported |
| Nausea; Pneumonia;                       | Zincum (Zinc)                   |              |            | C           |              |                    |                 | Not Reported |
| Pneumonia; Psychomotor                   | Neuralgin                       |              |            | C           |              |                    |                 | Not Reported |
| Retardation; Refusal Of                  | Gingium (Ginkgo Biloba Extract) |              |            | C           |              |                    |                 | Not Reported |
| Treatment By Patient;                    | Laif (Hypericum Extract)        |              |            | C           |              |                    |                 | Not Reported |
| Thinking Abnormal;                       | Remergil (Mirtazapine)          |              |            | C           |              |                    |                 | Not Reported |
| Transient Ischaemic                      |                                 |              |            |             |              |                    |                 |              |
| Attack; Treatment                        |                                 |              |            |             |              |                    |                 |              |
| Noncompliance                            |                                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2004              | 4191862       | DIRECT           | Y                  | HO              |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypotension; Syncope  | Lexapro        |              |            | S           | Oral         | Daily Oral         |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2004              | 4192525       | EXPEDITED (15-DAY) | Y                  | HO              | S04-GER-02852-01     |                      |            | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Intentional  | Cipralext               |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Seizure;    | Citalopram Hydrobromide |              |            | S           | Oral         | 600 Mg Once Po     |                 | Not Reported |
| Suicide Attempt       | Citalopram Hydrobromide |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 09-Aug-2004                                                                                                                                                   | 4112369        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-01206-01                     |                      | 39 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Confusional State;<br>Dizziness; Dysarthria;<br>Euphoric Mood; Nuclear<br>Magnetic Resonance<br>Imaging Brain Abnormal;<br>Treatment<br>Noncompliance; Tremor | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                   | 4169852        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-03696-01                     |                      | 67 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hyponatraemia                                                                                                                                                 | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                               | Bextra         |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                               | Lovastatin     |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                               | Xanax          |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                   | 4185089        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0491579A |                      | 26 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Feeling Jittery;<br>Headache; Mental<br>Impairment; Muscle<br>Twitching; Sleep Disorder;<br>Thirst                                                     | Paxil          |                    |                    | S               | Oral                                 | 20mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                                                               | Lexapro        |                    |                    | S               | Oral                                 | 20mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                               | Strattera      |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                   | 4185094        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0491910A |                      | 33 YR           | Female          | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Drug Withdrawal Syndrome;<br>Hypoaesthesia;<br>Paraesthesia; Vomiting;<br>Weight Decreased | Paxil          |                  |                    | S               | Oral                                 | 30mg Per Day         | 1 YR            | Glaxosmithkline |                |
|                                                                                            | Lexapro        |                  |                    | S               | Unknown                              |                      | 3 DAY           | Not Reported    |                |
|                                                                                            | Prevacid       |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                            | Zantac         |                  |                    | C               |                                      |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                | 4186422        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0504277A |                      | 53 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Sexual Dysfunction                                                                         | Paxil          |                  |                    | S               |                                      |                      |                 | Glaxosmithkline |                |
|                                                                                            | Lexapro        |                  |                    | S               |                                      | 10mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                | 4186542        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0504843A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain Upper;<br>Anxiety; Dyspnoea;<br>Palpitations                                | Paxil          |                  |                    | S               |                                      |                      |                 | Glaxosmithkline |                |
|                                                                                            | Lexapro        |                  |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                | 4186780        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0504223A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nightmare                                                                                  | Paxil Cr       |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                                            | Lexapro        |                  |                    | S               |                                      |                      |                 | Not Reported    |                |
|                                                                                            | Seroquel       |                  |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2004                                                                                | 4191613        | DIRECT           | Y                  | RI              |                                      |                      | 20 YR           | Male            | USA            |

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| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| Blood Pressure Diastolic Decreased; Blood Pressure Systolic Increased; Dyspnoea; Eye Disorder; Feeling Abnormal; Hypersensitivity; Pain; Rash Generalised; Seizure; Tremor | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Po Daily 1 Dose Only |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                                | 4193214        | EXPEDITED (15-DAY) | Y                  | DE              | S04-GER-03471-01     |                            | 45 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                          | Ciprallex      |                    |                    | S               | Oral                 | 20 Mg Qd Po                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                                | 4193269        | EXPEDITED (15-DAY) | Y                  | DE              | S04-GER-03466-01     |                            | 90 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Death Of Companion; Drug Interaction                                                                                                                            | Ciprallex      |                    |                    | S               |                      |                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2004                                                                                                                                                                | 4193495        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-04603-01     |                            | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Completed Suicide; Overdose; Toxicity To Various Agents                                                                                                              | Lexapro        |                    |                    | S               | Oral                 | 280 Mg Once Po             |                 | Not Reported |                |
|                                                                                                                                                                            | Lexapro        |                    |                    | S               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                            | Lamotrigine    |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                            | Seroquel       |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                            | Klonopin       |                    |                    | C               |                      |                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2004              | 5823358       | EXPEDITED (15-DAY) | Y                  | HO              | SO4-USA-04007-01     |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Basophil Count Increased; Blood Calcium Decreased; Blood Chloride Decreased; Blood Creatinine Decreased; Blood Urea Decreased; Haemoptysis; Hyponatraemia; Pneumonia; White Blood Cell Count Increased | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                 | Benicar Hct         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                 | Hydrochlorothiazide |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                 | Diovan              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2004              | 4161880       | EXPEDITED (15-DAY) | N                  | RI, OT          | SO4-USA-03236-01     |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Hypertension | Lexapro                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                        | Atacand (Candesarta Cilexetil) |              |            | C           |              |                    |                 | Not Reported |
|                        | Hydrochlorothiazide            |              |            | C           |              |                    |                 | Not Reported |
|                        | Zocor                          |              |            | C           |              |                    |                 | Not Reported |
|                        | Zyrtec                         |              |            | C           |              |                    |                 | Not Reported |
|                        | Allegra                        |              |            | C           |              |                    |                 | Not Reported |
|                        | Nexium (Esomeprazole)          |              |            | C           |              |                    |                 | Not Reported |
|                        | Advil                          |              |            | C           |              |                    |                 | Not Reported |
|                        | Tylenol (Paracetamol)          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2004              | 4193852       | EXPEDITED (15-DAY) | Y                  | HO              | SO4-ESP-03543-01     |                      | 79 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertensive Crisis   | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |



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| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 11-Aug-2004                                                                                                                                           | 4193890                | EXPEDITED (15-DAY) | Y                  | DS, HO          | HQWYE700902AUG04     |                                                                                                  | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Csf Test Abnormal; Feeling Abnormal; Headache; Hypersomnia; Impaired Work Ability; Migraine; Sleep Disorder; Subdural Haematoma | Effexor Xr             |                    |                    | S               | Oral                 | Started With 75 Mg, Then 150 Mg, Then 225 Mg/Day. Increased At 75 Mg Intervals Over A Year, Oral |                 | Not Reported |                |
|                                                                                                                                                       | Lexapro                |                    |                    | S               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Unspecified Ingredient |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2004                                                                                                                                           | 4194855                | DIRECT             | Y                  | HO, RI          |                      |                                                                                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Exfoliative; Drug Eruption; Dyspnoea; Erythema; Pruritus; Pyrexia; Throat Tightness; Urticaria                                             | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Po Qd                                                                                      |                 | Not Reported |                |
|                                                                                                                                                       | Glipizide              |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Albuterol              |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Prednisone             |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Potassium              |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Amitriptyline          |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Aspirin                |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Westcort               |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Advair Diskus          |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Diflucan               |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Zyrtec                 |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Metoprolol             |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Lisinopril             |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Lasix                  |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Xanax                  |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Norvasc                |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Nystatin               |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Diclofenac             |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |
|                                                                                                                                                       | Calcium W/Vit D        |                    |                    | C               |                      |                                                                                                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 11-Aug-2004                                                                                                                                                                                                                 | 4196198                 | DIRECT             | Y                  |                 |                      |                         | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Mental Status Changes; Tremor                                                                                                                                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 40 Mg Po Daily          |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Bupropion               |                    |                    | S               | Oral                 | 150 Mg Po Q Day         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Benazepril              |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Metronidazole           |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Benicar                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Advair Diskus           |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Morphine                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2004                                                                                                                                                                                                                 | 4103762                 | EXPEDITED (15-DAY) | Y                  | CA              | S04-USA-00732-02     |                         | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Limb Malformation; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities                                                                                                                                    | Lexapro                 |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Trazodone Hydrochloride |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2004                                                                                                                                                                                                                 | 4157603                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-03034-01     |                         | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Coma; Confusional State; Depression; Overdose; Rebound Effect; Suicidal Ideation; Treatment | Lexapro                 |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |

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## Noncompliance

| <a href="#">FDA Received Date</a>                                                                                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------------------|-------------------------|
| 12-Aug-2004                                                                                                               | 4195461                        | EXPEDITED (15-DAY)        | Y                           | CA                       | S04-UKI-03475-01              |                               | 39 YR                    | Female                                       | GBR                     |
| <a href="#">Preferred Term</a>                                                                                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Congenital Central Nervous System Anomaly; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Pregnancy | Cipralext                      |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 12-Aug-2004                                                                                                               | 4196808                        | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-03511-01              |                               |                          | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Blood Pressure Decreased; Drug Interaction; Loss Of Consciousness; Syncope                                                | Lexapro<br>Metoprolol          |                           |                             | S<br>S                   |                               |                               |                          | Not Reported<br>Not Reported                 |                         |
| <a href="#">FDA Received Date</a>                                                                                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 12-Aug-2004                                                                                                               | 4211081                        | NON-EXPEDITED             | Y                           | HO                       | 200318869US                   |                               | 67 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Hyponatraemia                                                                                                             | Lasix<br>Lexapro<br>Metolazone |                           |                             | S<br>S<br>S              | Oral                          | 10 Mg Qd Po                   | 4 MTH                    | Not Reported<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 16-Aug-2004                                                                                                               | 4172146                        | EXPEDITED (15-DAY)        | Y                           | HO                       | S04-USA-03774-01              |                               | 24 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |          |   |      |              |              |
|------------------------------|----------|---|------|--------------|--------------|
| Aggression; Amnesia;         | Lexapro  | S | Oral | 10 Mg Qd; Po | Not Reported |
| Coma; Diarrhoea;             | Lexapro  | S | Oral | 10 Mg Qd; Po | Not Reported |
| Dyskinesia; Hyperhidrosis;   | Vioxx    | C |      |              | Not Reported |
| Hypertension; Malaise;       | Elavil   | C |      |              | Not Reported |
| Refusal Of Treatment By      | Gabitril | C |      |              | Not Reported |
| Patient; Somatic Symptom     | Abilify  | C |      |              | Not Reported |
| Disorder; Speech             | Zyprexa  | C |      |              | Not Reported |
| Disorder; Suicidal           | Toradol  | C |      |              | Not Reported |
| Ideation; Tremor; Urticaria; | Sonata   | C |      |              | Not Reported |
| Vomiting                     |          |   |      |              |              |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 16-Aug-2004              | 4191149        | EXPEDITED (15-DAY) | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0521812A |                      | 43 YR           | Male            | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Insomnia; Medication     | Wellbutrin     |                    |                    | S               | Oral                                 | 300mg Per Day        |                 | Glaxosmithkline |                |
| Error; Somnolence        | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
|                          | Clonazepam     |                    |                    | S               |                                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2004               | 4195892        | DIRECT           | Y                  | OT              |                      |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase  | Lexapro        |                  |                    | S               | Oral                 | 20 Qd Po             |                 | Not Reported |                |
| Increased; Aspartate      | Prozac         |                  |                    | S               | Oral                 | 20 Qd Po             |                 | Not Reported |                |
| Aminotransferase          | Klonopin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Increased; Blood Alkaline |                |                  |                    |                 |                      |                      |                 |              |                |
| Phosphatase Increased;    |                |                  |                    |                 |                      |                      |                 |              |                |
| Dysphoria; Headache; Hot  |                |                  |                    |                 |                      |                      |                 |              |                |
| Flush; Restless Legs      |                |                  |                    |                 |                      |                      |                 |              |                |
| Syndrome                  |                |                  |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Aug-2004              | 4196055        | DIRECT           | Y                  | HO              |                      |                      | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |               |   |      |                 |              |
|----------------------|---------------|---|------|-----------------|--------------|
| Contusion; Epistaxis | Lexapro       | S | Oral | 20mg Daily Oral | Forest       |
|                      | Lorazepam     | C |      |                 | Not Reported |
|                      | Acetaminophen | C |      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2004              | 4195970       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S04-USA-04868-01     |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased;    | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depressed Level Of          | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Consciousness; Dizziness;   | Low Dose Hormone (Nos) |              |            | C           |              |                    |                 | Not Reported |
| Epistaxis; Haematocrit      | Aspirin                |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Haemoglobin      | Claritin-D             |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Haemorrhage;     |                        |              |            |             |              |                    |                 | Not Reported |
| Injury; Mean Cell           |                        |              |            |             |              |                    |                 |              |
| Haemoglobin Decreased;      |                        |              |            |             |              |                    |                 |              |
| Mean Platelet Volume        |                        |              |            |             |              |                    |                 |              |
| Decreased; Platelet Count   |                        |              |            |             |              |                    |                 |              |
| Increased; Platelet         |                        |              |            |             |              |                    |                 |              |
| Disorder; Platelet Function |                        |              |            |             |              |                    |                 |              |
| Test Abnormal;              |                        |              |            |             |              |                    |                 |              |
| Thrombocytosis              |                        |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2004              | 4195983       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-04852-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antidepressant Drug Level | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Above Therapeutic; Fall;  | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Forearm Fracture;         | Ativan                  |              |            | S           |              |                    |                 | Not Reported |
| Myocardial Infarction;    | Amitriptyline           |              |            | S           |              |                    |                 | Not Reported |
| Procedural Pain;          | Tramadol Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
| Respiratory Failure       |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2004              | 4196134       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-04615-01     |                      |            | Unknown    | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------|----------------------|----------------------|--------------|------------|----------------|
| Psychotic Disorder                                                                                                                                                               | Lexapro        |                    |                    | S               |              |                      |                      | Not Reported |            |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
| 17-Aug-2004                                                                                                                                                                      | 4196492        | EXPEDITED (15-DAY) | Y                  | DE              |              | 2004UW16878          |                      | 24 YR        | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Alcohol Use; Cardiac Arrest; Coma; Respiratory Arrest; Sudden Death                                                                                                              | Seroquel       |                    |                    | S               | Oral         | 25 Mg Qd Po          |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral         | 30 Mg Qd Po          |                      | Not Reported |            |                |
|                                                                                                                                                                                  |                |                    |                    |                 | Oral         | 30 Mg Qd Po          |                      |              |            |                |
|                                                                                                                                                                                  |                |                    |                    |                 | Oral         | 30 Mg Qd Po          |                      |              |            |                |
|                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral         | 10 Mg Qd Po          |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral         | 20 Mg Qd Po          |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Neurontin      |                    |                    | C               |              |                      |                      | Not Reported |            |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
| 18-Aug-2004                                                                                                                                                                      | 4197225        | DIRECT             | Y                  | OT              |              |                      |                      | 19 YR        | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Alopecia                                                                                                                                                                         | Lexapro        |                    |                    | S               | Oral         | Bid Po               |                      | Forest       |            |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
| 19-Aug-2004                                                                                                                                                                      | 4100774        | EXPEDITED (15-DAY) | Y                  | RI              |              | S04-USA-00713-01     |                      | 72 YR        | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Blood Glucose Increased; Blood Thyroid Stimulating Hormone Decreased; Catecholamines Urine Increased; Condition Aggravated; Epinephrine Increased; Metanephrine Urine Increased; | Lexapro        |                    |                    | S               | Oral         | 10 Mg Qd Po          |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Hytrin         |                    |                    | C               |              |                      |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Lipitor        |                    |                    | C               |              |                      |                      | Not Reported |            |                |
|                                                                                                                                                                                  | Viagra         |                    |                    | C               |              |                      |                      | Not Reported |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Onychomycosis;  
Onychomycosis; Panic  
Attack;  
Pheochromocytoma;  
Weight Increased

| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|------------------------------|----------------|
| 19-Aug-2004                                                                                                                                                                  | 4199248                                        | DIRECT             | Y                  | OT              |                                  |                      | 72 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                                                                                                                              | Escitalopram Oxalate<br>Unspecified Ingredient |                    |                    | S<br>C          | Oral                             | 10 Mg Q Day Po       |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Aug-2004                                                                                                                                                                  | 4199907                                        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-04906-01                 |                      | 43 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Psychotic Disorder;<br>Seizure                                                                                                                                               | Lexapro                                        |                    |                    | S               | Oral                             | 10 Mg Qd Po          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Aug-2004                                                                                                                                                                  | 4199911                                        | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-04856-01                 |                      | 62 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Agitation; Completed<br>Suicide; Compulsions;<br>Condition Aggravated;<br>Crying; Depression;<br>Dyspepsia; Flatulence;<br>Insomnia; Irritability; Loss<br>Of Libido; Tremor | Lexapro<br>Lexapro                             |                    |                    | S<br>S          |                                  |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-Aug-2004                                                                                                                                                                  | 4194036                                        | EXPEDITED (15-DAY) | Y                  | OT              | IE-GLAXOSMITHKLINE-<br>B0342249A |                      |                 | Female                       | IRL            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
|----------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|---------------------------------|----------------|
| Seizure                                                                                            | Lamictal<br>Lexapro     |                    |                    | S<br>S          |                      |                      |                 | Glaxosmithkline<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 20-Aug-2004                                                                                        | 4199894                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04981-01     |                      | 87 YR           | Female                          | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                                                    | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                    |                |
|                                                                                                    | Morphine                |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
|                                                                                                    | Fentanyl                |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
|                                                                                                    | Toprol XL               |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
|                                                                                                    | Zantac                  |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
|                                                                                                    | Ramipril                |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 23-Aug-2004                                                                                        | 4103030                 | EXPEDITED (15-DAY) | Y                  | DS              | S04-PRT-00593-01     |                      | 57 YR           | Female                          | PRT            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Diabetes Mellitus; Hepatic<br>Steatosis; Hepatomegaly                                              | Cipralax                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                    |                |
|                                                                                                    | Lorazepam               |                    |                    | C               |                      |                      |                 | Not Reported                    |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 23-Aug-2004                                                                                        | 4194929                 | EXPEDITED (15-DAY) | N                  | OT              | S04--USA-04732-01    |                      | 61 YR           | Male                            | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Abnormal Behaviour;<br>Agitation; Belligerence;<br>Confusional State;<br>Delusion; Mania; Paranoia | Wellbutrin              |                    |                    | S               | Oral                 | 300mg Per Day        | 5 YR            | Glaxosmithkline                 |                |
|                                                                                                    | Lexapro                 |                    |                    | S               | Oral                 | 10mg Per Day         | 2 MTH           | Not Reported                    |                |
|                                                                                                    | Ambien                  |                    |                    | C               | Oral                 |                      |                 | Not Reported                    |                |
|                                                                                                    | Trazodone Hydrochloride |                    |                    | C               | Unknown              | 25mg Per Day         |                 | Not Reported                    |                |
|                                                                                                    | Lipitor                 |                    |                    | C               | Unknown              |                      |                 | Not Reported                    |                |
|                                                                                                    | Aciphex                 |                    |                    | C               | Unknown              |                      |                 | Not Reported                    |                |



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| Aspirin                                                                                                                                                                                                                    |                     |                    | C                  |                 | Unknown              |                         |                 | Glaxosmithkline |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|-----------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Aug-2004                                                                                                                                                                                                                | 4199552             | DIRECT             | N                  | DS, HO, RI      |                      |                         | 48 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Balance Disorder;<br>Confusional State;<br>Dysarthria; Dyskinesia;<br>Gait Disturbance; Impaired<br>Work Ability; Muscle<br>Contractions Involuntary;<br>Muscle Twitching; Speech<br>Disorder; Tremor; Weight<br>Increased | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Tablet Daily Oral |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Aug-2004                                                                                                                                                                                                                | 4213798             | NON-EXPEDITED      | N                  |                 | PHEH2004US07700      |                         | 51 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;<br>Hyperhidrosis; Rash<br>Erythematous; Rash<br>Macular; Rash Pruritic                                                                                                                               | Zelnorm             |                    |                    | S               | Oral                 | 6 Mg Bid Oral           |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Lexapro             |                    |                    | S               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Potassium Chloride  |                    |                    | C               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Hydrochlorothiazide |                    |                    | C               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Klonopin            |                    |                    | C               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Estraderm           |                    |                    | C               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Celebrex            |                    |                    | C               |                      |                         |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Nexium              |                    |                    | C               |                      |                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Aug-2004                                                                                                                                                                                                                | 4147386             | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02765-01     |                         | 44 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>      |                |
| Gastritis; Hepatitis; Lipase<br>Decreased                                                                                                                                                                                  | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported    |                |
|                                                                                                                                                                                                                            | Ditropan            |                    |                    | C               |                      |                         |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

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|                           | Buspar         |                    |                    | C               |                      |                       |                 |              | Not Reported   |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
|                           | Armour Thyroid |                    |                    | C               |                      |                       |                 |              | Not Reported   |
|                           | Effexor        |                    |                    | C               |                      |                       |                 |              | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2004               | 4198227        | DIRECT             | Y                  | RI              |                      |                       | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia             | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Once Daily Oral |                 | Forest       |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2004               | 4199228        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-05502-01     |                       | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;        | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po           |                 | Not Reported |                |
| Dilatation Ventricular;   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |
| Injury; Intentional       | Celexa         |                    |                    | S               |                      |                       |                 | Not Reported |                |
| Overdose; Pulmonary       | Celexa         |                    |                    | S               | Oral                 | 40 Mg Qd Po           |                 | Not Reported |                |
| Oedema; Road Traffic      | Darvocet-N 100 |                    |                    | S               |                      |                       |                 | Not Reported |                |
| Accident                  | Flexeril       |                    |                    | C               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2004               | 4199234        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05501-01     |                       | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Contusion;       | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po           |                 | Not Reported |                |
| Depressed Level Of        | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |
| Consciousness;            | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |
| Depression; Fall; Loss Of |                |                    |                    |                 |                      |                       |                 |              |                |
| Consciousness; Muscle     |                |                    |                    |                 |                      |                       |                 |              |                |
| Spasms; Nystagmus;        |                |                    |                    |                 |                      |                       |                 |              |                |
| Postictal State; Seizure; |                |                    |                    |                 |                      |                       |                 |              |                |
| Suicidal Ideation; Tongue |                |                    |                    |                 |                      |                       |                 |              |                |
| Injury                    |                |                    |                    |                 |                      |                       |                 |              |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2004                | 4201459        | EXPEDITED (15-DAY) | Y                  | DS              | S04-DEN-03815-01     |                      | 45 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Mechanical      | Cipralext      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Urticaria; Miosis; Nausea; | Zyrtec         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Pruritus; Rash; Urticaria  | Salures-K      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2004                 | 4162917                       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-01889-01     |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Tenderness;       | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Back Pain; Ceruloplasmin    | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Increased; Condition        | Neurontin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Aggravated; Hepatic         | Glucotrol                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Steatosis; Hepatitis Toxic; | Copaxone                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hepatotoxicity;             | Nonsteroidal Antiinflammatory |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hypoaesthesia;              |                               |                    |                    |                 |                      |                      |                 |              |                |
| Musculoskeletal             |                               |                    |                    |                 |                      |                      |                 |              |                |
| Discomfort; Nausea;         |                               |                    |                    |                 |                      |                      |                 |              |                |
| Therapeutic Product Effect  |                               |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Urinary Tract    |                               |                    |                    |                 |                      |                      |                 |              |                |
| Infection                   |                               |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Aug-2004              | 4200310        | EXPEDITED (15-DAY) | Y                  | OT              | HQWYE139228MAY04     |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Condition        | Effexor Xr     |                    |                    | S               | Oral                 | See Image            |                 | Not Reported |                |
| Aggravated; Drug         |                |                    |                    |                 | Oral                 | See Image            |                 |              |                |
| Ineffective; Drug        | Lexapro        |                    |                    | S               |                      | See Image            |                 | Not Reported |                |
| Withdrawal Syndrome;     |                |                    |                    |                 |                      | See Image            |                 |              |                |
| Emotional Distress;      | Singulair      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Feeling Abnormal; Panic  | Clarinet       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Attack; Product Quality  |                |                    |                    |                 |                      |                      |                 |              |                |

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|                                     |                         |                    |                    |                 |                             |                      |                 |              |                |
|-------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|--------------|----------------|
| Issue; Suicidal Ideation            |                         | Synthroid          |                    | C               |                             | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2004                         | 5714342                 | EXPEDITED (15-DAY) | Y                  | DE              | 2003-UK-00153UK             |                      | 62 YR           | Female       | GBR            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death;<br>Unevaluable Event  | Spiriva                 |                    |                    | S               | Respiratory<br>(inhalation) | 18 Mcg (18 Mcg, Ih)  |                 | Not Reported |                |
|                                     | Escitalopram Oxalate    |                    |                    | S               |                             | 10 Mg                |                 | Not Reported |                |
|                                     | Temazepam               |                    |                    | C               |                             |                      |                 | Not Reported |                |
|                                     | Budesonide (Budesonide) |                    |                    | C               |                             |                      |                 | Not Reported |                |
|                                     | Morphine                |                    |                    | C               |                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2004                         | 4201804                 | DIRECT             | Y                  |                 |                             |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Medication<br>Error     | Lexapro                 |                    |                    | S               |                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2004                         | 4202242                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-AUT-03818-01            |                      | 22 YR           | Female       | AUS            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure | Lexapro                 |                    |                    | S               | Oral                        | 10 Mg Qd Po          |                 | Not Reported |                |
|                                     | Risperdal               |                    |                    | C               |                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2004                         | 4202244                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-UKI-03884-01            |                      | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                             | Ciprallex               |                    |                    | S               |                             |                      |                 | Not Reported |                |
|                                     | Flucloxacillin          |                    |                    | C               |                             |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2004              | 4195976       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-04867-01     |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Angle Closure Glaucoma;                                                                                                 | Lexapro                          |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Arthralgia; Circadian Rhythm Sleep Disorder;                                                                                            | Lexapro                          |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Cystitis Interstitial; Diplopia; Dry Mouth;                                                                                             | Lexapro                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Gastric Disorder; Hyperhidrosis;                                                                                                        | Lexapro                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Hypersensitivity; Insomnia; Intervertebral Disc Degeneration; Medication Error; Metastases To Bone; Metastases To Liver; Muscle Injury; | Lexapro                          |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Muscle Spasms; Myalgia; Osteoarthritis; Pelvic Floor Muscle Weakness;                                                                   | Lexapro                          |              |            | S           | Oral         | 5 Mg Qhs Po        |                 | Not Reported |
| Pneumonia Bacterial; Renal Disorder; Swollen Tongue; Tearfulness;                                                                       | Lexapro                          |              |            | S           | Oral         | 10 Mg Qam Po       |                 | Not Reported |
| Urethral Disorder; Urge Incontinence; Urinary Retention                                                                                 | Lexapro                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                         | Prozac                           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                         | Klonopin                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Digoxin                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Tiazac 9diltiazem Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Methotrexate                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Omega 3 Fatty Acids              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Isosorbide Mononitrate           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Warfarin Sodium                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Nitroglycerin                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2004              | 4204656       | EXPEDITED (15-DAY) | Y                  | HO              | S04-UKI-03828-01     |                      | 81 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Atrophy;     | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |

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|                                                                                  |                                      |   |      |               |              |
|----------------------------------------------------------------------------------|--------------------------------------|---|------|---------------|--------------|
| Circulatory Collapse;<br>Dizziness; Lacunar<br>Infarction; Myoclonus;<br>Seizure | Venlafaxine Hydrochloride            | S | Oral | 37.5 Mg Qd Po | Not Reported |
|                                                                                  | Simvastatin                          | C |      |               | Not Reported |
|                                                                                  | Aspirin (Acetylsalicylic Acid)       | C |      |               | Not Reported |
|                                                                                  | Cephalexin                           | C |      |               | Not Reported |
|                                                                                  | Imdur                                | C |      |               | Not Reported |
|                                                                                  | Teoptic (Carteolol<br>Hydrochloride) | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2004              | 4176131       | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-02983-01     |                      |            | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Cipralelex     |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |
|                       | Cipralelex     |              |            | S           |              | 5 Mg Qd            |                 | Not Reported |
|                       | Cipralelex     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2004              | 4204489       | DIRECT           | N                  | OT              |                      |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Asthenia; Crying;<br>Feeling Of Despair;<br>Paraesthesia; Self-<br>Injurious Ideation | Lexapro        |              |            | S           | Oral         | 1 A Day Oral       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2004              | 4206217       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05503-01     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Foetal Death; Foetal Heart<br>Rate Decreased; Maternal<br>Exposure During<br>Pregnancy; Peripartum<br>Haemorrhage; Pregnancy | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|------------------|------------------------------|---------------------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 30-Aug-2004                                                                                                                                                                                                                                                                        | 4206273                                  | EXPEDITED (15-DAY) | Y                  | OT               | S04-UKI-03883-01             |                                                         | 19 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Cholangitis; Contusion;<br>Liver Disorder; Liver<br>Function Test Abnormal                                                                                                                                                                                                         | Ciprallex<br>Depo-Provera                |                    |                    | S<br>S           | Intramuscular                | 150 Mg Im                                               |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 31-Aug-2004                                                                                                                                                                                                                                                                        | 4160204                                  | EXPEDITED (15-DAY) | Y                  | OT               | S04-USA-03133-01             |                                                         | 45 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Alanine Aminotransferase<br>Increased; Amnesia;<br>Aspartate<br>Aminotransferase<br>Increased; Blood Alkaline<br>Phosphatase Increased;<br>Dysphoria; Headache;<br>Hepatotoxicity; Hot Flush;<br>Liver Function Test<br>Abnormal; Restless Legs<br>Syndrome; Serotonin<br>Syndrome | Lexapro<br>Lexapro<br>Prozac<br>Klonopin |                    |                    | S<br>S<br>S<br>C | Oral<br>Oral                 | 20 Mg Qd Po<br>10 Mg Qd Po<br>20 Mg Qd                  |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 31-Aug-2004                                                                                                                                                                                                                                                                        | 4171821                                  | EXPEDITED (15-DAY) | Y                  | HO               | S04-USA-03703-01             |                                                         | 16 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Bipolar Ii Disorder; Road<br>Traffic Accident; Suicide<br>Attempt                                                                                                                                                                                                                  | Lexapro<br>Lexapro<br>Lexapro<br>Lexapro |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | 10 Mg Qd Po<br>15 Mg Qd Po<br>10 Mg Qd Po<br>5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 31-Aug-2004                                                                                                                                                | 4177625        | NON-EXPEDITED      | Y                  | OT              | S04-USA-04077-01             |                      | 43 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Seizure                                                                                                                                                    | Wellbutrin XI  |                    |                    | S               | Oral                         | 450mg Per Day        | 4 MTH           | Glaxosmithkline |                |
|                                                                                                                                                            | Lexapro        |                    |                    | S               | Oral                         | 10mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Aug-2004                                                                                                                                                | 4200585        | NON-EXPEDITED      | N                  | OT              | US-GLAXOSMITHKLINE-A0515395A |                      | 43 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Depressed Level Of Consciousness; Eye Movement Disorder; Generalised Tonic-Clonic Seizure; Postictal State; Tongue Biting; Tonic Clonic Movements | Wellbutrin     |                    |                    | S               | Oral                         | 450mg Per Day        | 3 MTH           | Glaxosmithkline |                |
|                                                                                                                                                            | Lexapro        |                    |                    | S               | Oral                         | 10mg Per Day         | 442 DAY         | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Aug-2004                                                                                                                                                | 4204792        | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-05535-01             |                      | 21 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alcohol Interaction; Breath Alcohol Test Positive; Potentiating Drug Interaction                                                                           | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                            | Strattera      |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                            | Alcohol        |                    |                    | S               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Sep-2004                                                                                                                                                | 4147390        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02766-01             |                      | 87 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                       |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Coma                                 | Lexapro               |                    | S                  | Oral            | 5 Mg Qd Po           |                      | Not Reported    |              |                |
|                                      | Buspirone             |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Doxozosin             |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Exelon                |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Furosemide            |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Mirtazapine           |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Nitro-Dur             |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Plavix                |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Potassium Chloride    |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Sotalol Hydrochloride |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|                                      | Synthroid             |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| Vitamin C                            |                       | C                  |                    |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Sep-2004                          | 4195940               | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWI-03547-01     |                      | 82 YR           | Male         | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury;<br>Thrombosis | Ciprallex             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                      | Pravastatin Sodium    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                      | Enalapril Maleate     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                      | Torem (Torasemide)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                      | Nexium (Esomeprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Aspirin                              |                       |                    | C                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Sep-2004                          | 4206127               | DIRECT             | Y                  |                 |                      |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                                 | Lexapro               |                    |                    | S               |                      | 5 Mg Qd              |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Sep-2004                          | 4148760               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02791-01     |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                             |                |                    |                    |                 |                      |                      |                 |            |                |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Abnormal Behaviour;<br>Coma; Depressed Level<br>Of Consciousness;<br>Dizziness; Seizure;<br>Sensory Disturbance;<br>Syncope | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                             | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 |            | Not Reported   |
|                                                                                                                             | Norvasc        |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Cardizem Cd    |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Diovan         |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Lisinopril     |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Pletal         |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Haldol         |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | K-Dur          |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Coumadin       |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                             | Insulin Nos    |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Sep-2004                                                                                                                 | 4206764        | DIRECT             | Y                  | HO              |                      |                      | 64 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Myocardial Infarction                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg/Day Po         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Sep-2004                                                                                                                 | 4208435        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-05846-01     |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Encephalitis; Seizure                                                                                                       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                             | Klonopin       |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Sep-2004                                                                                                                 | 4205519        | NON-EXPEDITED      | Y                  | OT              | 2004UW09813          |                      | 72 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity; Rash<br>Maculo-Papular; Skin<br>Exfoliation                                                               | Crestor        |                    |                    | S               | Oral                 | 10 Mg Dialy Po       |                 |            | Not Reported   |
|                                                                                                                             | Lexapro        |                    |                    | S               |                      |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Sep-2004                                                                                                                                            | 4208557                                  | DIRECT             | Y                  | HO              |                      |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Natriuretic Peptide Increased; Haemoglobin Decreased; Hyponatraemia; Pulmonary Oedema; Urinary Tract Infection; White Blood Cell Count Increased | Lexapro                                  |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Sep-2004                                                                                                                                            | 4090167                                  | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWI-00380-01     |                      | 79 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematocrit Decreased; Haemoglobin Decreased; Thrombocytopenia                                                                                         | Cipralext                                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                        | Cipralext                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                        | Betolvex (Cyanocobalamin-Tannin Complex) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                        | Haldol                                   |                    |                    | C               |                      |                      |                 | Janssen      |                |
|                                                                                                                                                        | Insulin Nos                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                        | Norvasc                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                        | Convulex (Valproate Sodium)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                        | "Byk Gulden"                             |                    |                    |                 |                      |                      |                 | Not Reported |                |
|                                                                                                                                                        | Orfiril Desitin (Valproate Sodium)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Sep-2004                                                                                                                                            | 4201203                                  | EXPEDITED (15-DAY) | Y                  | OT              | S04-ESP-03760-01     |                      | 78 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness Postural; Nystagmus; Vertigo                                                                                                                 | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                        | Xeloda                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------|--------------------------|---------------------|-------------------------|
| 07-Sep-2004                                                                                                                                                      | 4208711                 | DIRECT                    | N                           | HO, LT                   |                               |                                   | 14 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Condition Aggravated; Hallucination, Visual; Mood Swings; Obsessive-Compulsive Disorder; Suicide Attempt; Thinking Abnormal                             | Lexapro                 |                           |                             | S                        |                               | 10mg/Day Fall 2001<br>Winter 2004 |                          | Not Reported        |                         |
|                                                                                                                                                                  | Luvox                   |                           |                             | S                        |                               | 30mg/Day                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2004                                                                                                                                                      | 4212574                 | EXPEDITED (15-DAY)        | Y                           | OT                       | CH-JNJFOC-20040809666         |                                   | 26 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Thrombocytopenia                                                                                                                               | Risperdal               |                           |                             | S                        | Oropharyngeal                 |                                   |                          | Not Reported        |                         |
|                                                                                                                                                                  | Ciprallex               |                           |                             | S                        | Oropharyngeal                 |                                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Sep-2004                                                                                                                                                      | 4173248                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S04-UKI-02778-01              |                                   | 45 YR                    | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>       | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Burning Sensation; Completed Suicide; Dyspepsia; Dysphemia; Insomnia; Muscle Twitching; Nausea; Panic Attack; Paraesthesia; Pollakiuria; Treatment Noncompliance | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                       |                          | Not Reported        |                         |
|                                                                                                                                                                  | Ciprallex               |                           |                             | S                        | Oral                          | 20 Mg Qd Po                       |                          | Not Reported        |                         |
|                                                                                                                                                                  | Zopiclone               |                           |                             | C                        |                               |                                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>     | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Sep-2004                                                                                                                                                      | 4211724                 | DIRECT                    | Y                           | OT                       |                               |                                   | 53 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination; Speech Disorder | Ambien         |              |            | S           | Oral         | 10 Mg At Hs Po     |                 | Not Reported |
|                                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                | Zestril        |              |            | C           |              |                    |                 | Not Reported |
|                                | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
|                                | Vancocin       |              |            | C           |              |                    |                 | Not Reported |
|                                | Flagyl         |              |            | C           |              |                    |                 | Not Reported |
|                                | Diflucan       |              |            | C           |              |                    |                 | Not Reported |
|                                | Phenergan      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2004              | 4212314       | EXPEDITED (15-DAY) | Y                  | HO              | T04-USA-00447-01     |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Barrett's Oesophagus; Cerebral Ischaemia; Choking; Cough; Dandy-Walker Syndrome; Dizziness; Duodenal Neoplasm; Duodenal Ulcer; Dysphagia; Ectopic Gastric Mucosa; Gastrointestinal Disorder; Gastrointestinal Obstruction; Gastroesophageal Reflux Disease; Generalised Tonic-Clonic Seizure; Hiatus Hernia; Hypothyroidism; Metaplasia; Mucosal Inflammation; Nausea; Peptic Ulcer; Vomiting | Memantine Hydrochloride |              |            | S           | Oral                                  | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Escitalopram Oxalate    |              |            | S           | Oral                                  | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Escitalopram            |              |            | S           | Oral                                  | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Versed                  |              |            | S           | Intravenous (not otherwise specified) | 1 Mg Once Iv       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                               | Lansoprazole            |              |            | C           |                                       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2004              | 4212321       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-05944-01     |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Drug Interaction; Haemorrhage; International Normalised Ratio Increased; Mental Disorder | Lexapro                 |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                     | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                     | Warfarin Sodium         |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                     | Bethanecol              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Clotrimazole            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Levofloxacin            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Prednisone              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Risperidone             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Tamulosin               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Acetaminophen           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 4191672       | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-04404-01     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Decreased; Electroencephalogram Abnormal; Feeling Abnormal; Generalised Tonic-Clonic Seizure; Headache; Vision Blurred | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                      | Ortho Evra     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 4196776       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04782-01     |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Amnesia; Aphasia; Depressed Level Of Consciousness; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hypoaesthesia; Mental | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                           | Celexa         |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                           | Strattera      |              |            | S           |              | 80 Mg Qd           |                 | Not Reported |
|                                                                                                                                                           | Celexa         |              |            | C           | Oral         | 40 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Impairment; Muscle  
Spasms; Myoclonus;  
Seizure; Sensory  
Disturbance

| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|------------------------------|----------------|
| 10-Sep-2004                                                                   | 4202235                  | EXPEDITED (15-DAY) | Y                  | HO              | S04-DEN-03746-01     |                           | 33 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abortion Missed; Maternal Exposure During Pregnancy; Pregnancy                | Cipralelex<br>Cipralelex |                    |                    | S<br>S          | Oral                 | 20 Mg Qd Po               |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 10-Sep-2004                                                                   | 4210499                  | NON-EXPEDITED      | N                  | LT              | S04-USA-03249-01     |                           | 55 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Suicide Attempt                                                               | Lexapro                  |                    |                    | S               | Unknown              | Unk                       |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 10-Sep-2004                                                                   | 4210502                  | NON-EXPEDITED      | N                  | OT              | S04-USA-03106-01     |                           | 33 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depression; Muscle Spasms; Suicidal Ideation                                  | Lexapro<br>Zoloft        |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po               |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 10-Sep-2004                                                                   | 4210505                  | NON-EXPEDITED      | N                  | OT              | S04-USA-03101-01     |                           | 45 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Dreams; Confusional State; Mania; Suicidal Ideation; Suicide Attempt | Lexapro<br>Lexapro       |                    |                    | S<br>S          | Oral<br>Oral         | 5 Mg Qd Po<br>15 Mg Qd Po |                 | Not Reported<br>Not Reported |                |

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|                           | Ultram                  |                  |                    | S               | Unknown              | Unk                  |                 |            | Not Reported   |
|---------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
|                           | Ultram                  |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Vicodin                 |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Prilosec                |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Zantac                  |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Synthroid               |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Atenolol                |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Unspecified Ingredient  |                  |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Sep-2004               | 4210507                 | NON-EXPEDITED    | N                  | OT              | S04-USA-03008-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation         | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Sep-2004               | 4210509                 | NON-EXPEDITED    | N                  | OT              | S04-USA-02804-01     |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea                  | Lexapro                 |                  |                    | S               | Unknown              | Unk                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Sep-2004               | 4210514                 | NON-EXPEDITED    | Y                  | OT              | S04-USA-02763-01     |                      | 17 YR           | Female     | USA            |
| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Overdose;     | Lexapro                 |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| Lethargy; Suicide Attempt | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                           | Trazodone Hydrochloride |                  |                    | S               |                      | 150 Mg Once          |                 |            | Not Reported   |
|                           | Trazodone Hydrochloride |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                           | Depakote                |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                           | Seroquel                |                  |                    | C               |                      |                      |                 |            | Not Reported   |



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| <u>FDA Received Date</u>                               | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|-----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Sep-2004                                            | 4210516               | NON-EXPEDITED    | N                  | OT              | S04-USA-03072-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia;<br>Overdose; Suicidal<br>Ideation | Lexapro               |                  |                    | S               | Oral                 | 120 Mg Qd Po         |                 | Not Reported |                |
|                                                        | Lexapro               |                  |                    | S               | Oral                 | 60 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Lexapro               |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Lexapro               |                  |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
|                                                        | Lipitor               |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2004                                            | 4210524               | NON-EXPEDITED    | N                  | HO              | S04-USA-04974-01     |                      | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Flushing;<br>Nausea                        | Lexapro               |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Nexium (Esomeprazole) |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2004                                            | 4210526               | NON-EXPEDITED    | Y                  | RI, OT          | S04-USA-03011-01     |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                  | Lexapro               |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2004                                            | 4210528               | NON-EXPEDITED    | N                  | OT              | S04-USA-04959-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                          | Lexapro               |                  |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                        | Lexapro               |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Mysoline              |                  |                    | C               |                      |                      |                 | Not Reported |                |

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|                       |   |              |
|-----------------------|---|--------------|
| Gabitril              | C | Not Reported |
| Geodon                | C | Not Reported |
| Adderall Ar           | C | Not Reported |
| Doxepin               | C | Not Reported |
| Cogentin              | C | Not Reported |
| Levoxyl               | C | Not Reported |
| Nexium (Esomeprazole) | C | Not Reported |
| Crestor               | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 4210530       | NON-EXPEDITED    | Y                  | HO              | S04-USA-03010-01     |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Bleeding<br>Time Prolonged;<br>Hypersensitivity | Lexapro                    |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                      | Calcium Carbonate          |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                      | Potassium                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Prilosec                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Xanax                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Citrucel (Methylcellulose) |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Zocor                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 4210540       | NON-EXPEDITED    | N                  | OT              | S04-USA-04957-01     |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tremor                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Premarin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 4210543       | NON-EXPEDITED    | N                  | OT              | S04-USA-04943-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dry Skin; Hypotension;<br>Somnolence; Tongue<br>Blistering | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                            | Toprol XL      |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |                                             |                  |                    |                 |                      |                      |                 |                                              |                |
|-----------------------------------------------------------|---------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| Plavix                                                    |                                             | C                |                    | Not Reported    |                      |                      |                 |                                              |                |
| Klonopin                                                  |                                             | C                |                    | Not Reported    |                      |                      |                 |                                              |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 10-Sep-2004                                               | 4210546                                     | NON-EXPEDITED    | Y                  | HO              | S04-USA-04851-01     |                      | 50 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Thrombocytopenia                                          | Lexapro                                     |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 10-Sep-2004                                               | 4210550                                     | NON-EXPEDITED    | Y                  | OT              | S04-USA-04613-01     |                      | 45 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Bronchitis;<br>Electrocardiogram Qt<br>Prolonged; Vertigo | Lexapro                                     |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 10-Sep-2004                                               | 4210555                                     | NON-EXPEDITED    | Y                  | OT              | S04-USA-04181-01     |                      | 25 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Electrocardiogram Qt<br>Prolonged                         | Lexapro<br>Paxil<br>Methadone Hydrochloride |                  |                    | S<br>C<br>C     |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 10-Sep-2004                                               | 4210605                                     | NON-EXPEDITED    | Y                  | OT              | S04-USA-03938-01     |                      | 20 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anaemia                                                   | Lexapro                                     |                  |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported                                 |                |
|                                                           | Lexapro                                     |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported                                 |                |
|                                                           | Unspecified Ingredient                      |                  |                    | C               |                      |                      |                 | Not Reported                                 |                |
|                                                           | Atarax                                      |                  |                    | C               |                      |                      |                 | Not Reported                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
|--------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|------------------------------|
| 10-Sep-2004              | 4210608           | NON-EXPEDITED    | Y                  | OT              | S04-USA-03771-01     |                      |                 | Unknown    | USA                          |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                              |
| Weight Increased         | Lexapro           |                  |                    | S               |                      |                      |                 |            | Not Reported                 |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 10-Sep-2004              | 4210610           | NON-EXPEDITED    | Y                  | HO              | S04-USA-03713-01     |                      |                 | Female     | USA                          |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                              |
| Hyponatraemia            | Lexapro           |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported                 |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 10-Sep-2004              | 4210611           | NON-EXPEDITED    | N                  | HO              | S04-USA-03700-01     |                      | 53 YR           | Male       | USA                          |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                              |
| Hypertension             | Lexapro           |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported                 |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 10-Sep-2004              | 4210613           | NON-EXPEDITED    | Y                  | OT              | S04-USA-03699-01     |                      |                 | Unknown    | USA                          |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                              |
| Mania                    | Lexapro<br>Celexa |                  |                    | S<br>S          |                      |                      |                 |            | Not Reported<br>Not Reported |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 10-Sep-2004              | 4210616           | NON-EXPEDITED    | Y                  | OT              | S04-USA-03597-04     |                      |                 | Unknown    | USA                          |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                              |
| Dystonia                 | Lexapro           |                  |                    | S               |                      |                      |                 |            | Not Reported                 |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Sep-2004                                                                                | 4210618                 | NON-EXPEDITED             | Y                           | OT                       | S04-USA-03597-03              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia                                                                                   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2004                                                                                | 4210620                 | NON-EXPEDITED             | Y                           | OT                       | S04-USA-03597-02              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia                                                                                   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2004                                                                                | 4210622                 | NON-EXPEDITED             | Y                           | OT                       | S04-USA-03597-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia                                                                                   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2004                                                                                | 4210623                 | NON-EXPEDITED             | Y                           | HO                       | S04-USA-03279-01              |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                                                                              | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2004                                                                                | 4210934                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-UKI-03968-01              |                               | 24 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastritis;<br>Gastrooesophageal Reflux<br>Disease; Haematemesis;<br>Upper Gastrointestinal | Cipraxel                |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haemorrhage

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2004              | 5664250       | NON-EXPEDITED    | Y                  | HO              | S04-USA-01957-01     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Sep-2004              | 4092603       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00419-01     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Pain; Dilatation     | Lexapro               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Atrial; Electrocardiogram  | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Qt Prolonged; Mitral Valve | Lexapro               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Incompetence; Treatment    | Zonegran              |              |            | S           |              |                    |                 | Not Reported |
| Noncompliance;             | Klonopin              |              |            | C           |              |                    |                 | Not Reported |
| Ventricular Hypertrophy    | Flexeril              |              |            | C           |              |                    |                 | Not Reported |
|                            | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
|                            | Bextra                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Sep-2004              | 4212128       | EXPEDITED (15-DAY) | Y                  | HO              | LBID00204003065      |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;              | Lithium Carbonate             |              |            | S           | Oral         | Po, 300 Mg Qid Po  |                 | Not Reported |
| Atrioventricular Block First | Methylphenidate Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Degree; Blood Thyroid        | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
| Stimulating Hormone          | Clonidine (Clonidine)         |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Chest Pain;       |                               |              |            |             |              |                    |                 |              |
| Conduction Disorder;         |                               |              |            |             |              |                    |                 |              |
| Diarrhoea; Disorientation;   |                               |              |            |             |              |                    |                 |              |
| Dizziness; Drug Level        |                               |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Above Therapeutic;  
Electrocardiogram Qrs  
Complex Prolonged; Fluid  
Intake Reduced;  
Hyperhidrosis;  
Hypophagia; Hypotension;  
Mania; Pallor; Palpitations;  
Tachyarrhythmia; Toxicity  
To Various Agents;  
Ventricular Extrasystoles;  
Ventricular Tachycardia;  
Vomiting; White Blood Cell  
Count Increased

| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|------------------------------|----------------|
| 13-Sep-2004                                                                                                                  | 4212818              | DIRECT             | Y                  | DS              |                      |                              | 51 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Burning<br>Sensation; Disorientation;<br>Medication Error; Pain In<br>Extremity; Pruritus                           | Lexapro<br>Neurontin |                    |                    | S<br>S          |                      | 1 / Day<br>2 / Day As Needed |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Sep-2004                                                                                                                  | 4206275              | EXPEDITED (15-DAY) | Y                  | CA              | S04-SAF-03887-01     |                              | 41 YR           | Female                       | ZAF            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abortion Induced;<br>Complication Of<br>Pregnancy; Maternal<br>Exposure During<br>Pregnancy; Stress;<br>Unintended Pregnancy | Ciprallex            |                    |                    | S               | Oral                 | 5mg Qd Po                    |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Sep-2004                                                                                                                  | 4212352              | DIRECT             | Y                  | OT              |                      |                              | 41 YR           | Female                       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Agitation; Anxiety;<br>Influenza Like Illness;<br>Insomnia; Paraesthesia;<br>Sexual Dysfunction | Lexapro               |                    |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2004                                                                                     | 4212533               | DIRECT             | Y                  | OT              |                      |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion                                                                                       | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Daily Oral     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2004                                                                                     | 4214988               | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06016-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Completed<br>Suicide; Gun Shot Wound                                                   | Lexapro               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                 | Teventen (Eprosartan) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2004                                                                                     | 4213177               | DIRECT             | N                  | DE              |                      |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Homicide                                                                  | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2004                                                                                     | 4214067               | DIRECT             | Y                  | LT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Bipolar I<br>Disorder; Condition                                                     | Zoloft                |                    |                    | S               |                      | 100 Mg Am            | 1 YR            | Not Reported |                |
| Aggravated; Depression;                                                                         | Lexapro               |                    |                    | S               |                      | 10 Mg Am             | 1 MTH           | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Feeling Of Despair;  
Feelings Of  
Worthlessness; Insomnia;  
Irritability; Panic Reaction;  
Paranoia; Psychotic  
Disorder; Speech  
Disorder; Stress; Suicidal  
Ideation; Weight Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2004              | 4215373       | DIRECT           | Y                  | HO              |                      |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Dizziness; Dyspnoea;<br>Medication Error;<br>Palpitations | Lexapro        |              |            | S           | Oral         | 2 Tablets Po/ Prior To<br>Admssion |                 | Not Reported |
|                                                                                        | Xanax          |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                        | Feosol         |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2004              | 4216026       | DIRECT           | N                  | OT              |                      |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Child Abuse;<br>Euphoric Mood; Feeling<br>Abnormal; Hallucinations,<br>Mixed; Mania; Sexual<br>Abuse; Sexual<br>Dysfunction | Lexapro        |              |            | S           |              | 2 At Bedtime       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Sep-2004              | 4209581       | EXPEDITED (15-DAY) | Y                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12696381 |                      | 80 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                           |
|-------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------------------------|
| Confusional State; Drug<br>Interaction; Fall; Mental<br>Status Changes; | Sinemet<br>Lexapro |              |            | S<br>S      | Oral         |                    |                 | Bristol Myers Squibb<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Parkinson'S Disease

| <u>FDA Received Date</u>                                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------------------------|----------------|
| 16-Sep-2004                                                                            | 4215861                                 | EXPEDITED (15-DAY) | Y                  | OT              | S01-USA-06025-02          |                      |                 | Unknown                      | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Foetal Growth Restriction;<br>Maternal Exposure During<br>Pregnancy; Premature<br>Baby | Lexapro                                 |                    |                    | S               |                           |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Sep-2004                                                                            | 4217347                                 | DIRECT             | N                  | HO, OT          |                           |                      | 17 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depression; Drug<br>Ineffective; Off Label Use;<br>Seizure                             | Neurontin<br>Lexapro                    |                    |                    | S<br>S          |                           |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 17-Sep-2004                                                                            | 4220999                                 | NON-EXPEDITED      | Y                  | OT              | US-JNJFOC-<br>20040304012 |                      | 53 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Thrombocytopenia                                                                       | Topamax                                 |                    |                    | S               |                           | 300 Mg, In 1 Day     |                 | Not Reported                 |                |
|                                                                                        | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | S               |                           | 200 Mg, 2 In 1 Day   |                 | Not Reported                 |                |
|                                                                                        | Lexapro                                 |                    |                    | S               |                           | 20 Mg, In 1 Day      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-Sep-2004                                                                            | 4218910                                 | EXPEDITED (15-DAY) | Y                  | HO              | T04-USA-04025-00          |                      | 60 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Disorientation; Drug<br>Interaction;                                                   | Lexapro                                 |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |            |   |      |               |              |
|----------------------------------------------|------------|---|------|---------------|--------------|
| Hypersensitivity; Toxicity To Various Agents | Vistaril   | S | Oral | 50 Mg Qd Po   | Not Reported |
|                                              | Alprazolam | S | Oral | 0.25 Mg Qd Po | Not Reported |
|                                              | Metrogel   | S |      |               | Not Reported |
|                                              | Metrogel   | S |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2004              | 4221160       | DIRECT           | Y                  | OT              |                      |                      | 56 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disturbance In Attention; Feeling Abnormal; | Prozac         |              |            | S           |              | 20 -60 Mg          |                 | Not Reported |
| Hypoaesthesia; Pain;                        | Lexapro        |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Product Quality Issue;                      | Sonata         |              |            | C           |              |                    |                 | Not Reported |
| Sensory Disturbance;                        | Premarin Cream |              |            | C           |              |                    |                 | Not Reported |
| Thinking Abnormal                           | Ultracet       |              |            | C           |              |                    |                 | Not Reported |
|                                             | Lasix          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2004              | 4221498       | DIRECT           |                    | OT              |                      |                      | 26 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Anger; Condition                                                                                                                                                                                                               | Lexapro        |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
| Aggravated; Crying; Delusion; Depressed Mood; Disturbance In Attention; Drug Ineffective; Feeling Abnormal; Feeling Of Despair; Hypophagia; Irritability; Loss Of Employment; Personality Change; Social Fear; Thinking Abnormal; Weight Decreased | Lexapro        |              |            | S           |              | 10 Daily           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2004              | 5682296       | NON-EXPEDITED    | Y                  | HO              | S03-USA-05040-01     |                      | 48 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hyponatraemia                                                                        | Celexa                             |                    |                    | S               | Oral                 | 60 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Gabapentin                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Albuterol                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2004                                                                          | 4208840                            | EXPEDITED (15-DAY) | Y                  | DS              | S04-SWI-03896-01     |                      | 48 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Loss Of Consciousness; Road Traffic Accident                                | Cipralext                          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Cipralext                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                      | Femoston Estradiol/ Dydrogesterone |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Ponstel                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2004                                                                          | 4219123                            | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-04153-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous Complete; Maternal Exposure During Pregnancy; Pregnancy         | Cipralext                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2004                                                                          | 4219797                            | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06113-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Economic Problem; Gun Shot Wound; Refusal Of Treatment By Patient | Lexapro                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                      | Effexor                            |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2004              | 6747133       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20040903645 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Ph Decreased; Blood Potassium Increased; Bradycardia; Cardiac Arrest; Coma; Hypertension; Hypotension; Pco2 Decreased; Po2 Decreased; Respiratory Depression; Suicide Attempt | Tylenol                   |              | Y          | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                         | Desipramine Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                         | Lorazepam                 |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram Oxalate      |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2004              | 7879635       | NON-EXPEDITED    | Y                  | HO, OT          | 163-20785-03110514   |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder; Depressed Level Of Consciousness; Depression; Fatigue; Generalised Tonic-Clonic Seizure; Headache; Hypoaesthesia; Musculoskeletal Stiffness; Oedema Peripheral; | Thalomid       |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                                                                                                                                                                   |                |              |            |             | Oral         | See Image          |                 |              |
|                                                                                                                                                                                   | Temodar        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Celebrex       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Ambien         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Dilantin       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                   | Lasix          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                       |   |              |
|-----------------------------------------------|-----------------------|---|--------------|
| Restlessness; Sedation;<br>Somnolence; Tremor | Premarin              | C | Not Reported |
|                                               | Decadron              | C | Not Reported |
|                                               | Nexium (Esomeprazole) | C | Not Reported |
|                                               | Ativan                | C | Not Reported |
|                                               | Zofran                | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2004              | 4177605       | EXPEDITED (15-DAY) | N                  | RI, OT          | S04-USA-04018-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia; Blood Pressure<br>Fluctuation; Erectile<br>Dysfunction; Exostosis;<br>Fracture; Hypertension;<br>Joint Dislocation; Nausea;<br>Somnolence | Lexapro                                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                     | Lotrel                                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Clonidine                               |              |            | S           |              | 0.2 Mg Bid         |                 | Not Reported |
|                                                                                                                                                     | Amiloride Hcl W/<br>Hydrochlorothiazide |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Percocet                                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Percocet                                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Wellbutrin Sr                           |              |            | S           |              | 150 Mg             |                 | Not Reported |
|                                                                                                                                                     | Bextra                                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Trazodone Hydrochloride                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Nexium (Esomeprazole)                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Carisoprodol                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2004              | 4202970       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05546-01     |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diastolic Dysfunction;<br>Mitral Valve<br>Incompetence; Tricuspid<br>Valve Incompetence;<br>Ventricular Extrasystoles | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                       | Loestrin 1.5/30 21 Day |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2004              | 4215606       | EXPEDITED (15-DAY) |                    | HO, OT          | 2004-DE-04634GD      |                      | 10 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Abdominal Pain;<br>Atrioventricular Block First Degree; Chest Pain;<br>Diarrhoea; Disorientation;<br>Dizziness; Drug Interaction; Hyperhidrosis; Hypophagia; Hypotension; Hypothyroidism; Pallor; Palpitations; Rhythm Idioventricular; Toxicity To Various Agents; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased | Lithium Carbonate       |                    |                    | S               |                      | 1200 Mg Twice Daily                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Clonidine Hydrochloride |                    |                    | S               |                      | 0.4 Mg (Twice Daily)                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Methylphenidate         |                    |                    | S               |                      | 36 Mg (Once Daily) (In The Morning) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg (Once Daily)                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Oxcarbazepine           |                    |                    | S               |                      | 600 Mg (Once Daily)                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Depakote                |                    |                    | S               |                      | See Image                           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Levothyroxine Sodium    |                    |                    | S               |                      | 0.05 Mg (Once Daily)                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    |                         |                    |                    |                 |                      |                                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2004                                                                                                                                                                                                                                                                                                                                                        | 4219865                 | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-06147-01     |                                     | 18 YR           | Male         | USA            |
|                                                                                                                                                                                                                                                                                                                                                                    |                         |                    |                    |                 |                      |                                     |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                                                                                                                                                                                                  | Lexapro                 |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    |                         |                    |                    |                 |                      |                                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2004                                                                                                                                                                                                                                                                                                                                                        | 4221115                 | DIRECT             | Y                  | RI              |                      |                                     | 70 YR           | Male         | USA            |
|                                                                                                                                                                                                                                                                                                                                                                    |                         |                    |                    |                 |                      |                                     |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Drug Interaction; Haematoma                                                                                                                                                                                                                                                                                                                             | Warfarin Sodium         |                    |                    | S               |                      | 7.5 Mg M/W/F & 5 Mg Other           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               |                      | Alt 1 Tab Qd W/ 0.5 Qod             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Coreg                   |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Atacand                 |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Lipitor                 |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Furosemide              |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Propoxy/Apap            |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                    | Unspecified Ingredient  |                    |                    | C               |                      |                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Sep-2004                            | 4104971               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-00838-01     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Facial Paralysis           | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Klonopin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Arthrotec             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Ativan                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Vicodin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2004                            | 4194866               | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-04729-01     |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mouth Ulceration; Tongue Ulceration    | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                        | Lexapro               |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Zoloft                |                    |                    | S               |                      | 150 Mg Qd Po         |                 | Not Reported |                |
|                                        | Topamax               |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                        | Vioxx                 |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                        | Zocor                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Nexium (Esomeprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Mirapex               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2004                            | 4222983               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06150-01     |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Drug Level Increased | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                        | Lexapro               |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Lexapro               |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Lexapro               |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |



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|                                                                               | Lexapro        |                    | S                  | Oral            | 10 Mg Qd Po          |                      | Not Reported    |            |                |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
|                                                                               | Clozaril       |                    | S                  |                 | 500 Mg Qd            |                      | Not Reported    |            |                |
|                                                                               | Colace         |                    | C                  |                 |                      |                      | Not Reported    |            |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Sep-2004                                                                   | 4222470        | DIRECT             | Y                  | OT              |                      |                      | 52 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hyponatraemia                                                                 | Lexapro        |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Sep-2004                                                                   | 4223302        | DIRECT             | N                  | HO, LT, RI      |                      |                      | 37 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased;<br>Malignant Hypertension                               | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Once Oral      |                 |            | Forest         |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Sep-2004                                                                   | 4223909        | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWE-04214-01     |                      | 12 YR           | Female     | SWE            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Loss Of Consciousness;<br>Overdose                                            | Ciprallex      |                    |                    | S               | Oral                 | 220 Mg Once Po       |                 |            | Not Reported   |
|                                                                               | Ciprallex      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 |            | Not Reported   |
|                                                                               | Remeron        |                    |                    | S               |                      | 90 Mg Once           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Sep-2004                                                                   | 4224703        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06176-01     |                      | 36 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Alcohol Increased;<br>Completed Suicide; Gun<br>Shot Wound; Intentional | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                               | Buspar         |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                               | Insulin Nos    |                    |                    | C               |                      |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                |                    |                    |                 |                                      |                        |                 |            |                 |
|----------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|------------------------|-----------------|------------|-----------------|
| Self-Injury; Stress        | Metformin      |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
|                            | Starlix        |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
|                            | Lantus         |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 29-Sep-2004                | 4188598        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-04373-01                     |                        | 21 YR           | Male       | USA             |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                 |
| Rhabdomyolysis             | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po            |                 |            | Not Reported    |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 29-Sep-2004                | 4199905        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04958-01                     |                        | 47 YR           | Male       | USA             |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                 |
| Condition Aggravated;      | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po            |                 |            | Not Reported    |
| Diabetes Mellitus          | Lexapro        |                    |                    | S               | Oral                                 | 20 Mg Qd Po            |                 |            | Not Reported    |
| Inadequate Control;        |                |                    |                    |                 |                                      |                        |                 |            |                 |
| Hypoglycaemia; Loss Of     | Insulin Nos    |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
| Consciousness; Vision      | Percocet       |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
| Blurred                    | Topamax        |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 30-Sep-2004                | 4129526        | EXPEDITED (15-DAY) | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0506106A |                        | 42 YR           | Female     | USA             |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                 |
| Drug Ineffective; Feeling  | Wellbutrin XI  |                    |                    | S               | Oral                                 |                        |                 |            | Glaxosmithkline |
| Abnormal; Libido Disorder; | Wellbutrin     |                    |                    | S               |                                      | 150mg Per Day          |                 |            | Glaxosmithkline |
| Medication Error; Nausea;  | Paxil Cr       |                    |                    | S               |                                      | 12.5mg See Dosage Text |                 |            | Glaxosmithkline |
| Nightmare; Tobacco User    | Xanax          |                    |                    | S               |                                      |                        |                 |            | Not Reported    |
|                            | Lexapro        |                    |                    | S               |                                      |                        |                 |            | Not Reported    |
|                            | Seroquel       |                    |                    | C               |                                      |                        |                 |            | Not Reported    |
|                            | Advair Diskus  |                    |                    | C               |                                      |                        |                 |            | Glaxosmithkline |
|                            | Albuterol      |                    |                    | C               |                                      |                        |                 |            | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Sep-2004                                                                                 | 4223963                 | DIRECT             | N                  | OT              |                      |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Asthenia; Crying;<br>Feeling Abnormal;<br>Paraesthesia; Self-<br>Injurious Ideation | Lexapro                 |                    |                    | S               | Oral                 | 1 A Day Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2004                                                                                 | 4224883                 | DIRECT             | Y                  | DS, RI          |                      |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia                                                                                    | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Forest       |                |
|                                                                                             | Kcl                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Celebrex                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Amaryl                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Nifedipine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Zocor                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Toprol XL               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Plavix                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2004                                                                                 | 4196124                 | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-04780-01     |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Blood Pressure<br>Fluctuation;                                                      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Catecholamines Urine<br>Increased; Chest Pain;                                              | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Dyspnoea; Fatigue; Heart<br>Rate Increased; Tremor                                          | Verapamil Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Accupril                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Metformin Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Xanax                   |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 01-Oct-2004                                                                                                                                                                                                                                                                                              | 4206216                     | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05564-01     |                      | 23 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abortion Spontaneous;<br>Asthenia; Blood Thyroid<br>Stimulating Hormone<br>Decreased; Haemorrhage<br>In Pregnancy; Human<br>Chorionic Gonadotropin<br>Decreased; Maternal<br>Exposure During<br>Pregnancy; Pregnancy;<br>Respiratory Rate<br>Increased; Stress;<br>Tobacco Abuse; Vaginal<br>Haemorrhage | Lexapro<br>Methamphetamines |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 01-Oct-2004                                                                                                                                                                                                                                                                                              | 4223860                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-AUS-04156-01     |                      | 21 YR           | Female                       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Chest Pain;<br>Electrocardiogram<br>Change;<br>Electrocardiogram T Wave<br>Inversion                                                                                                                                                                                                                     | Lexapro<br>Triphasil-21     |                    |                    | S<br>C          | Oral                 | 20 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 01-Oct-2004                                                                                                                                                                                                                                                                                              | 5666892                     | EXPEDITED (15-DAY) | Y                  | HO              | S04-BEL-04992-01     |                      | 67 YR           | Female                       | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Generalised Erythema;<br>Pruritus; Rash Maculo-<br>Papular                                                                                                                                                                                                                                               | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Oct-2004                | 4105356               | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-00834-01     |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;        | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Asthenia; Atelectasis;     | Celebrex              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Blood Creatine             | Lorazepam             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Phosphokinase Increased;   | Xanax                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Blood Creatine             | Aciphex               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Phosphokinase Mb           | Tylenol (Paracetamol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Abnormal; Blood Glucose    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Increased; Blood Sodium    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Candida         |                       |                    |                    |                 |                      |                      |                 |              |                |
| Infection; Catatonia;      |                       |                    |                    |                 |                      |                      |                 |              |                |
| Cerebral Infarction; Chest |                       |                    |                    |                 |                      |                      |                 |              |                |
| X-Ray Abnormal; Coma;      |                       |                    |                    |                 |                      |                      |                 |              |                |
| Communication Disorder;    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Confusional State;         |                       |                    |                    |                 |                      |                      |                 |              |                |
| Corneal Reflex             |                       |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Cortisol        |                       |                    |                    |                 |                      |                      |                 |              |                |
| Increased; Csf Myelin      |                       |                    |                    |                 |                      |                      |                 |              |                |
| Basic Protein Increased;   |                       |                    |                    |                 |                      |                      |                 |              |                |
| Culture Urine Positive;    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Cyst; Decreased Appetite;  |                       |                    |                    |                 |                      |                      |                 |              |                |
| Diarrhoea; Eating          |                       |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Encephalitis     |                       |                    |                    |                 |                      |                      |                 |              |                |
| Viral; Fatigue; Feeling    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Abnormal; Haematuria;      |                       |                    |                    |                 |                      |                      |                 |              |                |
| Hepatic Enzyme             |                       |                    |                    |                 |                      |                      |                 |              |                |
| Increased;                 |                       |                    |                    |                 |                      |                      |                 |              |                |
| Hyponatraemia;             |                       |                    |                    |                 |                      |                      |                 |              |                |
| Hypothyroidism;            |                       |                    |                    |                 |                      |                      |                 |              |                |
| Inappropriate Antidiuretic |                       |                    |                    |                 |                      |                      |                 |              |                |
| Hormone Secretion; Liver   |                       |                    |                    |                 |                      |                      |                 |              |                |
| Function Test Abnormal;    |                       |                    |                    |                 |                      |                      |                 |              |                |
| Meningoencephalitis        |                       |                    |                    |                 |                      |                      |                 |              |                |
| Herpetic; Myalgia;         |                       |                    |                    |                 |                      |                      |                 |              |                |
| Nausea; Pleural Effusion;  |                       |                    |                    |                 |                      |                      |                 |              |                |
| Pneumonia; Pneumonia       |                       |                    |                    |                 |                      |                      |                 |              |                |
| Aspiration; Respiratory    |                       |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Restlessness;  
Rhabdomyolysis; Shift To  
The Left; Status  
Epilepticus; Troponin I  
Increased; Vomiting;  
Weight Decreased; White  
Blood Cell Count  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 4116787       | EXPEDITED (15-DAY) | Y                  | CA, OT          | S04-USA-01398-01     |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bacterial Vulvovaginitis; | Lexapro           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Chlamydial Infection;     | Lexapro           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Creatinine Urine          | Valium            |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Maternal       | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported |
| Exposure During           | Zoloft            |              |            | C           |              |                    |                 | Not Reported |
| Pregnancy; Pregnancy;     |                   |              |            |             |              |                    |                 | Not Reported |
| Uterine Contractions      |                   |              |            |             |              |                    |                 | Not Reported |
| During Pregnancy          |                   |              |            |             |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 4136007       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-02164-01     |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract; Eye             | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Haemorrhage; Eye Pain;    | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Retinal Disorder; Retinal | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Vein Occlusion;           | Cosamin Ds     |              |            | C           |              |                    |                 | Not Reported |
| Somnolence;               |                |              |            |             |              |                    |                 | Not Reported |
| Vasodilatation; Visual    |                |              |            |             |              |                    |                 | Not Reported |
| Acuity Reduced; Visual    |                |              |            |             |              |                    |                 | Not Reported |
| Field Defect              |                |              |            |             |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 4214986       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06024-01     |                      | 33 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Affective Disorder;<br>Aggression; Agitation;<br>Blood Pressure Increased;<br>Condition Aggravated;<br>Dyskinesia; Hallucination,<br>Visual; Heart Rate<br>Increased; Intentional Self-<br>Injury; Intentional Self-<br>Injury; Intermittent<br>Explosive Disorder; Major<br>Depression; Personality<br>Change Due To A General<br>Medical Condition; Social<br>Avoidant Behaviour;<br>Suicidal Ideation; Wound | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Dilantin                |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Seroquel                |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Depakote                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2004                                                                                                                                                                                                                                                                                                                                                                                                                            | 4215652                 | EXPEDITED (15-DAY) | N                  | HO              | 2004062385           |                          | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug<br>Interaction;<br>Hypersensitivity; Toxicity<br>To Various Agents                                                                                                                                                                                                                                                                                                                                                | Vistaril                |                    |                    | S               | Oral                 | 50 Mg (1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Alprazolam (Alprazolam) |                    |                    | S               | Oral                 | 0.25 Mg (1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Metronidazole           |                    |                    | S               | Topical              | (2 In 1 D), Topical      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Oct-2004                                                                                                                                                                                                                                                                                                                                                                                                                            | 5665174                 | DIRECT             | Y                  | HO              |                      |                          | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Blood Pressure<br>Decreased; Faeces<br>Discoloured; Hepatic<br>Enzyme Increased;                                                                                                                                                                                                                                                                                                                                | Lexapro                 |                    |                    | S               |                      | 10 Mg Once Daily         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Trileptal               |                    |                    | S               |                      | Mg Bid                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Levaquin                |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prevacid                |                    |                    | C               |                      |                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                                              |                  |  |  |  |  |  |                                                              |
|-------------------------------------------------------------------|----------------------------------------------|------------------|--|--|--|--|--|--------------------------------------------------------------|
| Myopathy; Pneumonia;<br>Respiratory Disorder;<br>Weight Decreased | Albuterol<br>Trileptal<br>Remeron<br>Lexapro | C<br>C<br>C<br>C |  |  |  |  |  | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------|----------------------------------------------|------------------|--|--|--|--|--|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 5665328       | EXPEDITED (15-DAY) | Y                  | CA, OT          | S04-USA-01398-02     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-----------------------|--------------|----------------------------|-----------------|------------------------------------------------------------------------------|
| Cardiac Disorder;<br>Maternal Exposure During<br>Pregnancy; Pulmonary<br>Artery Atresia; Truncus<br>Arteriosus Persistent;<br>Uterine Contractions<br>During Pregnancy | Lexapro<br>Lexapro<br>Valium<br>Prenatal Vitamins<br>Zoloft |              |            | S<br>S<br>C<br>C<br>C | Oral<br>Oral | 10 Mg Qd Po<br>10 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 5665400       | DIRECT           | N                  | HO, RI          |                      |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|------------------------------|
| Abnormal Behaviour;<br>Aggression; Hostility;<br>Legal Problem; Suicidal<br>Ideation | Zoloft<br>Lexapro |              |            | S<br>S      | Oral         | 1 Pill Daily Oral<br>1 Pill Daily |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2004              | 5665507       | DIRECT           | N                  |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-----------------------------------|--------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Mood Swings; Suicidal<br>Ideation | Lexapro<br>Microgestin Fe<br>Claritin<br>Flonase |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Daily Oral   |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 05-Oct-2004               | 6564589                   | EXPEDITED (15-DAY) | Y                  | HO              | 2004070771           |                           | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;       | Ziprasidone Hydrochloride |                    |                    | S               |                      | 40 Mg (20 Mg , 2 In 1 D)  |                 | Not Reported |                |
| Aggression; Agitation;    | Carbamazepine             |                    |                    | S               |                      | 400 Mg (200 Mg, 2 In 1 D) |                 | Not Reported |                |
| Condition Aggravated;     | Gabapentin                |                    |                    | S               |                      | 900 Mg (300 Mg In 1 D)    |                 | Not Reported |                |
| Confusional State;        | Escitalopram Oxalate      |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)   |                 | Not Reported |                |
| Disorientation;           |                           |                    |                    |                 |                      |                           |                 |              |                |
| Disturbance In Attention; |                           |                    |                    |                 |                      |                           |                 |              |                |
| Drug Ineffective;         |                           |                    |                    |                 |                      |                           |                 |              |                |
| Hallucinations, Mixed;    |                           |                    |                    |                 |                      |                           |                 |              |                |
| Incoherent; Mood Swings;  |                           |                    |                    |                 |                      |                           |                 |              |                |
| Speech Disorder           |                           |                    |                    |                 |                      |                           |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2004               | 4180784                   | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04184-01     |                           | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Headache;           | Lexapro                   |                    |                    | S               | Oral                 | 5 Mg Qd Po                |                 | Not Reported |                |
| Incoherent; Memory        | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
| Impairment; Seizure;      |                           |                    |                    |                 |                      |                           |                 |              |                |
| Tongue Biting             |                           |                    |                    |                 |                      |                           |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2004               | 4209226                   | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-05888-01     |                           | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;         | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
| Concussion; Confusional   | Sinemet                   |                    |                    | S               |                      |                           |                 | Not Reported |                |
| State; Drug Interaction;  | Sinemet                   |                    |                    | S               |                      |                           |                 | Not Reported |                |
| Fall; Gait Disturbance;   | Sinemet                   |                    |                    | S               |                      |                           |                 | Not Reported |                |
| Mental Status Changes     |                           |                    |                    |                 |                      |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Oct-2004                                                                                                                                                                     | 5667120        | DIRECT             | N                  | DS, HO          |                      |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Disorientation; Dizziness;<br>Fatigue; Feeling<br>Abnormal; Influenza Like<br>Illness; Loss Of Libido;<br>Nausea; Suicidal Ideation;<br>Weight Increased | Lexapro        |                    |                    | S               | Oral                 | 10mg Once A Day Oral |                 | Forest       |                |
|                                                                                                                                                                                 | Cardizem       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2004                                                                                                                                                                     | 5667133        | DIRECT             | N                  | DS, HO          |                      |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Disorientation; Dizziness;<br>Fatigue; Feeling<br>Abnormal; Influenza Like<br>Illness; Loss Of Libido;<br>Nausea; Suicidal Ideation;<br>Weight Increased | Lexapro        |                    |                    | S               | Oral                 | 10mg Once A Day Oral |                 | Forest       |                |
|                                                                                                                                                                                 | Cardizem       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Atenolol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2004                                                                                                                                                                     | 5668232        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06434-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose;<br>Toxicologic Test Abnormal                                                                                                        | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2004                                                                                                                                                                     | 4224938        | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2004US10486      |                      | 27 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug Level Above Therapeutic; Hallucination, Auditory | Clozaril       |              |            | S           | Oral         | 500 Mg, Qd         |                 | Novartis     |
|                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                         | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                                                         | Colace         |              |            | C           |              | 100 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2004              | 5669264       | EXPEDITED (15-DAY) | Y                  | HO              | T04-GER-06043-01     |                      | 90 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased; Drug Interaction; Gastrointestinal Ulcer Haemorrhage; Haemorrhagic Diathesis | Cipralext                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                      | Enoxaparin Sodium               |              |            | S           | Subcutaneous | 20 Mg Qd, Sc       |                 | Not Reported |
|                                                                                                      | Clopidogrel                     |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
|                                                                                                      | Vioxx                           |              |            | S           | Oral         | 12.5 Mg Qd Po      |                 | Not Reported |
|                                                                                                      | Avelox                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Disalunil (Hydrochlorothiazide) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Pantozol (Pantoprazole Sodium)  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Zocor                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2004              | 5650248       | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2004070987           |                      | 29 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest | Doxepin Hydrochloride  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                             | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Mirtazapine            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2004              | 5666981       | EXPEDITED (15-DAY) | Y                  | HO              | A044-002-005206      |                      | 77 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Bradycardia; Dizziness;<br>Drug Interaction; General<br>Physical Health<br>Deterioration;<br>Hyperkalaemia; Nausea;<br>Renal Failure; Vomiting                                                        | Aricept                                 |                    |                    | S               | Oral                 | 5 Mg, 1 In 1 D, Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                       | Ciprallex                               |                    |                    | S               | Oral                 | 20 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Digitoxin                               |                    |                    | S               | Oral                 | 0.07 Mg 5x Weekly, Oral |                 | Not Reported |                |
|                                                                                                                                                                                                       | Verapamil Hydrochloride                 |                    |                    | S               | Oral                 | 80 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Aldactone                               |                    |                    | S               | Oral                 | 25 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Bextra                                  |                    |                    | S               | Oral                 | 20 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Enalapril Maleate                       |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Furosemide (Furosemide)                 |                    |                    | S               | Oral                 | 40 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Clopidogrel                             |                    |                    | S               | Oral                 | 75 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                       | Insulin Nos                             |                    |                    | C               |                      |                         |                 | Not Reported |                |
| Thioctic Acid                                                                                                                                                                                         |                                         |                    | C                  |                 |                      |                         | Not Reported    |              |                |
| Insulin Nos                                                                                                                                                                                           |                                         |                    | C                  |                 |                      |                         | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2004                                                                                                                                                                                           | 5668363                                 | DIRECT             | Y                  | OT              |                      |                         | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Pyromania                                                                                                                                                                                  | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Oral           |                 | Not Reported |                |
|                                                                                                                                                                                                       | Seroquel                                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2004                                                                                                                                                                                           | 4061567                                 | EXPEDITED (15-DAY) | Y                  | HO              | S03-USA-05282-01     |                         | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Body Temperature<br>Decreased; Condition<br>Aggravated; Confusional<br>State; Depression;<br>Disorientation; Heart Rate<br>Increased; Hepatic<br>Encephalopathy; Hepatic | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                                       | Lactulose                               |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Aldactone                               |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Inderal                                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Lasix                                   |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure; Hepatitis C;  
Platelet Count Decreased;  
Prothrombin Time  
Prolonged; Somnolence;  
Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2004              | 4145738       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02679-01     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Bipolar I Disorder; Blood Pressure Increased; Confusional State; Delusion Of Grandeur; Delusional Perception; Dermatitis Exfoliative; Drug Ineffective; Encephalopathy; Grandiosity; Impulsive Behaviour; Limb Injury; Mania; Meningoencephalitis; Herpetic; Menorrhagia; Mental Disorder; Nail Discolouration; Neck Pain; Nuclear Magnetic Resonance Imaging Brain Abnormal; Post-Traumatic Neck Syndrome; Pruritus; Psychotic Disorder; Road Traffic Accident; Sexually Transmitted Disease; Tinea Pedis; West Nile Viral Infection | Lexapro<br>Vioxx<br>Protonix<br>Lipitor |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2004              | 5650899       | DIRECT           | Y                  | OT              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                      |   |                                          |                    |              |
|-------------------------------------------------------------------------------------------------------|----------------------|---|------------------------------------------|--------------------|--------------|
| Cardio-Respiratory Arrest;<br>Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Overdose | Meperidine           | S | Intravenous (not<br>otherwise specified) | 10 Mg Iv Prn (Pca) | Not Reported |
|                                                                                                       | Escitalopram Oxalate | S |                                          | 20 Mg Daily        | Not Reported |
|                                                                                                       | Claritin             | C |                                          |                    | Not Reported |
|                                                                                                       | Combivent            | C |                                          |                    | Not Reported |
|                                                                                                       | Serevent Diskus      | C |                                          |                    | Not Reported |
|                                                                                                       | Lexapro              | C |                                          |                    | Not Reported |
|                                                                                                       | Flonase              | C |                                          |                    | Not Reported |
|                                                                                                       | Seroquel             | C |                                          |                    | Not Reported |
|                                                                                                       | Flovent              | C |                                          |                    | Not Reported |
|                                                                                                       | Zyrtec               | C |                                          |                    | Not Reported |
|                                                                                                       | Prevacid             | C |                                          |                    | Not Reported |
|                                                                                                       | Asa                  | C |                                          |                    | Not Reported |
|                                                                                                       | Singulair            | C |                                          |                    | Not Reported |
|                                                                                                       | Pravachol            | C |                                          |                    | Not Reported |
|                                                                                                       | Gentamicin           | C |                                          |                    | Not Reported |
|                                                                                                       | Zosyn                | C |                                          |                    | Not Reported |
|                                                                                                       | Flagyl               | C |                                          |                    | Not Reported |
|                                                                                                       | Benadryl             | C |                                          |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2004              | 5652362       | DIRECT           | N                  | LT              |                      |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour;<br>Dizziness; Economic<br>Problem; Hostility;<br>Impulsive Behaviour;<br>Irritability; Job<br>Dissatisfaction; Mania;<br>Obsessive-Compulsive<br>Disorder; Partner Stress;<br>Personality Change;<br>Stress; Suicidal Ideation;<br>Verbal Abuse | Lexapro        |              |            | S           | Oral         | 1 Tab Daily Oral   |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2004              | 4130374       | EXPEDITED (15-DAY) | Y                  | DS              | S04-GER-01524-01     |                      | 62 YR      | Unknown    | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Breast Tenderness;<br>Muscle Spasms; Nausea;<br>Tinnitus; Tremor                                | Cipralelex           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2004                                                                                     | 4184924              | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-04304-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Cardiac<br>Arrest; Coma; Drug<br>Screen Positive;<br>Dyspnoea; Pulmonary<br>Oedema | Lexapro              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                 | Seroquel             |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                                                                                 | Neurontin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2004                                                                                     | 5652287              | EXPEDITED (15-DAY) | Y                  | DE              | K200401533           |                      | 30 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                                      | Cytomel              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                 | Fluoxetine           |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2004                                                                                     | 5652940              | EXPEDITED (15-DAY) | Y                  | LT              | S04-GER-02774-01     |                      | 86 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Skin Laceration; Suicide<br>Attempt                                                             | Cipralelex           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                 | Cipralelex           |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2004                                                                                                                                                                | 5669377                 | EXPEDITED (15-DAY) |                    | HO, OT          | DE-ABBOTT-04P-062-0276717-00 |                      | 77 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Bradycardia; Dialysis; Dizziness; Drug Interaction; Fluid Intake Reduced; General Physical Health Deterioration; Hyperkalaemia; Nausea; Renal Failure; Vomiting | Verapamil Hydrochloride |                    |                    | S               | Oral                         |                      | 3 YR            | Not Reported |                |
|                                                                                                                                                                            | Cipralex                |                    |                    | S               |                              |                      | 3 YR            | Not Reported |                |
|                                                                                                                                                                            | Digitoxin               |                    |                    | S               |                              |                      | 10 YR           | Not Reported |                |
|                                                                                                                                                                            | Spironolactone          |                    |                    | S               |                              |                      | 5 YR            | Not Reported |                |
|                                                                                                                                                                            | Valdecoxib              |                    |                    | S               |                              |                      | 10 DAY          | Not Reported |                |
|                                                                                                                                                                            | Enalapril Maleate       |                    |                    | S               |                              |                      | 5 YR            | Not Reported |                |
|                                                                                                                                                                            | Furosemide              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Clopidogrel Bisulfate   |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Donepezil Hydrochloride |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Insulin Nos             |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Lipon Acid              |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Insulin Nos             |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2004                                                                                                                                                                | 5651719                 | DIRECT             | Y                  | OT              |                              |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Epistaxis; Feeling Abnormal; Hypoaesthesia; Mydriasis                                                                                                           | Lexapro                 |                    |                    | S               | Oral                         | 10 Mg Daily Oral     |                 | Not Reported |                |
|                                                                                                                                                                            | Clonazepam              |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2004                                                                                                                                                                | 5651879                 | DIRECT             | N                  | LT              |                              |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Aggression; Anger; Anxiety; Condition Aggravated; Indifference                                                                                         | Lexapro                 |                    |                    | S               | Oral                         | Morning Night Oral   |                 | Forest       |                |
|                                                                                                                                                                            | Alprazolam              |                    |                    | C               |                              |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2004                                                                                                                                                                                                                          | 5683271                                 | NON-EXPEDITED      | Y                  | HO, OT          | 2003115804           |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                                                                                                                                                                                      | Neurontin                               |                    |                    | S               |                      | 900 Mg Tid           |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Escitalopram Oxalate                    |                    |                    | S               |                      | 10 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Praxiten Pliva (Oxazepam)               |                    |                    | S               |                      | 30 Mg Tid            |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Alcohol                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Nadolol                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2004                                                                                                                                                                                                                          | 5683281                                 | NON-EXPEDITED      | Y                  | OT              | 2003035281           |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract; Depression;<br>Vision Blurred                                                                                                                                                                                              | Neurontin                               |                    |                    | S               | Oral                 | 300 Mg Tid Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Escitalopram Oxalate                    |                    |                    | S               |                      | 10 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Methylphenidate Hydrochloride           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Unspecified Ingredient                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2004                                                                                                                                                                                                                          | 4147426                                 | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-02684-01     |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Carbon<br>Monoxide Poisoning;<br>Completed Suicide;<br>Condition Aggravated;<br>Death Of Relative;<br>Decreased Appetite;<br>Decreased Interest;<br>Disturbance In Attention;<br>Emotional Distress;<br>Feeling Abnormal; | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                                 |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                                 |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Remeron                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                |                                                           |                  |                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------|--------------------------------------------------------------|
| Generalised Anxiety Disorder; Hypersomnia; Major Depression; Malaise; Mood Altered; Paraesthesia; Partner Stress; Reading Disorder; Restlessness; Sleep Disorder; Terminal Insomnia; Therapeutic Product Effect Decreased; Thinking Abnormal; Weight Decreased | Zoloft<br>Lorazepam<br>Trazodone Hydrochloride<br>Zyprexa | C<br>C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2004              | 4191690       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04606-01     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Condition Aggravated; Diabetic Nephropathy; Polyuria | Lexapro<br>Celexa |              |            | S<br>C      | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2004              | 5653904       | DIRECT           | Y                  | OT              |                      |                      | 273 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                       |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------|
| Caesarean Section; Congenital Anomaly; Developmental Delay; Foetal Hypokinesia; Hypotonia; Maternal Drugs Affecting Foetus | Lexapro<br>Zoloft<br>Zantac |              |            | S<br>S<br>C | Oral<br>Oral | 10-20 Mg Qd Oral   |                 | Forest<br>Pfizer<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2004              | 5654213       | DIRECT           | Y                  | OT              |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |         |   |      |                                                |              |
|-------------------------------------------------|---------|---|------|------------------------------------------------|--------------|
| Inappropriate Antidiuretic<br>Hormone Secretion | Lexapro | S | Oral | 20 Mg Po Qd [Pta Prior To 2 WEEK<br>Admission] | Not Reported |
|-------------------------------------------------|---------|---|------|------------------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2004              | 5655046       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06734-02     |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Treatment<br>Noncompliance; Trisomy<br>21 | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2004              | 4189307       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04405-01     |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Amnesia; Loss Of<br>Consciousness; Postictal<br>State; Seizure; Tongue<br>Biting; Tonic Clonic<br>Movements | Lexapro<br>Dilantin<br>Klonopin<br>Prevacid |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2004              | 5655810       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06766-01     |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Band Neutrophil Count<br>Increased; Burning<br>Sensation; Confusional<br>State; Feeling Hot;<br>Generalised Tonic-Clonic<br>Seizure; Neutrophil Count<br>Increased; Postictal State;<br>White Blood Cell Count<br>Increased | Lexapro<br>Estratest<br>Menest |              |            | S<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2004              | 4148655       | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | S04-GER-02020-01     |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Atrioventricular Block; Blood Pressure Systolic Increased; Bradycardia; Bradypnoea; Coma; Cyanosis; Electrocardiogram Qt Prolonged; Heart Rate Increased; Hypotension; Impulsive Behaviour; Intentional Overdose; Major Depression; Malaise; Pallor; Suicide Attempt; Syncope; Tongue Disorder; Tremor; Vertigo | Escitalopram Oxalate  |              |            | S           | Oral         | 480 Mg Once Po     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Escitalopram Oxalate  |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Zyprexa               |              |            | S           | Oral         | 67 Tablet Once Po  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Zyprexa               |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Doxepin Hydrochloride |              |            | S           | Oral         | 20 Tablet Once Po  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Doxepin Hydrochloride |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Clonazepam            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2004              | 5654693       | DIRECT           | Y                  | RI              |                      |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Metoprolol Tartrate      |              |            | C           |              |                    |                 | Not Reported |
|                       | Miconazole Nitrate       |              |            | C           |              |                    |                 | Not Reported |
|                       | Ranitidine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2004              | 5658334       | EXPEDITED (15-DAY) | Y                  | HO              | S04-GER-02574-01     |                      | 38 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Drug Withdrawal Syndrome; Hypertension; Intracardiac Thrombus; Mood Altered; | Cipraxel       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                   | Epivir         |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |
|                                                                                                   | Kaletra        |              |            | S           | Oral         | 6 Qd Po            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                   |                                           |                    |                    |                  |                      |                              |                 |              |                                                              |
|---------------------------------------------------|-------------------------------------------|--------------------|--------------------|------------------|----------------------|------------------------------|-----------------|--------------|--------------------------------------------------------------|
| Sinus Tachycardia;<br>Suicidal Ideation           | Videx                                     |                    | S                  | Oral             | 400 Mg Qd Po         |                              |                 | Not Reported |                                                              |
| <u>FDA Received Date</u>                          | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                                               |
| 25-Oct-2004                                       | 5656204                                   | DIRECT             | N                  | LT, OT           |                      |                              | 33 YR           | Male         | USA                                                          |
| <u>Preferred Term</u>                             | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                                                              |
| Medication Error                                  | Lexapro<br>Alprazolam                     |                    |                    | S<br>S           |                      |                              |                 |              | Not Reported<br>Not Reported                                 |
| <u>FDA Received Date</u>                          | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                                               |
| 25-Oct-2004                                       | 5659527                                   | EXPEDITED (15-DAY) | N                  | RI               | 2004UW21436          |                              | 50 YR           | Female       | USA                                                          |
| <u>Preferred Term</u>                             | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                                                              |
| Encephalopathy; Hepatic<br>Failure                | Nexium<br>Lexapro<br>Premarin             |                    |                    | S<br>S<br>C      | Oral                 | 40 Mg Daily Po               | 2 YR<br>2 WEEK  |              | Not Reported<br>Not Reported<br>Not Reported                 |
| <u>FDA Received Date</u>                          | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                                               |
| 25-Oct-2004                                       | 5661674                                   | EXPEDITED (15-DAY) | Y                  | DE               | S04-USA-06880-01     |                              | 22 YR           | Male         | USA                                                          |
| <u>Preferred Term</u>                             | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                                                              |
| Alcohol Use; Completed<br>Suicide; Gun Shot Wound | Lexapro<br>Lexapro<br>Alcohol<br>Concerta |                    |                    | S<br>S<br>C<br>C | Oral<br>Oral         | 20 Mg Qd; Po<br>10 Mg Qd; Po |                 |              | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                          | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                                               |
| 26-Oct-2004                                       | 4167471                                   | EXPEDITED (15-DAY) | Y                  | DE               | S04-USA-03515-02     |                              | < 1 DAY         | Female       | USA                                                          |
| <u>Preferred Term</u>                             | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                                                              |
| Atelectasis Neonatal;<br>Blood Ph Decreased;      | Lexapro                                   |                    |                    | S                | Transplacental       | 10 Mg Qd Transplacental      |                 |              | Not Reported                                                 |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                          |   |              |              |
|---------------------------|--------------------------|---|--------------|--------------|
| Cyanosis Neonatal; Death  | Zofran                   | C | Transmammary | Not Reported |
| Neonatal; Endotracheal    | Phenergan                | C |              | Not Reported |
| Intubation Complication;  | Prenatal Vitamins        | C |              | Not Reported |
| Hypotonia Neonatal;       | Macrobid                 | C |              | Not Reported |
| Maternal Exposure During  | Compazine                | C |              | Not Reported |
| Pregnancy; Neonatal       | Stool Softeners          | C |              | Not Reported |
| Respiratory Arrest;       | Amoxicillin              | C |              | Not Reported |
| Neonatal Tachycardia;     | Monistat                 | C |              | Not Reported |
| Pallor; Pulmonary         | Tums (Calcium Carbonate) | C |              | Not Reported |
| Hypoplasia; Pulse Absent; | Antacids Nos             | C |              | Not Reported |
| Respiratory Disorder      | Calcium                  | C |              | Not Reported |
| Neonatal; Sudden Death;   | Vitamin D Nos            | C |              | Not Reported |
| White Blood Cell Count    | Vitamin K                | C |              | Not Reported |
| Increased                 | Erythromycin             | C |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2004              | 4167501       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-USA-03515-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Drug          | Lexapro           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Ineffective; Dry Skin;   | Lexapro           |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Dyspepsia; Fungal        | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported |
| Infection; Maternal      | Stool Softeners   |              |            | C           |              |                    |                 | Not Reported |
| Exposure During          | Calcium           |              |            | C           |              |                    |                 | Not Reported |
| Pregnancy;               | Vitamin D Nos     |              |            | C           |              |                    |                 | Not Reported |
| Nasopharyngitis; Nausea; |                   |              |            |             |              |                    |                 |              |
| Premature Separation Of  |                   |              |            |             |              |                    |                 |              |
| Placenta; Rash; Urethral |                   |              |            |             |              |                    |                 |              |
| Disorder; Urinary Tract  |                   |              |            |             |              |                    |                 |              |
| Infection; Uterine       |                   |              |            |             |              |                    |                 |              |
| Prolapse; Vaginal        |                   |              |            |             |              |                    |                 |              |
| Prolapse; Vomiting;      |                   |              |            |             |              |                    |                 |              |
| Weight Decreased         |                   |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2004              | 4200180       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04732-01     |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                                      |   |      |             |              |
|---------------------------|--------------------------------------|---|------|-------------|--------------|
| Abnormal Behaviour;       | Lexapro                              | S | Oral | 10 Mg Qd Po | Not Reported |
| Agitation; Belligerence;  | Lexapro                              | S | Oral | 20 Mg Qd Po | Not Reported |
| Confusional State;        | Wellbutrin (Bupropion Hydrochloride) | S | Oral | 300 Mg Qd   | Not Reported |
| Delusion; Diet Refusal;   | Wellbutrin (Bupropion Hydrochloride) | S | Oral | 150 Mg Qd   | Not Reported |
| Insomnia; Mania; Paranoia | Ambien                               | C |      |             | Not Reported |
|                           | Trazodone Hydrochloride              | C |      |             | Not Reported |
|                           | Lipitor                              | C |      |             | Not Reported |
|                           | Aciphex                              | C |      |             | Not Reported |
|                           | Aspirin                              | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2004              | 5657322       | DIRECT           | Y                  | HO              |                      |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Fall; Mental Status Changes; Somnolence | Lexapro                       |              |            | S           | Oral         | 10 Mg Daily Oral   |                 | Not Reported |
|                                                            | Ms Contin                     |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Oxycodone                     |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Lorazepam                     |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Humibi La                     |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Combivent                     |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Furosemide                    |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Atenolol                      |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Methimazole                   |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Prednisone                    |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Cyclobenzaprine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Aspirin                       |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Advair                        |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Sucralfate                    |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Miralax                       |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Gefitinib                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2004              | 5658530       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06959-01     |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                          |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Coagulopathy; Platelet Adhesiveness Increased                                            |                | Lexapro            | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2004                                                                              | 5661796        | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-06842-01     |                      | 40 YR           | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Status Epilepticus                                     | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Carbamazepine  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2004                                                                              | 5652949        | EXPEDITED (15-DAY) | Y                  | DE, HO          | S04-UKI-06403-01     |                      | 64 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Withdrawal Syndrome; Hyperhidrosis; Intentional Overdose; Tremor | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Cipralext      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Diazepam       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Diazepam       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Atenolol       |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                                                                          | Atenolol       |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                                                                          | Atenolol       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Simvastatin                                                                              |                |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2004                                                                              | 5660318        | DIRECT             | N                  | DS, HO          |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Work Ability; Panic Attack                                                      | Paxil Cr       |                    |                    | S               | Oral                 | 1 Day Oral           |                 | Not Reported |                |
|                                                                                          | Lexapro        |                    |                    | S               | Oral                 | 1 Day Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2004                                                                              | 5660363        | DIRECT             | N                  | DE              |                      |                      | 64 YR           | Female       | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Medication Error                   | Lexapro                |                    |                    | S               | Oral                 | 1/2 To 1 Per Day Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2004                                              | 5660893                | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06960-01     |                       | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Drug<br>Interaction; Loss Of<br>Consciousness | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po           |                 | Not Reported |                |
|                                                          | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |
|                                                          | Gabitril               |                    |                    | S               |                      | 2 Mg Qd               |                 | Not Reported |                |
|                                                          | Gabitril               |                    |                    | S               |                      | 4 Mg Qd               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2004                                              | 5662289                | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-07036-01     |                       |                 | Female       | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema; Thrombosis                                       | Ciprallex              |                    |                    | S               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2004                                              | 4096509                | EXPEDITED (15-DAY) | Y                  | DS              | S04-GER-00523-01     |                       | 43 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Impulse-Control Disorder;<br>Peroneal Nerve Palsy        | Ciprallex              |                    |                    | S               | Oral                 | 20 Mg Qd Po           |                 | Not Reported |                |
|                                                          | Remergil (Mirtazapine) |                    |                    | C               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2004                                              | 4206280                | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-05601-01     |                       | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia;                                     | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |             |   |              |
|-----------------------------|-------------|---|--------------|
| Blood Glucose Increased;    | Hydrocodone | C | Not Reported |
| Confusional State; Drug     | Remicade    | C | Not Reported |
| Screen Positive;            | Pepcid Ac   | C | Not Reported |
| Headache; Mental Status     | Paxil       | C | Not Reported |
| Changes; Metabolic          | Lantus      | C | Not Reported |
| Acidosis; Psychotic         |             |   |              |
| Disorder; Respiratory       |             |   |              |
| Alkalosis; White Blood Cell |             |   |              |
| Count Increased             |             |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2004              | 4218960       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06118-01     |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Medication Error;<br>Overdose; Self-Medication; Toxicity To Various Agents | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                            | Clozapine      |              |            | S           |              | 300 Mg             |                 | Not Reported |
|                                                                            | Vicodin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Topamax        |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Depakote       |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Lopid          |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Inderal        |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Doxepin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Flexeril       |              |            | C           |              |                    |                 | Not Reported |
|                                                                            | Promethazine   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2004              | 4224264       | EXPEDITED (15-DAY) | Y                  | DS              | S04-GER-04155-01     |                      | 30 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eosinophilia; Monocytosis; Peroneal Nerve Palsy; Weight Increased | Cipraxel       |              |            | S           | Oral         | 10 Mg Po           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2004              | 5654792       | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20041005895 |                      | 43 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Drug Interaction | Remicade                 |                    |                    | S               | Intravenous (not otherwise specified)<br>Oropharyngeal |                      |                 | Not Reported |                |
|                                                                                            | Lexapro                  |                    |                    | S               |                                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2004                                                                                | 5660406                  | DIRECT             | N                  | HO, LT          |                                                        |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Overdose; Suicidal Ideation                                              | Lexapro                  |                    |                    | S               | Oral                                                   | 10 Mg Per Day Oral   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2004                                                                                | 5660541                  | DIRECT             | Y                  | OT              |                                                        |                      | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased                                                                     | Escitalopram Oxalate     |                    |                    | S               | Oral                                                   | 10 Mg Oral           |                 | Forest       |                |
|                                                                                            | Dexamethasone            |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Lorazepam                |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Calcium Carbonate        |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Tamsulosin Hydrochloride |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Pantoprazole Sodium      |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Vitamin E                |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Celecoxib                |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Ramipril                 |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Fluconazole              |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
|                                                                                            | Insulin Nos              |                    |                    | C               |                                                        |                      | Not Reported    |              |                |
| Trazodone Hydrochloride                                                                    |                          |                    | C                  | Not Reported    |                                                        |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2004                                                                                | 5662795                  | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-07039-01                                       |                      | 17 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                              |                     |   |      |             |              |
|--------------------------------------------------------------|---------------------|---|------|-------------|--------------|
| Alcohol Use; Hallucination, Auditory; Hallucination, Tactile | Cipralext           | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                              | Cipralext           | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                              | Pulmicort Flexhaler | C |      |             | Not Reported |
|                                                              | Bricanyl            | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2004              | 5662306       | EXPEDITED (15-DAY) | Y                  | DS, LT          | 2004067358           |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Agitation; Bipolar li Disorder; Depression; Feelings Of Worthlessness; Irritability; Panic Attack; Paranoia; Psychotic Disorder; Sleep Disorder; Speech Disorder; Stress; Suicidal Ideation; Weight Increased | Zoloft                  |              |            | S           |              | 100 Mg (1 In1 D)        | 1 YR            | Not Reported |
|                                                                                                                                                                                                               | Escitalopram Oxalate    |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) | 1 MTH           | Not Reported |
|                                                                                                                                                                                                               | Semisodium Valproate    |              |            | S           |              |                         |                 | Not Reported |
|                                                                                                                                                                                                               | Olanzapine (Olanzapine) |              |            | S           |              |                         |                 | Not Reported |
|                                                                                                                                                                                                               | Topiramate              |              |            | S           |              | 50 Mg                   |                 | Not Reported |
|                                                                                                                                                                                                               | Quetiapine Fumarate     |              |            | S           |              | 50 Mg                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2004              | 5663031       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-07061-01     |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autoimmune Thyroiditis; Weight Increased | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                          | Strattera             |              |            | C           |              |                    |                 | Not Reported |
|                                          | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2004              | 4146407       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02672-01     |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension; Blood Glucose Increased; Constipation; Diarrhoea; Diverticulum; Drug | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Lexapro        |              |            | S           | Oral         | 10 Mg Qod Po       |                 | Not Reported |
|                                                                                            | Lexapro        |              |            | S           | Oral         | 7.5 Mg Qod Po      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |          |   |      |              |              |
|-------------------------|----------|---|------|--------------|--------------|
| Interaction; Fatigue;   | Lexapro  | S | Oral | 10 Mg Qd Po  | Not Reported |
| Glossodynia;            | Lexapro  | S | Oral | 5 Mg Qd Po   | Not Reported |
| Hypersomnia; Pyrexia;   | Lexapro  | S | Oral | 2.5 Mg Qd Po | Not Reported |
| Tongue Coated; Urinary  | Lexapro  | S |      |              | Not Reported |
| Tract Infection; Weight | Ceclor   | S |      |              | Not Reported |
| Decreased               | Lanoxin  | C |      |              | Not Reported |
|                         | Cozaar   | C |      |              | Not Reported |
|                         | Tenormin | C |      |              | Not Reported |
|                         | Maxzide  | C |      |              | Not Reported |
|                         | Prilosec | C |      |              | Not Reported |
|                         | Percocet | C |      |              | Not Reported |
|                         | Diazepam | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2004              | 5673158       | EXPEDITED (15-DAY) |                    | DE              | 2004-BP-10345RO      |                      | 29 YR      | Unknown    | USA            |

| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; | Mirtazapine           |              |            | S           |              |                    |                 | Not Reported |
| Completed Suicide;         | Doxepin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Overdose                   | Escitalopram Oxalate  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2004              | 4200342       | EXPEDITED (15-DAY) | Y                  | HO, LT          | US-ROCHE-372529      |                      | 45 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Alanine Aminotransferase   | Peginterferon Alfa-2a |              |            | S           | Subcutaneous | Unknown Dose Given   | 155 DAY         | Roche        |
| Increased; Anxiety;        |                       |              |            |             |              | Weekly               |                 |              |
| Aspartate                  | Ribavirin             |              |            | S           | Oral         | Given Daily          | 159 DAY         | Roche        |
| Aminotransferase           | Lexapro               |              |            | S           | Unknown      |                      |                 | Not Reported |
| Increased; Depression;     | Multivitamins         |              |            | C           |              |                      |                 | Not Reported |
| Drug Screen Positive;      | Vitamin E             |              |            | C           |              |                      |                 | Not Reported |
| Homicidal Ideation;        | Ambien                |              |            | C           |              |                      |                 | Not Reported |
| Nausea; Overdose;          | Hydrocodone           |              |            | C           |              | Total Daily Dose Was |                 | Not Reported |
| Paranoia; Psychotic        |                       |              |            |             |              | Variable             |                 |              |
| Disorder; Suicidal         |                       |              |            |             |              |                      |                 |              |
| Ideation; Suicide Attempt; | Ibuprofen             |              |            | C           |              | Total Daily Dose Was |                 | Not Reported |
| Tremor                     |                       |              |            |             |              |                      |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Lotrisone                                                                                                                                                           |                    |                    | C                  |                 |                      | Variable             |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2004                                                                                                                                                         | 5664750            | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06177-01     |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Bipolar Disorder;<br>Cyclothymic Disorder;<br>Hypomania; Loss Of<br>Employment; Mania;<br>Refusal Of Treatment By<br>Patient; Treatment<br>Noncompliance | Lexapro            |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2004                                                                                                                                                         | 5673314            | DIRECT             | Y                  | HO              |                      |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                                                                                                                     | Lexapro            |                    |                    | S               | Oral                 | 10 Mg Qd Oral        |                 | Forest       |                |
|                                                                                                                                                                     | Aspirin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Synthroid          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Nifedipine         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Sodium Bicarbonate |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Diovan Hct         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Atenolol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2004                                                                                                                                                         | 5676571            | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-07132-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Drug<br>Level Increased;<br>Respiratory Failure                                                                                                   | Lexapro            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Demerol            |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Nov-2004                                                                                                                                                                                                       | 5653406              | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2004237015NO         |                      | 84 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Hepatic Failure; Hepatitis; Hyperhidrosis; Hyperventilation; International Normalised Ratio Increased; Multiple Organ Dysfunction Syndrome; Pain; Pancreatitis; Rales; White Blood Cell Count Increased | Aldactone            |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg, Qd, Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2004                                                                                                                                                                                                       | 4193688              | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-04678-01     |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death; Anxiety; Insomnia; Pulmonary Congestion; Pulmonary Oedema; Toxicity To Various Agents                                                                                                           | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Propoxyphene         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Klonopin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Ativan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Remeron              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                   | Alcohol              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2004                                                                                                                                                                                                       | 5657270              | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06767-01     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                                                                                  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2004                                                                                             | 5679638                                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07186-01     |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness Transitory;<br>Tinnitus                                                                        | Lexapro                                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2004                                                                                             | 5681181                                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-ESP-07168-01     |                      | 84 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                           | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Tamsulosine (Tamsulosin)                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Diosmine/ Hesperidine                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Betahistine Hydrochloride               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Timolol Maleate                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Lormetazepam                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2004                                                                                             | 5679587                                 | EXPEDITED (15-DAY) | Y                  | DS              | S04-NOR-07415-01     |                      | 68 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Dysphonia;<br>Facial Paresis; Lethargy;<br>Listless; Rash<br>Erythematous; Rash<br>Pruritic | Cipralex                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Paracetamol                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Thyroxin-Natrium (Levothyroxine Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Cozaar                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Ibux (Ibuprofen)                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2004                                                                                             | 5679747                                 | EXPEDITED (15-DAY) | Y                  | OT              | SO4-USA-06959-01     |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                 |         |   |      |             |              |
|---------------------------------|---------|---|------|-------------|--------------|
| Platelet Aggregation Increased; | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
| Thrombocytopenia                | Yasmin  | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2004              | 4221601       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20040908837 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|---------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Blood Pressure Abnormal;                     | Tylenol With Codeine      |              |            | S           | Oropharingeal |                    |                 | Not Reported |
| Cardio-Respiratory Arrest;                   | Acetaminophen\Hydrocodone |              |            | S           | Oropharingeal |                    |                 | Not Reported |
| Coma; Completed Suicide;                     | Acetaminophen\Hydrocodone |              |            | S           | Oropharingeal |                    |                 | Not Reported |
| Heart Rate Increased;                        | Amitriptyline             |              |            | S           | Oropharingeal |                    |                 | Not Reported |
| Intentional Overdose; Loss Of Consciousness; | Baclofen                  |              |            | S           |               |                    |                 | Not Reported |
| Oxygen Saturation Decreased; Pupil Fixed;    | Zolpidem                  |              |            | S           |               |                    |                 | Not Reported |
| Status Epilepticus                           | Valdecoxib                |              |            | S           |               |                    |                 | Not Reported |
|                                              | Escitalopram Oxalate      |              |            | S           |               |                    |                 | Not Reported |
|                                              | Fentanyl                  |              |            | S           |               |                    |                 | Not Reported |
|                                              | Orphenadrine              |              |            | S           |               |                    |                 | Not Reported |
|                                              | Pantoprazole Sodium       |              |            | S           |               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2004              | 4194833       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S04-USA-04604-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autonomic Nervous System Imbalance;          | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Dizziness; Dizziness Postural; Hypertension; | Clonidine      |              |            | C           |              |                    |                 | Not Reported |
| Hypotension; Syncope;                        | Keppra         |              |            | C           |              |                    |                 | Not Reported |
| Vocal Cord Paralysis                         | Topamax        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2004              | 5654096       | EXPEDITED (15-DAY) | Y                  | DE              | S04-NOR-06614-01     |                      | 84 YR      | Female     | NOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                             |                                                                                                                                                                                                                            |                                                               |              |                             |                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Drug Interaction; Hepatic Failure; Hepatitis; Hyperhidrosis; Hyperventilation; International Normalised Ratio Increased; Multiple Organ Dysfunction Syndrome; Pain; Pancreatitis; Right Ventricular Failure | Ciprallex<br>Aldactone<br>Digitoxin<br>Synalar (Fluocinolone Acetonide)<br>Betnovate (Betamethasone)<br>Phu Chee<br>Konakion<br>Warfarin Sodium<br>Amoxicillin<br>Paracet (Paracetamol)<br>Cozaar<br>Furosemide<br>Lipitor | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral | 5 Mg Qd Po<br>12.5 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 15-Nov-2004                         | 4194134        | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-0408USA01341 |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mouth Ulceration; Tongue Ulceration | Vioxx          |                    |                    | S               | Oral                  |                      |                 | Merck        |                |
|                                     | Zoloft         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                     | Topamax        |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                     | Lexapro        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                     | Lexapro        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                     | Zocor          |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                     | Nexium         |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                     | Mirapex        |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 15-Nov-2004              | 5673141                  | EXPEDITED (15-DAY) | Y                  | HO              | DE-GLAXOSMITHKLINE-D0045166A |                      | 39 YR           | Female          | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain Upper;    | Paroxetine Hydrochloride |                    |                    | S               | Oral                         | 10mg Per Day         | 39 DAY          | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                              |                                          |        |                 |                              |                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------|-----------------|------------------------------|---------------------------------|
| Circulatory Collapse; Cold Sweat; Cyanosis; Depression; Dizziness; Drug Interaction; Heart Rate Increased; Ill-Defined Disorder; Nausea; Pallor; Poor Peripheral Circulation; Pulse Abnormal | Ciprallex<br>Amitriptyline Hydrochloride | S<br>C | Oral<br>Unknown | 10mg Per Day<br>25mg Per Day | Not Reported<br>Glaxosmithkline |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------|-----------------|------------------------------|---------------------------------|

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2004                                                            | 5654946        | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2004GB02412          |                      | 64 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Withdrawal Syndrome; Overdose; Suicide Attempt | Atenolol       |                    |                    | S               |                      | 25 Mg Daily          |                 | Not Reported |                |
|                                                                        | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                        | Ciprallex      |                    |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Not Reported |                |
|                                                                        | Diazepam       |                    |                    | S               |                      | 2.5-5 Mg /Day        |                 | Not Reported |                |
|                                                                        | Simvastatin    |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2004                                                                | 5662539        | EXPEDITED (15-DAY) | Y                  | HO              | S04-BRA-07037-01     |                      | 30 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Coma; Hallucination; Loss Of Consciousness; Unevaluable Event | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                            | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Clonazepam     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 16-Nov-2004                       | 5679893        | DIRECT           | N                  | DE              |                      |                       | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound | Clonazepam     |                  |                    | S               | Intravenous (not     | 3 Time Day Intravenou |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                     |                |                    |                    |                      |                      |                                       |                 |                      |                |              |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|----------------------|----------------------|---------------------------------------|-----------------|----------------------|----------------|--------------|
| Lexapro                                                                                             |                | S                  |                    | otherwise specified) |                      | Intravenous (not otherwise specified) |                 | Once Day Intravenous |                | Not Reported |
| Verapamil Hydrochloride                                                                             |                | C                  |                    |                      |                      |                                       |                 |                      |                | Not Reported |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |              |
| 16-Nov-2004                                                                                         | 5681200        | DIRECT             | Y                  | HO                   |                      |                                       | 86 YR           | Female               | USA            |              |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |              |
| Hyponatraemia                                                                                       | Lexapro        |                    |                    | S                    | Oral                 | # 1 Po Daily                          | 30 DAY          | Not Reported         |                |              |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |              |
| 16-Nov-2004                                                                                         | 5683628        | DIRECT             | Y                  | OT                   |                      |                                       | 39 YR           | Female               | USA            |              |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |              |
| Anxiety; Panic Disorder                                                                             | Lexapro        |                    |                    | S                    | Oral                 | 10 Mg One Po Q Day                    |                 | Not Reported         |                |              |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |              |
| 16-Nov-2004                                                                                         | 5684463        | EXPEDITED (15-DAY) | Y                  | HO                   | S04-USA-07340-01     |                                       |                 | Male                 | USA            |              |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |              |
| Agitation; Delusion; Drug Interaction; Hallucination                                                | Lexapro        |                    |                    | S                    |                      |                                       |                 | Not Reported         |                |              |
|                                                                                                     | Adderall       |                    |                    | S                    |                      |                                       |                 | Not Reported         |                |              |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |              |
| 16-Nov-2004                                                                                         | 5684469        | EXPEDITED (15-DAY) | Y                  | HO                   | S04-USA-07307-01     |                                       | 46 YR           | Female               | USA            |              |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>           |                |              |
| Condition Aggravated; Delusional Disorder, Persecutory Type; Depression; Social Avoidant Behaviour; | Lexapro        |                    |                    | S                    | Oral                 | 10 Mg Qd Po                           |                 | Not Reported         |                |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

## Treatment Noncompliance

| <u>FDA Received Date</u>                                                           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 17-Nov-2004                                                                        | 5686256                                   | EXPEDITED (15-DAY) | N                  | HO              | RS004775-USA         |                         | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Chills; Disorientation; Influenza Like Illness; Nausea; Vomiting | Aciphex                                   |                    |                    | S               | Oral                 | 60 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
|                                                                                    | Provigil                                  |                    |                    | S               | Oral                 | See Image               |                 | Not Reported |                |
|                                                                                    |                                           |                    |                    |                 | Oral                 | See Image               |                 |              |                |
|                                                                                    |                                           |                    |                    |                 | Oral                 | See Image               |                 |              |                |
|                                                                                    | Klonopin                                  |                    |                    | S               | Oral                 | 2.25 Mg, 1 In 1 D, Oral |                 | Not Reported |                |
|                                                                                    | Neurontin                                 |                    |                    | S               | Oral                 | 1200 Mg, 1 In 1 D, Oral |                 | Not Reported |                |
|                                                                                    | Hydrochlorothiazide (Hydrochlorothiazide) |                    |                    | S               | Oral                 | 100 Mg, 1 In 1 D, Oral  |                 | Not Reported |                |
|                                                                                    | Doryx                                     |                    |                    | S               | Oral                 | 100 Mg, 1 In 1 D, Oral  |                 | Not Reported |                |
|                                                                                    | Lexapro                                   |                    |                    | S               | Oral                 | 10 Mg, 1 In 1 D, Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2004                                                                        | 5686620                                   | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-07609-01     |                         | 24 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                   | Cipralext                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                    | Olanzapine                                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2004                                                                        | 5686344                                   | EXPEDITED (15-DAY) | Y                  | HO              | US014248             |                         | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Drug Interaction; Loss Of Consciousness                                 | Gabitril                                  |                    |                    | S               | Oral                 | 2 Mg Qd Oral            |                 | Not Reported |                |
|                                                                                    | Gabitril                                  |                    |                    | S               | Oral                 | 4 Mg Qd Oral            |                 | Not Reported |                |
|                                                                                    | Lexapro                                   |                    |                    | S               | Oral                 | 10 Mg Qd Oral           |                 | Not Reported |                |
|                                                                                    | Lexapro                                   |                    |                    | S               | Oral                 | 20 Mg Qd Oral           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 19-Nov-2004                                                                                                                                                                                                                             | 5653999                                                              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2004075222           |                                  | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia;<br>Depression; Foot<br>Operation; Gastritis;<br>Headache; Mania;<br>Neuralgia; Sleep Disorder;<br>Somnolence; Suicidal<br>Ideation; Therapeutic<br>Product Effect Decreased;<br>White Blood Cell Count<br>Increased | Neurontin                                                            |                    |                    | S               | Oral                 | 600 Mg, Oral                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Prednisone                                                           |                    |                    | S               | Oral                 | 60 Mg (15 Mg, 4 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Vicodin                                                              |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Escitalopram Oxalate                                                 |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Provela-14 (Estrogens<br>Conjugated,<br>Medroxyprogesterone Acetate) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Nifedipine                                                           |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Propranolol Hydrochloride<br>(Propranolol Hydrochloride)             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Cetirizine Hydrochloride                                             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Lansoprazole (Lansoprazole)                                          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2004                                                                                                                                                                                                                             | 5654074                                                              | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-06633-01     |                                  | 24 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure                                                                                                                                                                                                     | Cipralext                                                            |                    |                    | S               | Oral                 | 10 Mg Qd Po                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Olanzapine                                                           |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2004                                                                                                                                                                                                                             | 5681482                                                              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07280-01     |                                  | 91 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged                                                                                                                                                                                                       | Namenda                                                              |                    |                    | S               | Oral                 | 5 Mg Bid Po                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Namenda                                                              |                    |                    | S               | Oral                 | 5 Mg Qd Po                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Namenda                                                              |                    |                    | S               | Oral                 | 5 Mg Bid Po                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Namenda                                                              |                    |                    | S               | Oral                 | 5 Mg Qd Po                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |            |   |      |             |              |
|--|------------|---|------|-------------|--------------|
|  | Lexapro    | S | Oral | 10 Mg Qd Po | Not Reported |
|  | Lexapro    | S | Oral | 20 Mg Qd Po | Not Reported |
|  | Lexapro    | S | Oral | 10 Mg Qd Po | Not Reported |
|  | Detrol     | C |      |             | Not Reported |
|  | Plavix     | C |      |             | Not Reported |
|  | Lovastatin | C |      |             | Not Reported |
|  | Levoxyl    | C |      |             | Not Reported |
|  | Zantac     | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2004              | 5688053       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-UKI-07537-01     |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Glycosylated Haemoglobin Increased; Hypoglycaemia | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                   | Insulin Nos    |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Humalog        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2004              | 5688057       | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-07418-01     |                      | 43 YR      | Male       | GBR            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation; Anger; Paranoia | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                        | Quetiapine     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2004              | 5688312       | DIRECT           | N                  | DS              |                      |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Malaise               | Lexapro        |              |            | S           | Oral         | Once A Day Oral    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2004              | 5688443       | EXPEDITED (15-DAY) | N                  | HO              | 2004090030           |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Fatigue; Sedation; Suicide Attempt                                                                                                                                  | Geodon                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Diphenhydramine Hydrochloride      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Escitalopram                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2004                                                                                                                                                         | 4196797                            | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-04731-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Gangrene; Infarction; Limb Discomfort; Raynaud'S Phenomenon; Skin Discolouration; Skin Irritation; Skin Ulcer                                                   | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2004                                                                                                                                                         | 5662294                            | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-06841-01     |                      | 20 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased; Blood Thyroid Stimulating Hormone Increased; Galactorrhoea; Hypothyroidism; Thyroxine Free Increased; Weight Decreased; Weight Increased | Ciprallex                          |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Ciprallex                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Seroquel                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Neurocil (Levomepromazine Maleate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Biviol                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2004                                                                                                                                                         | 5687368                            | DIRECT             | Y                  | LT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Decreased Appetite; Gastric Disorder; Headache; Insomnia; Simple Partial Seizures;                                                                       | Tagamet Hb                         |                    |                    | S               | Oral                 | 200 Mg Bid Oral      |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro                            |                    |                    | S               | Oral                 | 20 Mg Qd Oral        |                 | Forest       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stress; Toxicity To Various  
Agents; Vomiting

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2004                    | 5691448        | DIRECT           | N                  | DE              |                      |                      | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Daily , Orally |                 | Not Reported |                |
|                                | Meprobamate    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Proscar        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Ambien         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Lisinopril     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Amoxicillin    |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2004                                                                                                | 4126692        | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-01550-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease<br>Progression; Intentional<br>Self-Injury; Personality<br>Disorder; Suicidal Ideation | Lexapro        |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro        |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Risperdal      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2004                                                      | 5657807              | EXPEDITED (15-DAY) | Y                  | HO              | S04-ESP-06636-01     |                      | 64 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Confusional State;<br>Dystonia; Hyponatraemia;<br>Vomiting | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Metoclopramide       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                  | Lorazepam            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Zopiclone            |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 23-Nov-2004                                                                                             | 5661788           | EXPEDITED (15-DAY) | Y                  | OT              | S04-FIN-06912-01             |                      | 50 YR           | Female          | FIN            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arrhythmia; Atrial Fibrillation; Blood Pressure Increased; Bradycardia; Extrasystoles; Long Qt Syndrome | Cipralext         |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                         | Indapamide        |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                         | Opamox (Oxazepam) |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2004                                                                                             | 5680354           | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0429814A |                      | 75 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Irritability; Sexual Dysfunction                                                             | Wellbutrin        |                    |                    | S               | Oral                         | 300mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                         | Zoloft            |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                         | Effexor           |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                         | Paxil             |                    |                    | S               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                         | Lexapro           |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                         | Lithium           |                    |                    | C               | Unknown                      |                      |                 | Glaxosmithkline |                |
|                                                                                                         | Armour Thyroid    |                    |                    | C               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2004                                                                                             | 5681035           | NON-EXPEDITED      | N                  |                 | 2004S1001835                 |                      | 42 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Sexual Dysfunction                                                                                      | Wellbutrin Sr     |                    |                    | S               | Oral                         | 150mg Unknown        |                 | Glaxosmithkline |                |
|                                                                                                         | Lotrel            |                    |                    | S               | Oral                         | 10mg Per Day         |                 | Not Reported    |                |
|                                                                                                         | Lexapro           |                    |                    | S               | Oral                         | 10mg Unknown         |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |   |         |                    |              |
|-----------------------------------------|---|---------|--------------------|--------------|
| Clonidine Hydrochloride                 | C | Oral    | .2mg Twice Per Day | Not Reported |
| Amiloride Hcl W/<br>Hydrochlorothiazide | C | Oral    | 50mg Per Day       | Not Reported |
| Percocet                                | C | Oral    | 10mg Unknown       | Not Reported |
| Trazodone Hydrochloride                 | C | Unknown | 150mg Unknown      | Not Reported |
| Nexium                                  | C | Unknown | 40mg Per Day       | Not Reported |
| Bextra                                  | C | Unknown | 20mg Unknown       | Not Reported |
| Carisoprodol                            | C | Unknown | 350mg Unknown      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2004              | 5681068       | NON-EXPEDITED    | N                  |                 | S04-USA-04583-01     |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Screen Positive  | Wellbutrin Sr       |              |            | S           | Oral         | 300mg Per Day      |                 | Glaxosmithkline |
|                       | Lexapro             |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |
|                       | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2004              | 5663732       | EXPEDITED (15-DAY) | Y                  | DE, HO          | M2004-1630           |                      | 64 YR      | Male       | GBR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed       | Atenolol       |              |            | S           |              | 25 Mg Daily        |                 | Not Reported |
| Suicide; Drug Withdrawal  | Diazepam       |              |            | S           |              | 2.5-5 Mg Daily     |                 | Not Reported |
| Syndrome; Intentional     | Ciprallex      |              |            | S           |              | 10-20 Mg Daily     |                 | Not Reported |
| Overdose; Suicide Attempt | Simvastatin    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2004              | 5689339       | EXPEDITED (15-DAY) | Y                  | DE              | A03200403896         |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug | Demerol              |              |            | S           |              |                    |                 | Not Reported |
| Level Increased;       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

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Respiratory Failure

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2004              | 5690931       | EXPEDITED (15-DAY) | Y                  | HO              | DSA_25380_2004       |                      | 44 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral;<br>Weight Decreased; Weight Increased | Lorazepam      |              |            | S           | Oral         | Df Q Day Po        |                 | Not Reported |
|                                                          | Cipralext      |              |            | S           | Oral         | 10 Mg Q Day Po     |                 | Not Reported |
|                                                          | Nolvadex       |              |            | S           | Oral         | 20 Mg Q Day Po     |                 | Not Reported |
|                                                          | Surmontil      |              |            | S           | Oral         | 75 Mg Q Day Po     |                 | Not Reported |
|                                                          | Surmontil      |              |            | S           | Oral         | 50 Mg Q Day Po     |                 | Not Reported |
|                                                          | Zyprexa        |              |            | S           | Oral         | 2.5 Mg Q Day Po    |                 | Not Reported |
|                                                          | Zyprexa        |              |            | S           | Oral         | 5 Mg Q Day Po      |                 | Not Reported |
|                                                          | Zyprexa        |              |            | S           | Oral         | 10 Mg Q Day Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2004              | 5690274       | EXPEDITED (15-DAY) | Y                  | OT              | 2004083738           |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Serotonin Syndrome    | Geodon               |              |            | S           | Oral         | 40 Mg (1 In 1 D), Oral |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (1 In 1 D), Oral |                 | Not Reported |
|                       | Lorazepam            |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2004              | 5692187       | DIRECT           | N                  | LT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Abnormal Behaviour; Self-Injurious Ideation; Suicide Attempt | Lexapro        |              |            | S           |              | 1/2 Tab X 6 Days Then 1 Tab After |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Nov-2004                                                  | 4223243                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S04-USA-06175-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intracranial Pressure Increased                              | Lexapro                       |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Lexapro                       |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Naprosyn                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Pseudoephedrine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Advil                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2004                                                  | 5677399                       | EXPEDITED (15-DAY) | N                  | HO              | A03200403628         |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Loss Of Consciousness; Overdose; Suicide Attempt | Plavix                        |                    |                    | S               | Oral                 | 1500 Mg Once Oral    |                 | Not Reported |                |
|                                                              | Ambien                        |                    |                    | S               | Oral                 | 130 Mg Once - Oral   |                 | Not Reported |                |
|                                                              | Depakote                      |                    |                    | S               | Oral                 | 4 Gr Once Oral       |                 | Not Reported |                |
|                                                              | Xanax                         |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                              | Klonopin                      |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                              | Lexapro                       |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                              | Acetylsalicylic Acid          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Clopidogrel Bisulfate         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2004                                                  | 5681235                       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-07259-01     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Phlebitis                                                    | Lexapro                       |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Klonopin                      |                    |                    | S               | Oral                 | 8 Mg Qd Po           |                 | Not Reported |                |
|                                                              | Abilify                       |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                         | Trileptal                   |                    | S                  | Oral            |                      | 900 Mg Qd Po         |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                         | Zocor                       |                    | C                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2004                                                                                                                                                                             | 5690152                     | DIRECT             | Y                  | OT              |                      |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paraesthesia                                                                                                                                                                            | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Po Daily       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2004                                                                                                                                                                             | 5692623                     | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05880-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Confusional State; Drug Interaction; Electroencephalogram Abnormal; Eye Movement Disorder; Fatigue; Focal Dyscognitive Seizures; Headache; Mental Disorder; Tardive Dyskinesia | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                         | Tigan                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Fentanyl Transdermal System |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Klonopin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Trazodone Hydrochloride     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Vicodin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Estrogens                                                                                                                                                                               |                             |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2004                                                                                                                                                                             | 5692917                     | EXPEDITED (15-DAY) | Y                  | HO              | SUS1-2004-00788      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Delusion; Drug Interaction; Hallucination                                                                                                                                    | Adderall                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2004              | 5693043        | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07493-01     |                      | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anosmia                  | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Tegretol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Propranolol    |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2004                                                                                                                                                                                                     | 5693090                       | EXPEDITED (15-DAY) | Y                  | HO              | L04-USA-07679-01     |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Chorea; Disturbance In Attention; Heart Rate Increased; Logorrhoea; Nausea; Pyrexia; Tremor | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Mixed Amphetamine Salts       |                    |                    | S               |                      | 45 Mg Tid            |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Mixed Amphetamine Salts       |                    |                    | S               |                      | 20 Mg Bid            |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Mixed Amphetamine Salts       |                    |                    | S               |                      | 30 Mg Tid            |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Methylphenidate Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 01-Dec-2004                                             | 5693638                            | EXPEDITED (15-DAY) | Y                  | CA, HO          | S04-FRA-07819-02     |                          | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract Congenital; Maternal Exposure During Pregnancy | Escitalopram Oxalate               |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                                                         | Seropram (Citalopram Hydrobromide) |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental  |                 | Not Reported |                |
|                                                         | Seloken                            |                    |                    | S               | Transplacental       | 200 Mg Qd Transplacental |                 | Not Reported |                |
|                                                         | Stagid (Metformin Embonate)        |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                                                         | Benfluorex Hydrochloride           |                    |                    | S               | Transplacental       | 150 Mg Qd Transplacental |                 | Not Reported |                |
|                                                         | Spironolactone                     |                    |                    | S               | Transplacental       | 50 Mg Qd Transplacental  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|                                                                            |                | Tranxene T-Tab     |                    | S               |                      |                      |                 |                 | Not Reported   |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
|                                                                            |                | Zolpidem Tartrate  |                    | S               |                      |                      |                 |                 | Not Reported   |
|                                                                            |                | Lysanxia           |                    | S               |                      |                      |                 |                 | Not Reported   |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Dec-2004                                                                | 5687184        | NON-EXPEDITED      | N                  |                 | S04-USA-02595-01     |                      | 56 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthralgia; Mastitis                                                       | Augmentin      |                    |                    | S               | Unknown              |                      |                 | Glaxosmithkline |                |
|                                                                            | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Not Reported    |                |
|                                                                            | Levaquin       |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
|                                                                            | Caltrate       |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                                            | Actonel        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                            | Fosamax        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Dec-2004                                                                | 4206282        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-05603-01     |                      | 35 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asphyxia; Completed Suicide; Depression                                    | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qam Po         |                 | Not Reported    |                |
|                                                                            | Ambien         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Dec-2004                                                                | 4209331        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-05897-01     |                      | 23 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Overdose; Cardiomegaly; Feeling Abnormal; Road Traffic Accident | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Dec-2004                                                                | 5666200        | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06268-01     |                      | 27 YR           | Male            | USA            |



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| <u>Preferred Term</u>                                                                      | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Overdose; Toxicity To<br>Various Agents                              | Lexapro          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                            | Lamictal         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Lithium          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Unisom Sleep Aid |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | No-Doz           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2004                                                                                | 5693813          | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07554-01     |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neoplasm Recurrence;<br>Ovarian Cancer                                                     | Lexapro          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2004                                                                                | 5694315          | DIRECT             | Y                  | DE              |                      |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Myocardial Infarction;<br>Poisoning; Toxicity To<br>Various Agents | Ultracet         |                    |                    | S               | Oral                 | 1 4-6 Hrs Oral       |                 | Not Reported |                |
|                                                                                            | Lexapro          |                    |                    | S               | Oral                 | 1 Day Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2004                                                                                | 5694521          | DIRECT             | N                  | OT              |                      |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Imprisonment; Intentional<br>Self-Injury; Suicidal<br>Ideation      | Lexapro          |                    |                    | S               | Oral                 | Oral                 |                 | Forest       |                |
|                                                                                            | Seroquel         |                    |                    | S               | Oral                 | Oral                 |                 | Astrazeneca  |                |
|                                                                                            | Seroquel         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Lexapro          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2004                                                                                | 4224055          | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06202-01     |                      | 65 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain; Blood Alkaline Phosphatase Increased; C-Reactive Protein Increased; Diarrhoea; Nausea | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Coreg                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Amaryl               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Lotrel               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Zocor                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Aspirin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Lasix                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Potassium Chloride   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Humulin N            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2004                                                                                           | 5695948              | EXPEDITED (15-DAY) | N                  | HO, RI          | S04-USA-07587-01     |                      | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis; Treatment Noncompliance                                                         | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Multi-Vitamin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2004                                                                                           | 5681131              | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWE-07227-01     |                      | 57 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium Decreased; Blood Sodium Decreased; Diarrhoea; Painful Respiration                     | Ciprallex            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2004                                                                                           | 5691139              | EXPEDITED (15-DAY) | N                  | OT              | PHEH2004US12835      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Limb Discomfort; Thrombophlebitis                                                                     | Trileptal            |                    |                    | S               | Oral                 | 900 Mg, Qd           |                 | Novartis     |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               |                      | 15 Mg, Qd            |                 | Not Reported |                |

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|              |   |           |              |
|--------------|---|-----------|--------------|
| Clonazepam   | S | 8 Mg, Qd  | Not Reported |
| Aripiprazole | S | 5 Mg, Qd  | Not Reported |
| Simvastatin  | C | 20 Mg, Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2004              | 5695487       | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-07892-01     |                      |            | Female     | GBR            |

| <u>Preferred Term</u>         | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Faeces Discoloured | Cipralext                              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                               | Promazine                              |              |            | C           |              |                    |                 | Not Reported |
|                               | Trimethoprim                           |              |            | C           |              |                    |                 | Not Reported |
|                               | Cetirizine Hydrochloride               |              |            | C           |              |                    |                 | Not Reported |
|                               | Thyroxine "Aps" (Levothyroxine Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                               | Co-Amilofruse                          |              |            | C           |              |                    |                 | Not Reported |
|                               | Sumatriptan                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2004              | 5695515       | EXPEDITED (15-DAY) | Y                  | DS              | S04-DEN-07964-01     |                      | 60 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Parkinson'S Disease   | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2004              | 4061550       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S03-USA-05298-01     |                      | 91 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage; Cerebrovascular Accident; Generalised Tonic-Clonic Seizure; Lethargy | Lexapro         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Zyprexa         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Ferrous Sulfate |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Levothroid      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Lortab          |              |            | C           |              |                    |                 | Not Reported |

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|                                                                                                                                                              |                              |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Ativan                                                                                                                                                       |                              |                    | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2004                                                                                                                                                  | 5664048                      | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-07158-01     |                      | 28 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Rhabdomyolysis                            | Cipralelex                   |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Cipralelex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2004                                                                                                                                                  | 5700006                      | DIRECT             | Y                  | RI              |                      |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drooling; Dyskinesia; Fall; Mydriasis; Pyrexia; Reduced Facial Expression; Refusal Of Treatment By Patient; Respiratory Disorder; Urinary Incontinence | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                                                                                                                                                              | Dextromethorphan\Guaifenesin |                    |                    | S               | Oral                 | 600mg/30mg Po Bid    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2004                                                                                                                                                  | 5700028                      | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-07954-01     |                      | 35 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia                                                                                                                                                   | Cipralelex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Diazepam                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Buspirone                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Trimethoprim                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Eugynon (Ethiny)             |                    |                    | C               |                      |                      |                 | Not Reported |                |

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Estradiol/Norgestrel)

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Dec-2004                                                                                                                                      | 4160400               | NON-EXPEDITED      | Y                  | RI, OT          | S04-USA-01391-01     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Face Oedema;<br>Mental Status Changes;<br>Migraine; Muscle<br>Twitching                                                                 | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                                                      | 4210521               | NON-EXPEDITED      | Y                  | HO              | S04-USA-03012-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Gamma-<br>Glutamyltransferase<br>Increased;<br>Rhabdomyolysis | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Seroquel              |                    |                    | S               | Oral                 | 300 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                                                                  | Neurontin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                                                      | 5664251               | NON-EXPEDITED      | Y                  | HO              | S04-USA-04369-01     |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Depression                                                                                                                          | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Lamictal              |                    |                    | S               |                      | 150 Mg Qd            |                 | Not Reported |                |
|                                                                                                                                                  | Nexium (Esomeprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                                                      | 5690576               | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07469-01     |                      | 65 YR           | Male         | USA            |

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| <u>Preferred Term</u>                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Delirium; Dementia;<br>Encephalopathy;<br>Hallucination; Psychotic<br>Disorder                                  | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               | Oral                 | 1.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               | Oral                 | 0.75 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               | Unknown              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                     | 5701035                    | EXPEDITED (15-DAY) | Y                  | DE              | S04-UKI-07898-01     |                      | 52 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                                    | Ciprallex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Metformin Hydrochloride    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Pioglitazone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                     | 5701890                    | NON-EXPEDITED      | Y                  | HO              | S04-USA-07134-01     |                      | 87 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cellulitis; Fall;<br>Hyponatraemia; Skin<br>Laceration                                                          | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                 | Detrol                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                                                                     | 5703495                    | EXPEDITED (15-DAY) | Y                  | HO              | T04-USA-07469-01     |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Confusional State;<br>Delirium; Dementia;<br>Encephalopathy;<br>Hallucination; Psychotic | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               | Oral                 | 1.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               | Oral                 | 0.75 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                 | Mirapex                    |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                                                       |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Disorder                                                       | Mirapex                                               |                    | S                  | Unknown         | Unk                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2004                                                    | 5715385                                               | NON-EXPEDITED      | N                  |                 | 2004241306US         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychomotor<br>Hyperactivity; Weight<br>Increased              | Bextra                                                |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                | Wellbutrin                                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                | Lexapro                                               |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                | Multivitamins (Panthenol,<br>Retinal, Ergocalciferol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Vitamin E                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2004                                                    | 5703474                                               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07767-01     |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Sedation                                                 | Lexapro                                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2004                                                    | 4218862                                               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06119-01     |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Seizure                              | Lexapro                                               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2004                                                    | 5703921                                               | EXPEDITED (15-DAY) | Y                  | RI              | S04-USA-06697-01     |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Citric Acid<br>Increased; Blood<br>Creatinine Increased; | Lexapro                                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Lexapro                                               |                    |                    | S               | Oral                 | 10 Mg Qod Po         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                 |         |   |      |              |              |
|-----------------------------------------------------------------------------------------------------------------|---------|---|------|--------------|--------------|
| Dizziness; Hypercalciuria;<br>Hyperoxaluria;<br>Nephrolithiasis;<br>Ureterolithiasis; Urine<br>Output Increased | Lexapro | S | Oral | 10 Mg Biw Po | Not Reported |
|-----------------------------------------------------------------------------------------------------------------|---------|---|------|--------------|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Dec-2004                       | 5703934                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-07725-01              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure; Treatment             | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Once Po               |                          | Not Reported        |
| Noncompliance                  | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                | Ultram                  |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Dec-2004                       | 5711683                | NON-EXPEDITED             | Y                           | OT                       | HQWYE691410MAR04              |                               |                     | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Condition             | Effexor Xr              |                       |                     | S                    | Oral                  | 150 Mg 1x Per 1 Day,        |                          | Not Reported        |
| Aggravated; Depression;        |                         |                       |                     |                      | Oral                  | Oral; See Image             |                          |                     |
| Disturbance In Attention;      |                         |                       |                     |                      |                       | 150 Mg 1x Per 1 Day,        |                          |                     |
| Drug Ineffective For           |                         |                       |                     |                      |                       | Oral; See Image             |                          |                     |
| Unapproved Indication;         | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
| Drug Withdrawal                | Paxil                   |                       |                     | S                    |                       |                             |                          | Not Reported        |
| Syndrome; Gait                 | Zoloft                  |                       |                     | S                    |                       |                             |                          | Not Reported        |
| Disturbance;                   |                         |                       |                     |                      |                       |                             |                          |                     |
| Gynaecomastia;                 |                         |                       |                     |                      |                       |                             |                          |                     |
| Headache; Insomnia;            |                         |                       |                     |                      |                       |                             |                          |                     |
| Vomiting; Weight               |                         |                       |                     |                      |                       |                             |                          |                     |
| Increased                      |                         |                       |                     |                      |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Dec-2004                       | 5704523                | EXPEDITED (15-DAY)        | N                           | OT                       | S04-USA-07777-01              |                               | 45 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Toxicity To Various Agents     | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 17-Dec-2004                                                                                                                                                                                    | 5704802                                                         | EXPEDITED (15-DAY) | Y                  | OT              | S04-UKI-08105-01         |                      | 55 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Nephrotic Syndrome                                                                                                                                                   | Cipralext                                                       |                    |                    | S               | Oral                     | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                | Cipralext                                                       |                    |                    | S               | Oral                     | 10 Mg Qod Po         |                 | Not Reported |                |
|                                                                                                                                                                                                | Penicillin V "Aliud Pharma" (Phenoxymethylpenicillin Potassium) |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Diclofenac                                                      |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2004                                                                                                                                                                                    | 5715695                                                         | NON-EXPEDITED      | N                  |                 | 2004-BP-08982BP          |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Swollen Tongue                                                                                                                                                               | Spiriva                                                         |                    |                    | S               | Respiratory (inhalation) | 18 Mcg (18 Mcg) Ih   |                 | Not Reported |                |
|                                                                                                                                                                                                | Lexapro                                                         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Prednisolone                                                    |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Xanax                                                           |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2004                                                                                                                                                                                    | 7385659                                                         | EXPEDITED (15-DAY) | Y                  | OT              | K200401860               |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Aphasia; Confusional State; Depressed Level Of Consciousness; Disorientation; Drug Interaction; Electroencephalogram Abnormal; Eye Movement Disorder; Fatigue; Fear; Headache; Mental | Tigan                                                           |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Lexapro                                                         |                    |                    | S               | Oral                     | See Image            |                 | Not Reported |                |
|                                                                                                                                                                                                |                                                                 |                    |                    |                 | Oral                     | See Image            |                 |              |                |
|                                                                                                                                                                                                |                                                                 |                    |                    |                 | Oral                     | See Image            |                 |              |                |
|                                                                                                                                                                                                | Fentanyl                                                        |                    |                    | C               |                          | See Image            |                 | Not Reported |                |
|                                                                                                                                                                                                | Klonopin                                                        |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Trazodone Hydrochloride                                         |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Vicodin                                                         |                    |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                           |                                      |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Impairment; Partial Seizures; Tardive Dyskinesia                                                                                                          |                                      | Estrogen Nos       |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2004                                                                                                                                               | 5705736                              | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07808-01     |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Infection; Priapism                                                                                                                                       | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Trazodone Hydrochloride              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2004                                                                                                                                               | 5690544                              | EXPEDITED (15-DAY) | Y                  | DS              | S04-ITA-07674-01     |                      | 63 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nerve Compression; Optic Nerve Disorder; Optic Neuropathy; Pituitary Tumour; Retinal Vascular Disorder; Toxicity To Various Agents; Visual Acuity Reduced | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Escitalopram Oxalate                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Altiazem (Diltiazem Hydrochloride)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Enalapril                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Cardioaspirin (Acetylsalicylic Acid) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Xanax                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Azyr                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2004                                                                                                                                               | 5695491                              | EXPEDITED (15-DAY) | Y                  | HO              | S04-SWE-07890-02     |                      | 10 DAY          | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropathy; Body Temperature Increased; Drug Withdrawal Syndrome; Hyperreflexia; Hypertension Neonatal; Hypertonia Neonatal; Irritability; Maternal      | Cipralext                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Valproic Acid                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Trandate                             |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During  
Pregnancy; Nervousness;  
Screaming; Tremor  
Neonatal

| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------------------------|----------------|
| 21-Dec-2004                                          | 5695498                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-SWE-07890-01     |                                  |                 | Female                       | SWE            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Maternal Exposure During<br>Pregnancy; Pre-Eclampsia | Ciprallex<br>Valproate Sodium |                    |                    | S<br>S          |                      |                                  |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Dec-2004                                          | 5699344                       | EXPEDITED (15-DAY) | N                  | HO              | US-ROCHE-389132      |                                  | 40 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Loss Of Consciousness;<br>Overdose; Overdose         | Klonopin                      |                    |                    | S               | Unknown              | Dose Reported As Large<br>Amount |                 | Roche                        |                |
|                                                      | Plavix                        |                    |                    | S               | Oral                 |                                  |                 | Not Reported                 |                |
|                                                      | Plavix                        |                    |                    | S               | Oral                 |                                  |                 | Not Reported                 |                |
|                                                      | Ambien                        |                    |                    | S               | Oral                 |                                  | 1 DAY           | Not Reported                 |                |
|                                                      | Depakote                      |                    |                    | S               | Unknown              |                                  |                 | Not Reported                 |                |
|                                                      | Lexapro                       |                    |                    | S               | Unknown              | Dose Reported As Large<br>Amount |                 | Not Reported                 |                |
|                                                      | Xanax                         |                    |                    | S               | Unknown              | Dose Reported As Large<br>Amount |                 | Not Reported                 |                |
|                                                      | Acetylsalicylic Acid          |                    |                    | C               | Oral                 |                                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Dec-2004                                          | 5704969                       | EXPEDITED (15-DAY) | Y                  |                 | S04-USA-07795-01     |                                  |                 | Unknown                      | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Overdose; Seizure                                    | Lexapro                       |                    |                    | S               |                      |                                  |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                       |                      |                    |                    |                 |                              |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                                                                                                                               |                      |                    | S                  |                 |                              | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2004                                                                                                                                           | 5705543              | EXPEDITED (15-DAY) | Y                  | DE              | MK200412-0150-1              |                      | 30 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                                                                                            | Fluoxetine           |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                       | Liothyronine Sodium  |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2004                                                                                                                                           | 5681485              | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-07285-01             |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Amnesia; Breast<br>Discharge; Feeling<br>Abnormal; Incoherent;<br>Nasopharyngitis;<br>Purulence; Shoplifting;<br>Tooth Abscess | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                       | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                       | Depo-Provera         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                       |                      |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2004                                                                                                                                           | 5689751              | EXPEDITED (15-DAY) |                    | HO, OT          | SE-ABBOTT-04P-150-0281644-00 |                      |                 | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During<br>Pregnancy; Pre-Eclampsia                                                                                                  | Valproic Acid        |                    |                    | S               |                              |                      | 1 YR            | Not Reported |                |
|                                                                                                                                                       | Ciprallex            |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2004                                                                                                                                           | 5689753              | EXPEDITED (15-DAY) |                    | HO              | SE-ABBOTT-04P-150-0281642-00 |                      | < 1 DAY         | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropathy; Body                                                                                                                                     | Valproic Acid        |                    |                    | S               |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                               |           |   |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|--------------|
| Temperature Increased;<br>Drug Withdrawal<br>Syndrome; Drug<br>Withdrawal Syndrome<br>Neonatal; Hyperreflexia;<br>Hypertension; Hypertonia;<br>Irritability; Maternal<br>Exposure During<br>Pregnancy; Nervousness;<br>Tremor | Ciprallex | S | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2004              | 5704189       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07773-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coeliac Disease; Impaired<br>Gastric Emptying;<br>Oesophageal Dysplasia;<br>Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 23-Dec-2004              | 5687648       | EXPEDITED (15-DAY) |                    | HO              | US-ABBOTT-04P-163-<br>0281753-00 |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased;<br>Cerebrovascular Accident;<br>Depression Suicidal;<br>Encephalopathy;<br>Hyperammonaemia;<br>Hypotension; Intentional<br>Overdose; Lethargy; Loss<br>Of Consciousness;<br>Pneumonia Haemophilus | Depakote              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Depakote              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Depakote              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Lexapro               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Lexapro               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Clopidogrel Bisulfate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Clopidogrel Bisulfate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Clopidogrel Bisulfate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Zolpidem Tartrate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Zolpidem Tartrate     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                      | Alprazolam            |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                            |   |      |  |  |  |  |              |
|--|----------------------------|---|------|--|--|--|--|--------------|
|  | Alprazolam                 | S |      |  |  |  |  | Not Reported |
|  | Clonazepam                 | S | Oral |  |  |  |  | Not Reported |
|  | Clonazepam                 | S |      |  |  |  |  | Not Reported |
|  | Phenergan                  | S |      |  |  |  |  | Not Reported |
|  | Acetylsalicylic Acid       | C | Oral |  |  |  |  | Not Reported |
|  | Dihydroergotamine Mesylate | C |      |  |  |  |  | Not Reported |
|  | Prednisone                 | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2004              | 5708823       | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-08107-01     |                      | 34 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuser; Medication Error; Overdose; Restlessness; Self-Medication; Therapeutic Product Effect Increased; Treatment Noncompliance | Cipralext            |              |            | S           | Oral         | 160 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                       | Cipralext            |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                       | Solian (Amisulpride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Methadon (Methadone) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Diazepam             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                       | Cocaine              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2004              | 5708978       | EXPEDITED (15-DAY) | N                  | OT              | 2004113561           |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Dysstasia; Incoherent | Neurontin                                 |              |            | S           | Oral         | (400 Mg), Oral     |                 | Not Reported |
|                                       | Escitalopram Oxalate                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                       | Alprazolam (Alprazolam)                   |              |            | C           |              |                    |                 | Not Reported |
|                                       | Meloxicam (Meloxicam)                     |              |            | C           |              |                    |                 | Not Reported |
|                                       | Tizanidine Hydrochloride                  |              |            | C           |              |                    |                 | Not Reported |
|                                       | Quetiapine Fumarate (Quetiapine Fumarate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2004              | 5706160       | DIRECT           | N                  | OT              |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                            |                     |        |  |  |  |  |  |                              |
|----------------------------------------------------------------------------------------------------------------------------|---------------------|--------|--|--|--|--|--|------------------------------|
| Condition Aggravated;<br>Depression; Emotional<br>Disorder; Feeling Of<br>Despair; Suicidal Ideation;<br>Thinking Abnormal | Lexapro<br>Lopresor | S<br>C |  |  |  |  |  | Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------|---------------------|--------|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2004              | 5710160       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S04-AUS-08252-01     |                      | 27 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Mouth; Systemic<br>Lupus Erythematosus;<br>Throat Tightness; Urticaria | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                               | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                               | Pamol (Paracetamol) |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Contraceptive Nos   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2004              | 5711284       | EXPEDITED (15-DAY) | Y                  | HO, OT          | KII-2004-0014321     |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Aspiration; Drug<br>Withdrawal Syndrome;<br>Hyperhidrosis;<br>Hypertension; Mydriasis;<br>Overdose; Pyrexia;<br>Somnolence; Tachycardia;<br>Therapy Non-Responder | Oxycontin                                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                              | Lexapro                                        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                              | Tetrahydrocannabinol<br>(Tetrahydrocannabinol) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                              | Skelaxin                                       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2004              | 4223523       | EXPEDITED (15-DAY) | N                  | HO, OT          | 2004S1002746         |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Drug<br>Hypersensitivity; Drug<br>Interaction; Toxicity To<br>Various Agents | Vistaril       |              |            | S           | Oral         | 50 Mg Qd, Oral     |                 | Not Reported |
|                                                                                              | Lexapro        |              |            | S           | Oral         | 10 Mg Qd, Oral     |                 | Not Reported |
|                                                                                              | Alprazolam     |              |            | S           | Oral         | 0.25 Mg Qd, Oral   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                          |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Metrogel                   |                          |                    | S                  |                 | Bid                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2004                | 5676544                  | EXPEDITED (15-DAY) | Y                  |                 | T04-USA-07232-01     |                      | 83 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood            | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Potassium Increased;       | Prevacid                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Blood Urea Increased;      | Detrol - Slow Release    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Condition Aggravated;      | (Tolterodine L-Tartrate) |                    |                    |                 |                      |                      |                 |              |                |
| Dehydration; Dyspepsia;    | Digoxin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Dysstasia; Gait Inability; | Lasix                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Gastroesophageal Reflux    | Coumadin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Disease; Hypertension;     | Lipitor                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hypophagia; Insomnia;      | Lisinopril               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Orthostatic Hypotension    | Potassium                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Reglan                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Prednisone               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Calcium With Vitamin D   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Tylenol (Paracetamol)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2004                | 5711792                  | DIRECT             | N                  |                 |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Headache;         | Lexapro                  |                    |                    | S               |                      | Tablet               |                 | Not Reported |                |
| Medication Error; Nausea   | Lipitor                  |                    |                    | S               |                      | Tablet               |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2004                | 5711840                  | DIRECT             | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error           | Lexapro                  |                    |                    | S               |                      | Tablet               |                 | Forest       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2004                                                                                                                                                                                       | 5711619                               | EXPEDITED (15-DAY) | Y                  | HO              | 2004AL001968         |                      | 29 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Dependence; Drug Withdrawal Syndrome; Fear; Maternal Exposure During Pregnancy                                                                                          | Oxazepam                              |                    |                    | S               | Oral                 | 15mg, Tid; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                   | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 20 Mg; Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lamotrigine                           |                    |                    | S               | Oral                 | 100 Mg Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                   | Trazodone Hydrochloride               |                    |                    | S               | Oral                 | 100 Mg Qd; Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2004                                                                                                                                                                                       | 5655800                               | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06678-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction; Attention Deficit/Hyperactivity Disorder; Autoimmune Thyroiditis; Depression; Disease Recurrence; Oropharyngeal Pain; Ovulation Pain; Therapeutic Product Effect Decreased | Lexapro                               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lexapro                               |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lexapro                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lexapro                               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                   | Minocycline\Minocycline Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Dicyclomine Hydrochloride             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Clarinet                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Prilosec                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Effexor Xr                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2004                                                                                                                                                                                       | 5669464                               | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-06411-01     |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Craniocerebral Injury; Gun Shot Wound; Insomnia; Medication Error                                                                                                              | Lexapro                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                   | Restoril                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Ambien                                |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Dec-2004                                                                                              | 5712096                       | EXPEDITED (15-DAY)        | Y                           | DS                       | S04-UKI-08245                 |                               | 58 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic Seizure                                                                         | Cipralext                     |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Dec-2004                                                                                              | 7385701                       | NON-EXPEDITED             | Y                           | DE                       | 04-06-0954                    |                               | 31 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Toxicity To Various Agents                                                                               | Clozapine                     |                           |                             | S                        | Oral                          | 300mg Hs Oral                 |                          | Ivax                |                         |
|                                                                                                          | Lexapro                       |                           |                             | S                        | Oral                          | 30mg Am Oral                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2005                                                                                              | 5662314                       | EXPEDITED (15-DAY)        | Y                           | DE, OT                   | 2004080312                    |                               | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arrhythmia; Brain Death; Circulatory Collapse; Fall; Loss Of Consciousness; Post Procedural Complication | Geodon                        |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Zyrtec                        |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Lipitor                       |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Ibuprofen (Ibuprofen)         |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Oxcarbazepine                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Escitalopram Oxalate          |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Lorazepam                     |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Metoprolol                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Zolpidem Tartrate             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Methylphenidate Hydrochloride |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                          | Lansoprazole                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                        | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Jan-2005                                                                                              | 5712848                       | DIRECT                    | Y                           | DE                       |                               |                               | 43 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                           | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                   |                 |   |                                       |                                |              |
|-------------------|-----------------|---|---------------------------------------|--------------------------------|--------------|
| Knee Arthroplasty | Meperidine      | S | Intravenous (not otherwise specified) | Pca Cont. + Demand Intravenous | Abbott       |
|                   | Lexapro         | S | Oral                                  | 30mg Daily Oral                | Not Reported |
|                   | Prevacid        | C |                                       |                                | Not Reported |
|                   | Klonopin        | C |                                       |                                | Not Reported |
|                   | Corgard         | C |                                       |                                | Not Reported |
|                   | Ferrous Sulfate | C |                                       |                                | Not Reported |
|                   | Pepcid          | C |                                       |                                | Not Reported |
|                   | Colace          | C |                                       |                                | Not Reported |
|                   | Kefzol          | C |                                       |                                | Not Reported |
|                   | Zofran          | C |                                       |                                | Not Reported |
|                   | Narcan          | C |                                       |                                | Not Reported |
|                   | Morphine        | C |                                       |                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2005              | 5709701       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06933-01     |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Feeling Abnormal; Feeling Hot; Hyperhidrosis;<br>Hypertension;<br>Hypoaesthesia; Pain In Extremity; Paraesthesia;<br>Vision Blurred | Lexapro                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                              | Lexapro                          |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                              | Cozaar                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Toprol XL (Metoprolol Succinate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Hydrochlorothiazide              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Clonidine                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Vivelle                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                              | Alphagan P                       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jan-2005              | 5718118       | EXPEDITED (15-DAY) | Y                  | RI              | S04-USA-05530-01     |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholelithiasis; False Labour; Induced Labour; Maternal Exposure During Pregnancy; Pregnancy | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                             | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

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| <u>FDA Received Date</u>                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 11-Jan-2005                                                     | 5708009                                 | EXPEDITED (15-DAY) | Y                  | HO              | S04-ITA-08108-01     |                          | 80 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Hyponatraemia                          | Ciprallex                               |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                 | Gabapentin                              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Deltacortene (Prednisone)               |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Lioresal "Ciba-Geigy" (Balclofen)       |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Enapren (Enalapril Maleate)             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Moduretic "Du Pont"                     |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Lansox (Lansoprazole)                   |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Pradif (Tamsulosin Hydrochloride)       |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Asa (Acetylsalicylic Acid)              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                 | Topical Broncodilatators For Inhalation |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2005                                                     | 5717041                                 | DIRECT             | Y                  | OT              |                      |                          | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Intentional Self-Injury; Skin Laceration   | Lexapro                                 |                    |                    | S               |                      | 10mg Am 047 11/7-11/24 ; |                 | Not Reported |                |
|                                                                 |                                         |                    |                    |                 |                      | 20mg Am 047 11/25-12/30  |                 |              |                |
|                                                                 |                                         |                    |                    |                 |                      | 10mg Am 047 11/7-11/24 ; |                 |              |                |
|                                                                 |                                         |                    |                    |                 |                      | 20mg Am 047 11/25-12/30  |                 |              |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2005                                                     | 5717749                                 | EXPEDITED (15-DAY) | N                  | LT              | S05-USA-00011-01     |                          | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Impulsive Behaviour; Mental Disorder; Suicide Attempt | Lexapro                                 |                    |                    | S               |                      |                          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|-----------------|----------------|
| 11-Jan-2005                                                                                                | 5718477                     | DIRECT             | Y                  | OT              |                      |                                             | 79 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| Constipation; Dementia;<br>Diarrhoea;<br>Haematochezia; Memory<br>Impairment; Vision Blurred               | Lexapro                     |                    |                    | S               |                      | 10mg Daily Decreased To<br>1/2 Tablet Daily |                 | Forest          |                |
|                                                                                                            | Zocor                       |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
|                                                                                                            | Actonel                     |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
|                                                                                                            | Zyrtec                      |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
|                                                                                                            | Levocabastine Hydrochloride |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
|                                                                                                            | Levoxyl                     |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 12-Jan-2005                                                                                                | 5674107                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | S04-USA-07135-01     |                                             | 24 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Depression;<br>Dizziness; Eating<br>Disorder; Fatigue; Sinus<br>Bradycardia; Weight<br>Decreased | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg Qd Po                                 |                 | Not Reported    |                |
|                                                                                                            | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po                                 |                 | Not Reported    |                |
|                                                                                                            | Prilosec                    |                    |                    | C               |                      |                                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jan-2005                                                                                                | 5714027                     | EXPEDITED (15-DAY) | Y                  | OT              | 2005000542           |                                             | 18 YR           | Female          | DEU            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| III-Defined Disorder;<br>Intentional Overdose;<br>Overdose; Somnolence;<br>Suicide Attempt                 | Lithium Carbonate           |                    |                    | S               | Oral                 | 9450mg Single Dose                          |                 | Glaxosmithkline |                |
|                                                                                                            | Risperdal                   |                    |                    | S               | Oral                 | 17.5mg Single Dose                          |                 | Not Reported    |                |
|                                                                                                            | Trileptal                   |                    |                    | S               | Oral                 | 11550mg Single Dose                         |                 | Not Reported    |                |
|                                                                                                            | Cipralext                   |                    |                    | S               | Oral                 | 350mg Single Dose                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Jan-2005                                                                                                | 5720917                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00062-01     |                                             | 31 YR           | Male            | USA            |

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| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Alcohol Increased                                                                                                                          | Lexapro                              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Alcohol                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                  | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2005                                                                                                                                      | 5761479                              | NON-EXPEDITED      | Y                  | DE              | HQWYE177723SEP04     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                | Effexor                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                  | Lexapro                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2005                                                                                                                                      | 5655808                              | EXPEDITED (15-DAY) | Y                  | HO, RI          | S04-USA-06784-01     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction; Post Procedural Complication; Priapism; Thrombosis                                                                         | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Seroquel                             |                    |                    | S               |                      | 400 Mg Qd            |                 | Not Reported |                |
|                                                                                                                                                  | Ambien                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2005                                                                                                                                      | 5661474                              | EXPEDITED (15-DAY) | Y                  | DE              | T04-SWI-06911-01     |                      | 79 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Shock; Cardiac Arrest; Cardiac Failure; Dermatitis Allergic; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased; Rash | Ebixa                                |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Ebixa                                |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Ebixa                                |                    |                    | S               |                      | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                  | Ciprallex                            |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                  | Ciprallex                            |                    |                    | S               |                      | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                  | Metolazone                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                  | Konakion                             |                    |                    | S               |                      | 5 Mg Qd Po           |                 | Not Reported |                |

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|  |                                  |   |      |                |              |
|--|----------------------------------|---|------|----------------|--------------|
|  | Beloc Zok (Metoprolol Succinate) | S | Oral | 25 Mg Qd Po    | Not Reported |
|  | Digoxin                          | S | Oral | 0.125 Mg Qd Po | Not Reported |
|  | Trospium Chloride                | S | Oral | 40 Mg Qd Po    | Not Reported |
|  | Aspirin                          | S | Oral | 100 Mg Qd Po   | Not Reported |
|  | Tramadol Hydrochloride           | S | Oral | 50 Mg Qd Po    | Not Reported |
|  | Zyrtec                           | S | Oral | 10 Mg Qd Po    | Not Reported |
|  | Zaroxolyn                        | C |      |                | Not Reported |
|  | Paragol                          | C |      |                | Not Reported |
|  | Calcium Gluconate                | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2005              | 5711447       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07931-01     |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block First Degree; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Electrocardiogram Pr Prolongation;   | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Electrocardiogram Qt Prolonged       | Androgel       |              |            | C           |              |                    |                 | Not Reported |
|                                      | Ambien         |              |            | C           |              |                    |                 | Not Reported |
|                                      | Prevacid       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2005              | 5722409       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07916-01     |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Rash Generalised; Skin Burning Sensation; | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
| Stevens-Johnson Syndrome; Vasculitis      | Ativan                 |              |            | C           |              |                    |                 | Not Reported |
|                                           | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2005              | 5722818       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-00083-01     |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                     |         |   |      |             |              |
|---------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Completed Suicide; Gun Shot Wound; Intentional Self-Injury; Scratch | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                     | Lexapro | S | Oral | 20 Mg Qd Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2005              | 5662669       | EXPEDITED (15-DAY) | Y                  | DE              | T04-SWI-06971-01     |                      | 48 YR      | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Completed Suicide | Cipralext                     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                              | Cipralext                     |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                              | Cipralext                     |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                              | Chlorprothixene Hydrochloride |              |            | S           | Oral         | 60 Mg Qd Po        |                 | Not Reported |
|                              | Lorazepam                     |              |            | S           | Oral         | 1 Mg Qd Po         |                 | Not Reported |
|                              | Lorazepam                     |              |            | S           | Oral         | 0.5 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2005              | 5726806       | EXPEDITED (15-DAY) | Y                  | HO              | US013912             |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atelectasis; Balance Disorder; Disorientation; Dizziness; Hypotension; Influenza Like Illness; Lung Infiltration; Myalgia; Pneumonia; Pyuria; Seizure; Septic Shock; Urinary Tract Infection; Vomiting | Provigil            |              |            | S           | Oral         | 100 Mg Qd Oral     |                 | Not Reported |
|                                                                                                                                                                                                        | Provigil            |              |            | S           | Oral         | 200 Mg Qd Oral     |                 | Not Reported |
|                                                                                                                                                                                                        | Provigil            |              |            | S           | Oral         | 50 Mg Once Oral    |                 | Not Reported |
|                                                                                                                                                                                                        | Klonopin            |              |            | S           | Oral         | 2.25 Mg Qd Oral    |                 | Not Reported |
|                                                                                                                                                                                                        | Neurontin           |              |            | S           | Oral         | 1200 Mg Qd Oral    |                 | Not Reported |
|                                                                                                                                                                                                        | Aciphex             |              |            | S           | Oral         | 60 Mg Qd Oral      |                 | Not Reported |
|                                                                                                                                                                                                        | Hydrochlorothiazide |              |            | S           | Oral         | 100 Mg Qd Oral     |                 | Not Reported |
|                                                                                                                                                                                                        | Doryx               |              |            | S           | Oral         | 100 Mg Qd Oral     |                 | Not Reported |
|                                                                                                                                                                                                        | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2005              | 5727110       | EXPEDITED (15-DAY) | Y                  | HO              | T04-SWI-08295-01     |                      | 32 YR      | Female     | CHE            |



# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acoustic Neuroma;<br>Antipsychotic Drug Level<br>Above Therapeutic;<br>Encopresis; Enuresis;<br>Hypertonic Bladder;<br>Incontinence; Therapy<br>Non-Responder; Urinary<br>Tract Infection | Ciprallex                                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Clozapine                                           |                    |                    | S               | Oral                 | 300 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                           | Clozapine                                           |                    |                    | S               | Oral                 | 275 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                           | Clozapine                                           |                    |                    | S               | Oral                 | 287.5 Mg Qd Po       |                 | Not Reported |                |
|                                                                                                                                                                                           | Orfiril (Valproate Sodium)                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Magnesiocard (Magnesium<br>Aspartate Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2005                                                                                                                                                                               | 5727324                                             | EXPEDITED (15-DAY) | Y                  | RI              | S05-USA-00188-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                                                                                                                                                                                  | Lexapro                                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Zyprexa                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2005                                                                                                                                                                               | 5727328                                             | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07366-01     |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alcohol Use;<br>Spousal Abuse                                                                                                                                                 | Lexapro                                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                           | Alcohol                                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                  | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2005                                                                                                                                                                               | 5727344                                             | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00195-01     |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure                                                                                                                                                       | Lexapro                                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro                                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Lexapro                                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                           | Combivent                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Jan-2005                                                                                                                                                                                                                                                                                 | 5728754                       | DIRECT             | Y                  | DE              |                      |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Amnesia; Anger;<br>Completed Suicide; Drug<br>Interaction; Economic<br>Problem; Fear; Gun Shot<br>Wound; Insomnia;<br>Movement Disorder;<br>Overdose; Salivary<br>Hypersecretion; Serotonin<br>Syndrome; Speech<br>Disorder; Thinking<br>Abnormal; Tremor | Lexapro                       |                    |                    | S               | Oral                 | 1 Daily Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Phentermine                   |                    |                    | S               | Oral                 | 1 Daily Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Avandamet 4/500               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Glyburide                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Synthroid                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Temazepam                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Esgic-Plus                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Lipitor                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Lexapro                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2005                                                                                                                                                                                                                                                                                 | 5673287                       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_25219_2004       |                      | 56 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Completed<br>Suicide                                                                                                                                                                                                                                                             | Lorazepam                     |                    |                    | S               | Oral                 | 0.5 Mg Q Day Po      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Lorazepam                     |                    |                    | S               | Oral                 | 1 Mg Q Day Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Chlorprothixene Hydrochloride |                    |                    | S               |                      | 60 Mg Q Day          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Cipralext                     |                    |                    | S               |                      | 20 Mg Q Day          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Cipralext                     |                    |                    | S               |                      | 15 Mg Q Day          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Cipralext                     |                    |                    | S               |                      | 10 Mg Q Day          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2005                                                                                                                                                                                                                                                                                 | 5658471                       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06881-01     |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intracranial Hypotension;                                                                                                                                                                                                                                                                   | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |                        |   |      |             |              |
|-------------------------------------------------|------------------------|---|------|-------------|--------------|
| Migraine; Nausea; Post Procedural Complication; | Lexapro                | S | Oral | 5 Mg Qd Po  | Not Reported |
| Therapy Non-Responder;                          | Lexapro                | S | Oral | 10 Mg Qd Po | Not Reported |
| Vomiting                                        | Unspecified Ingredient | C |      |             | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2005                       | 5676569                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-07185-01              |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| No Adverse Event               | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2005                       | 5684451                | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-USA-07370-01              |                               | 32 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Conversion Disorder; Loss Of Consciousness | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg Qd Po                  |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2005                       | 5712288                | EXPEDITED (15-DAY)        | N                           | OT                       | S04-USA-07926-01              |                               | 19 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|------------------------------|
| Abnormal Behaviour; Amnesia; Blood Alcohol Increased; Concussion; Delirium; Drug Screen Positive; Fall; Gait Disturbance; Head Injury; Headache; Loss Of Consciousness; Sedation | Lexapro Alcohol         |                       |                     | S<br>S               |                       |                             |                          | Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2005                       | 5731866                | EXPEDITED (15-DAY)        | N                           | HO                       | S05-USA-00194-01              |                               | 18 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |                          |                    |                    |                 |                      |                      |                 |                              |                |
|-----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Influenza Like Illness;<br>Pulmonary Embolism                               | Lexapro<br>Adderall      |                    | S<br>C             | Oral            | 10 Mg Qd Po          |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 27-Jan-2005                                                                 | 5731867                  | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00234-01     |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Accommodation Disorder;<br>Eye Disorder; Eye<br>Haemorrhage;<br>Maculopathy | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 27-Jan-2005                                                                 | 5732483                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-00210-01     |                      | 87 YR           | Unknown                      | GBR            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hypoglycaemia                                                               | Ciprallex                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported                 |                |
|                                                                             | Albuterol                |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                             | Warfarin Sodium          |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                             | Ramipril                 |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                             | Rabeprazle (Rabeprazole) |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                             | Isosorbide Mononitrate   |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Jan-2005                                                                 | 5650833                  | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06456-01     |                      | 28 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Dizziness;<br>Hyperthyroidism;<br>Palpitations                     | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                             | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qod Po         |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Jan-2005                                                                 | 5712269                  | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-07727-01     |                      | 59 YR           | Female                       | USA            |

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| <u>Preferred Term</u>                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Abscess; Furuncle;<br>Immune System Disorder;<br>Therapy Non-Responder;<br>Vaginal Abscess | Lexapro           |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                            | Tamoxifen Citrate |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                                                | 5719085           | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-08050-01     |                      | 43 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Screen Positive;<br>Generalised Tonic-Clonic<br>Seizure; Status Epilepticus           | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                            | Protonix          |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                                                | 5724614           | NON-EXPEDITED      | N                  |                 | S03-USA-04967-01     |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Fatigue                                                                                    | Wellbutrin        |                    |                    | S               | Oral                 | 200mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                            | Lexapro           |                    |                    | S               | Oral                 | 10mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                                                | 5724615           | NON-EXPEDITED      | N                  |                 | S03-USA-04869-01     |                      | 53 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Diffuse Alopecia                                                                           | Wellbutrin        |                    |                    | S               | Oral                 |                      | 6 MTH           | Glaxosmithkline |                |
|                                                                                            | Lexapro           |                    |                    | S               | Oral                 | 10mg Per Day         | 1 YR            | Not Reported    |                |
|                                                                                            | Risperdal         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                            | Klonopin          |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                                                | 5724642           | NON-EXPEDITED      | N                  |                 | S03-USA-05410-01     |                      |                 | Female          | USA            |

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| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|--------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Drug Interaction; Feeling Abnormal; Impaired Driving Ability | Wellbutrin             |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                                              | Lexapro                |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                  | 5724813                | NON-EXPEDITED      | Y                  | OT              | 20040304012          |                      | 53 YR           | Female          | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Immune Thrombocytopenic Purpura; Platelet Count Decreased    | Wellbutrin             |                    |                    | S               | Oral                 | 200mg Twice Per Day  | 317 DAY         | Glaxosmithkline |                |
|                                                              | Topamax                |                    |                    | S               | Unknown              | 300mg Per Day        |                 | Not Reported    |                |
|                                                              | Lexapro                |                    |                    | S               | Unknown              | 20mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                  | 5724822                | NON-EXPEDITED      | Y                  | OT              | S04-USA-04203-01     |                      |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Mania; Weight Increased                                      | Wellbutrin             |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                                              | Lexapro                |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2005                                                  | 5725209                | EXPEDITED (15-DAY) | N                  | HO              | US-ROCHE-391291      |                      | 69 YR           | Female          | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Chest Discomfort; Drug Withdrawal Syndrome                   | Valium                 |                    |                    | S               | Oral                 |                      |                 | Roche           |                |
|                                                              | Unspecified Ingredient |                    |                    | S               | Intrathecal          | Generic: Ziconotide  |                 | Not Reported    |                |
|                                                              | Norco                  |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
|                                                              | Lexapro                |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
|                                                              | Avinza                 |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2005               | 5730766                         | EXPEDITED (15-DAY) | Y                  | HO              | S05-AUT-00145-01     |                      | 59 YR           | Male         | AUS            |
| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;     | Lexapro                         |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
| Burning Sensation; Chest  | Minipress                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Pain; Duodenal Ulcer;     | Atacand (Candesartan Cilexetil) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Gastrointestinal          | Zocor                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Haemorrhage; Overdose     | Glyburide                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2005               | 5712271                         | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-07918-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Abscess; Furuncle; | Lexapro                         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Immune System Disorder;   |                                 |                    |                    |                 |                      |                      |                 |              |                |
| Subcutaneous Abscess;     |                                 |                    |                    |                 |                      |                      |                 |              |                |
| Vaginal Abscess           |                                 |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2005               | 5676565                         | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07189-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Optic Neuritis            | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2005               | 5705662                         | EXPEDITED (15-DAY) | N                  | HO, OT          | PHEH2004US13574      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder; Drug    | Vivelle Dot                     |                    |                    | S               | Transdermal          | 0.05mg/Day           |                 | Novartis     |                |
| Withdrawal Syndrome;      | Lexapro                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Headache; Heart Injury;   |                                 |                    |                    |                 |                      |                      |                 |              |                |
| Transient Ischaemic       |                                 |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

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Attack

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2005              | 5727755       | EXPEDITED (15-DAY) | Y                  | HO              | US-MERCK-0501USA04023 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder; Chills;  | Hydrodiuril    |              |            | S           | Oral         |                    |                 | Merck        |
| Diarrhoea; Disorientation; | Provigil       |              |            | S           | Oral         |                    |                 | Not Reported |
| Dizziness;                 | Provigil       |              |            | S           | Oral         |                    | 1 DAY           | Not Reported |
| Electroencephalogram       | Provigil       |              |            | S           | Oral         |                    |                 | Not Reported |
| Abnormal; Fatigue;         | Provigil       |              |            | S           | Oral         |                    |                 | Not Reported |
| Feeling Abnormal;          | Provigil       |              |            | S           | Oral         |                    | 1 DAY           | Not Reported |
| Hypotension; Influenza     | Provigil       |              |            | S           | Oral         |                    |                 | Not Reported |
| Like Illness; Lung         | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Infiltration; Myalgia;     | Doryx          |              |            | S           | Oral         |                    |                 | Not Reported |
| Nausea; Pleural Effusion;  | Neurontin      |              |            | S           | Oral         |                    |                 | Not Reported |
| Pneumonia; Pyrexia;        | Aciphex        |              |            | S           | Oral         |                    |                 | Not Reported |
| Pyuria; Seizure; Urinary   | Klonopin       |              |            | S           | Oral         |                    |                 | Not Reported |
| Tract Infection; Vomiting; |                |              |            |             |              |                    |                 |              |
| White Blood Cell Count     |                |              |            |             |              |                    |                 |              |
| Increased                  |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2005              | 3980648       | EXPEDITED (15-DAY) | Y                  | OT              | T03-SWI-02920-01     |                      | 37 YR      | Male       | CHE            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electroencephalogram       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Hypersomnia;     | Placebo              |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |
| Hyperventilation; Syncope; | Similasan            |              |            | C           |              |                    |                 | Not Reported |
| Tremor                     |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2005              | 6747135       | EXPEDITED (15-DAY) | Y                  | DE              | T05-JPN-00135-01     |                      | 54 YR      | Male       | JPN            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Cold Exposure     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Injury; Completed Suicide; |                      |              |            |             |              |                    |                 |              |



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|                                               |                                         |                           |                             |                          |                                                 |                               |                          |                     |                         |
|-----------------------------------------------|-----------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Micturition Disorder;<br>Stress               | Escitalopram Oxalate                    |                           | S                           | Oral                     | 20 Mg Qd Po                                     |                               | Not Reported             |                     |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Feb-2005                                   | 4197942                                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S04-IRL-03671-01                                |                               | 46 YR                    | Female              | IRL                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>                 | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypochromic Anaemia;<br>Menorrhagia           | Lexapro                                 |                           |                             | S                        | Oral                                            | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                               | Amitriptyline Hydrochloride             |                           |                             | C                        |                                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Feb-2005                                   | 5729160                                 | EXPEDITED (15-DAY)        | Y                           | HO                       | ES-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12837597 |                               | 78 YR                    | Female              | ESP                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>                 | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                                 | Deprax (Trazodone<br>Hydrochloride)     |                           |                             | S                        | Oral                                            |                               | 14 DAY                   | Apothecon           |                         |
|                                               | Escitalopram Oxalate                    |                           |                             | S                        | Oral                                            |                               | 14 DAY                   | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Feb-2005                                   | 5741073                                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1722                                            |                               | 69 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>                 | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Discomfort; Drug<br>Withdrawal Syndrome | Avinza                                  |                           |                             | S                        | Oral                                            | 120 Mg Daily Po               |                          | Not Reported        |                         |
|                                               | Avinza                                  |                           |                             | S                        | Oral                                            | 60 Mg Daily Po                |                          | Not Reported        |                         |
|                                               | Ziconotide                              |                           |                             | S                        |                                                 | 0.3 Mcg                       |                          | Not Reported        |                         |
|                                               | Acetaminophen\Hydrocodone<br>Bitartrate |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                               | Valium                                  |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                               | Lexapro                                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Feb-2005                                   | 4161881                                 | EXPEDITED (15-DAY)        | N                           | OT                       | S04-USA-03238-01                                |                               | 53 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------|------------------------|-----------------|-----------------|----------------|
| Condition Aggravated;<br>Drug Level Decreased;<br>Electroencephalogram<br>Abnormal; Seizure; Simple<br>Partial Seizures | Lexapro              |                    |                    | S               | Oral                                 | 10 Mg Qd Po            |                 | Not Reported    |                |
|                                                                                                                         | Depakote             |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Levothroid           |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Feb-2005                                                                                                             | 5718063              | EXPEDITED (15-DAY) | Y                  | OT              | 2005001209                           |                        | 62 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>      |                |
| Atrial Fibrillation; Condition<br>Aggravated; Heart Rate<br>Increased;<br>Supraventricular<br>Extrasystoles             | Tikosyn              |                    |                    | S               | Oral                                 | See Image<br>See Image |                 | Not Reported    |                |
|                                                                                                                         | Escitalopram Oxalate |                    |                    | S               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Ezetimibe            |                    |                    | S               |                                      |                        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Feb-2005                                                                                                             | 5718982              | EXPEDITED (15-DAY) | N                  | HO              | US-<br>GLAXOSMITHKLINE-<br>A0540443A |                        |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure<br>Decreased; Coma; Drug<br>Ineffective; Drug<br>Interaction; Medication<br>Error                        | Wellbutrin           |                    |                    | S               | Oral                                 | 300mg See Dosage Text  |                 | Glaxosmithkline |                |
|                                                                                                                         | Lexapro              |                    |                    | S               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Atenolol             |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Avandia              |                    |                    | C               |                                      |                        |                 | Glaxosmithkline |                |
|                                                                                                                         | Nexium               |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Aspirin              |                    |                    | C               |                                      |                        |                 | Glaxosmithkline |                |
|                                                                                                                         | Aricept              |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Neurontin            |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Centrum Silver       |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Magnesium            |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Potassium            |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Duragesic            |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Cyanocobalamin       |                    |                    | C               |                                      |                        |                 | Glaxosmithkline |                |
|                                                                                                                         | Hydrocodone          |                    |                    | C               |                                      |                        |                 | Not Reported    |                |
|                                                                                                                         | Zocor                |                    |                    | C               |                                      |                        |                 | Not Reported    |                |

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| Diazepam                                                                                                   |                                                                      |                    | C                  |                  |                              | Not Reported         |                 |                                                              |                |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
| Isosorbide                                                                                                 |                                                                      |                    | C                  |                  |                              | Not Reported         |                 |                                                              |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 04-Feb-2005                                                                                                | 5739827                                                              | EXPEDITED (15-DAY) | Y                  | OT               | S05-UKI-00220-01             |                      | 28 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Intentional Self-Injury;<br>Self-Injurious Ideation;<br>Suicidal Ideation                                  | Cipralelex                                                           |                    |                    | S                | Oral                         | 10 Mg Qd Po          |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 05-Feb-2005                                                                                                | 5730301                                                              | EXPEDITED (15-DAY) |                    | OT               | US-ABBOTT-05P-163-0288882-00 |                      | 15 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Aggression; Depression;<br>Drug Interaction; Feeling<br>Hot; Hyperhidrosis;<br>Seizure; Suicidal Ideation  | Biaxin<br>Biaxin<br>Lexapro                                          |                    |                    | S<br>S<br>S      | Oral                         |                      |                 | Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 07-Feb-2005                                                                                                | 5726393                                                              | EXPEDITED (15-DAY) | Y                  | DE               | S05-ISR-00201-01             |                      | 24 YR           | Female                                                       | ISR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Abdominal Pain Upper;<br>Blood Cholesterol<br>Increased; Hepatitis<br>Fulminant; Pyrexia; Renal<br>Failure | Cipralelex<br>Clonazepam<br>Calcium Gluconate<br>Normiten (Atenolol) |                    |                    | S<br>C<br>C<br>C | Oral                         | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 07-Feb-2005                                                                                                | 5740253                                                              | EXPEDITED (15-DAY) | Y                  | OT               | S05-UKI-00351-01             |                      | 30 YR           | Female                                                       | GBR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |

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|                                                          |                                    |                    |                    |                 |                              |                      |                 |                 |                |
|----------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Dissociation; Gait Disturbance; Paranoia; Vision Blurred |                                    | Ciprallex          | S                  | Oral            | 10 Mg Qd Po                  | Not Reported         |                 |                 |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Feb-2005                                              | 5740261                            | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-00353-01             |                      | 55 YR           | Male            | GBR            |
| <u>Preferred Term</u>                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Prostatitis; Urethritis                                  | Ciprallex                          |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2005                                              | 5700173                            | EXPEDITED (15-DAY) | Y                  | OT              | S04-FRA-07953-01             |                      | 50 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypertensive Crisis                                      | Escitalopram Oxalate               |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                          | Zyprexa                            |                    |                    | S               | Oral                         | 7.5 Mg Qd Po         |                 | Not Reported    |                |
|                                                          | Seropram (Citalopram Hydrobromide) |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                          | Atarax                             |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2005                                              | 5732224                            | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0523042A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nausea                                                   | Paroxetine Hydrochloride           |                    |                    | S               |                              |                      |                 | Glaxosmithkline |                |
|                                                          | Lexapro                            |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2005                                              | 5733144                            | NON-EXPEDITED      | N                  |                 | S03-USA-05182-01             |                      | 26 YR           | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Anger;                                        | Paxil                              |                    |                    | S               | Oral                         | 20mg Per Day         |                 | Glaxosmithkline |                |

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|                                                                       |                      |        |      |              |                              |
|-----------------------------------------------------------------------|----------------------|--------|------|--------------|------------------------------|
| Headache; Insomnia;<br>Mental Impairment;<br>Muscle Twitching; Thirst | Lexapro<br>Strattera | S<br>C | Oral | 20mg Per Day | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------|----------------------|--------|------|--------------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2005              | 5741539       | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-00436-01     |                      | 78 YR      | Unknown    | GBR            |

| <u>Preferred Term</u> | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erythema; Flushing    | Cipralax                                   |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Temazepam                                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Aspirin                                    |              |            | C           |              |                    |                 | Not Reported |
|                       | Betahistine (Betahistine)                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Losartan (Losartan)                        |              |            | C           |              |                    |                 | Not Reported |
|                       | Ranitidine                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Prochlorperazine                           |              |            | C           |              |                    |                 | Not Reported |
|                       | Risedronate Sodium<br>(Residronate Sodium) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2005              | 5744003       | DIRECT           | Y                  | OT              |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Abnormal;<br>Drug Ineffective; Product<br>Quality Issue; Sexual<br>Dysfunction; Thinking<br>Abnormal | Prozac         |              |            | S           |              | Po                 |                 | Not Reported |
|                                                                                                                    | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2005              | 6962477       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00455-02     |                      | 60 DAY     | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During<br>Breast Feeding; Social<br>Problem; Somnolence;<br>Weight Gain Poor | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Mircette       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Feb-2005                                                                                    | 4219898                 | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-06121-01     |                      | 10 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Loss Of Consciousness; Seizure                                                         | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                | Strattera               |                    |                    | S               | Oral                 | 40 Mg Po             |                 | Not Reported |                |
|                                                                                                | Strattera               |                    |                    | S               |                      | 25 Mg                |                 | Not Reported |                |
|                                                                                                | Strattera               |                    |                    | S               |                      | 18 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2005                                                                                    | 5744252                 | EXPEDITED (15-DAY) | Y                  | LT              | S05-UKI-00435-01     |                      | 45 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Mental Impairment; Negativism; Self-Injurious Ideation                         | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                | Diazepam                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2005                                                                                    | 5744363                 | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00559-01     |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Choking                                                                                        | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2005                                                                                    | 5656345                 | EXPEDITED (15-DAY) | Y                  | DE              | 2004AL000785         |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma; Completed Suicide; Hypotension; Intentional Overdose; Therapy Non-Responder | Verapamil Hydrochloride |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                                                | Clonazepam              |                    |                    | S               | Oral                 | Po                   |                 | Purepac      |                |
|                                                                                                | Atorvastatin            |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |

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|                            |                                |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate       |                                |                    | S                  | Oral            | Po                   | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2005                | 5657530                        | EXPEDITED (15-DAY) | Y                  | DE              | 2004AL000733         |                      | 84 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;         | Clonidine Hydrochloride        |                    |                    | S               | Oral                 | Po                   |                 | Purepac      |                |
| Haemodialysis;             | Amlodipine Besylate\Benazepril |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| Hyperglycaemia;            | Hydrochloride                  |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| Hypotension; Overdose;     | Glimepiride                    |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| Renal Failure; Therapy     | Promethazine Hydrochloride     |                    |                    | S               | Oral                 | Po                   |                 | Alphapharm   |                |
| Non-Responder              | Diazepam                       |                    |                    | S               | Oral                 | Po                   |                 | Purepac      |                |
|                            | Lorazepam                      |                    |                    | S               | Oral                 | Po                   |                 | Purepac      |                |
|                            | Risperidone                    |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                            | Escitalopram Oxalate           |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2005                | 5657623                        | EXPEDITED (15-DAY) | Y                  | DE              | 2004AL000681         |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase   | Lorazepam                      |                    |                    | S               | Oral                 | Po                   |                 | Purepac      |                |
| Increased; Aspartate       | Childrens Acetaminophen        |                    |                    | S               | Oral                 | Po                   |                 | Alphapharm   |                |
| Aminotransferase           | Acetaminophen                  |                    |                    | S               |                      |                      |                 | Alphapharm   |                |
| Increased; Blood           | Desipramine Hydrochloride      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Bicarbonate Decreased;     | Escitalopram Oxalate           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Blood Calcium Decreased;   |                                |                    |                    |                 |                      |                      |                 |              |                |
| Blood Creatinine           |                                |                    |                    |                 |                      |                      |                 |              |                |
| Phosphokinase Increased;   |                                |                    |                    |                 |                      |                      |                 |              |                |
| Blood Creatinine           |                                |                    |                    |                 |                      |                      |                 |              |                |
| Increased; Blood Ph        |                                |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Blood           |                                |                    |                    |                 |                      |                      |                 |              |                |
| Potassium Decreased;       |                                |                    |                    |                 |                      |                      |                 |              |                |
| Bradycardia; Cardiac       |                                |                    |                    |                 |                      |                      |                 |              |                |
| Arrest; Completed Suicide; |                                |                    |                    |                 |                      |                      |                 |              |                |
| Hypotension; Overdose;     |                                |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oxygen Saturation  
Decreased; Pco2  
Decreased; Po2  
Decreased; Respiratory  
Arrest; Respiratory  
Depression

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2005              | 5657624       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2004AL000823         |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Body<br>Temperature Increased;<br>Cardiac Arrest; Coma;<br>Completed Suicide;<br>Electrocardiogram Qt<br>Prolonged; Haemodialysis;<br>Hypotension; Hypoxia;<br>Intentional Overdose;<br>Nodal Rhythm;<br>Pneumonia Aspiration;<br>Renal Failure; Respiratory<br>Arrest; Supraventricular<br>Tachycardia; Therapy<br>Non-Responder | Lorazepam               |              |            | S           | Oral         | Po                 |                 | Purepac      |
|                                                                                                                                                                                                                                                                                                                                                        | Diltiazem Hydrochloride |              |            | S           | Oral         | Po                 |                 | Purepac      |
|                                                                                                                                                                                                                                                                                                                                                        | Benzotropine            |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate    |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Ziprasidone             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Fenofexadine            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Oxcarbazepine           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2005              | 5659632       | EXPEDITED (15-DAY) | N                  | OT              | S04-USA-06883-01     |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intraocular Pressure<br>Increased; Sinusitis | Lexapro            |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                              | Lexapro            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                              | Prosom (Estazolam) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2005              | 5712064       | EXPEDITED (15-DAY) | Y                  | HO              | S04-AUS-08256-01     |                      | 41 YR      | Female     | AUS            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Overdose; Urinary Retention                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qid Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Seroquel             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Edronax              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2005                                                                                                                                                                                                                                                                                                                        | 5745037              | EXPEDITED (15-DAY) | Y                  | RI              | S05-USA-00383-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Anaemia; Drug Ineffective; Drug Interaction; Lichen Planus; Uterine Leiomyoma                                                                                                                                                                                                                                             | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Lupron               |                    |                    | S               | Intramuscular        | 3.75 Mg Im           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Lupron               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Lupron               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Topamax              |                    |                    | S               | Oral                 | 100 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Unisom Sleeptabs     |                    |                    | S               | Oral                 | 1 Tablet Qd Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Feb-2005                                                                                                                                                                                                                                                                                                                        | 5692881              | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07514-01     |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Decreased; Blood Bicarbonate Decreased; Blood Glucose Increased; Blood Ph Increased; Blood Potassium Decreased; Coma; Encephalopathy; Hyperammonaemia; Hypotension; Intentional Overdose; Lethargy; Pco2 Decreased; Pneumonia | Lexapro              |                    |                    | S               | Oral                 | 300 Mg Once Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Lexapro              |                    |                    | S               | Oral                 | 80 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Plavix               |                    |                    | S               |                      | 20 Tablet Once       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Plavix               |                    |                    | S               |                      | 75 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Ambien               |                    |                    | S               |                      | 130 Mg Once          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Ambien               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Depakote             |                    |                    | S               |                      | 4 G Once             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Depakote             |                    |                    | S               |                      | 125 Mg Bid           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Depakote             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Xanax                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Xanax                |                    |                    | S               |                      | 0.5 Mg Tid           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Klonopin             |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                      |   |          |              |
|------------------------------|----------------------|---|----------|--------------|
| Haemophilus; Suicide Attempt | Klonopin             | S | 5 Mg Tid | Not Reported |
|                              | Phenergan            | S |          | Not Reported |
|                              | Acetylsalicylic Acid | C |          | Not Reported |
|                              | Migranal             | C |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 4217727       | EXPEDITED (15-DAY) | N                  | DE              | DSA_24891_2004       |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Completed Suicide; Condition Aggravated; Depression; Disease Recurrence; Gun Shot Wound; Lung Disorder | Teveten        |              |            | S           | Oral         | 250 Mg Q Day Po    |                 | Not Reported |
|                                                                                                                 | Lexapro        |              |            | S           |              | 5 Mg Qhs           |                 | Not Reported |
|                                                                                                                 | Protonix       |              |            | S           |              | 40 Mg Qhs          |                 | Pharmacia    |
|                                                                                                                 |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 5692597       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07506-01     |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Crying; Depression; Panic Attack; Psychotic Disorder; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 5 Mg Tid Po        |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Qhs Po       |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                               | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                               |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 5717674       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00020-01     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |                        |   |      |             |  |              |
|----------------------------------|------------------------|---|------|-------------|--|--------------|
| Generalised Tonic-Clonic Seizure | Lexapro                | S | Oral | 10 Mg Qd Po |  | Not Reported |
|                                  | Advair Diskus          | C |      |             |  | Not Reported |
|                                  | Allerx                 | C |      |             |  | Not Reported |
|                                  | Nexium (Esomeprazole)  | C |      |             |  | Not Reported |
|                                  | Unspecified Ingredient | C |      |             |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 5737550       | NON-EXPEDITED    | N                  |                 | S04-USA-02836-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Bradycardia           | Lamotrigine    |              |            | S           | Oral         | 25mg Per Day       | 5 WEEK          | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |
|                       | Lexapro        |              |            | S           | Oral         | 5mg Per Day        |                 | Not Reported    |
|                       | Abilify        |              |            | C           | Unknown      | 30mg Per Day       |                 | Not Reported    |
|                       | Benadryl       |              |            | C           | Unknown      | 50mg Per Day       |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 5737858       | NON-EXPEDITED    | N                  | HO              | S04-USA-04591-01     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Choreoathetosis; Hypomania | Lamictal                  |              |            | S           | Oral         | 150mg Per Day      |                 | Glaxosmithkline |
|                            | Lexapro                   |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |
|                            | No Concurrent Medications |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2005              | 5738437       | NON-EXPEDITED    | Y                  |                 | US-GLAXOSMITHKLINE-A0501198A |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Alopecia              | Lamictal       |              |            | S           | Oral         | 200mg Per Day      | 666 DAY         | Glaxosmithkline |
|                       | Risperidal     |              |            | S           | Oral         | 1mg Per Day        |                 | Not Reported    |
|                       | Lexapro        |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                           | Centrum Silver      |                    | C                  |                 |                              |                      |                 |                 | Not Reported    |
|-----------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|-----------------|
|                                                                                                           | Neurontin           |                    | C                  |                 |                              | 600mg Per Day        |                 |                 | Not Reported    |
|                                                                                                           | Klonopin            |                    | C                  |                 |                              |                      |                 |                 | Not Reported    |
|                                                                                                           | Adderall            |                    | C                  |                 |                              |                      |                 |                 | Not Reported    |
|                                                                                                           | Synthroid           |                    | C                  |                 |                              | .025mg Per Day       |                 |                 | Glaxosmithkline |
|                                                                                                           | Omega 3 Fatty Acids |                    | C                  |                 |                              |                      |                 |                 | Glaxosmithkline |
|                                                                                                           | Vitamin E           |                    | C                  |                 |                              |                      |                 |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 14-Feb-2005                                                                                               | 5738539             | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0505421A |                      | 25 YR           | Female          | USA             |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Disorientation; Dizziness; Eye Irritation; Nausea                                                         | Lamictal            |                    |                    | S               | Oral                         | 100mg Twice Per Day  | 1 MTH           | Glaxosmithkline |                 |
|                                                                                                           | Lexapro             |                    |                    | S               |                              |                      |                 | Not Reported    |                 |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 14-Feb-2005                                                                                               | 5739677             | EXPEDITED (15-DAY) | Y                  |                 | S05-USA-00396-01             |                      |                 | Unknown         | USA             |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Akathisia; Restless Legs Syndrome                                                                         | Lexapro             |                    |                    | S               |                              |                      |                 | Not Reported    |                 |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>  |
| 15-Feb-2005                                                                                               | 5709666             | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-0412USA03322        |                      | 62 YR           | Male            | USA             |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                 |
| Atrial Fibrillation; Electrocardiogram Qt Prolonged; Heart Rate Increased; Supraventricular Extrasystoles | Zetia               |                    |                    | S               | Oral                         |                      |                 | Merck           |                 |
|                                                                                                           | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                 |
|                                                                                                           | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                 |
|                                                                                                           | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                 |
|                                                                                                           | Tikosyn             |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                 |
|                                                                                                           | Tikosyn             |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                 |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 15-Feb-2005                                                                   | 5746112        | DIRECT           | Y                  |                 |                      |                        | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                                                                     | Lexapro        |                  |                    | S               | Oral                 | 1 Po Daily             |                 | Forest       |                |
|                                                                               | Clonopin       |                  |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2005                                                                   | 5746115        | DIRECT           | N                  | OT              |                      |                        | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Ineffective; Drug Withdrawal Syndrome; Panic Attack | Lexapro        |                  |                    | S               |                      | Sample Size 1/Day Oral |                 | Not Reported |                |
|                                                                               | Multi-Vitamin  |                  |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2005                                                                   | 5747471        | DIRECT           | Y                  | RI              |                      |                        | 79 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Gambling                                                  | Lexapro        |                  |                    | S               |                      | Per Orem               | 2 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2005                                                                   | 5749490        | DIRECT           | N                  | DE              |                      |                        | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                             | Lexapro        |                  |                    | S               |                      | 10 Mg 1 Per Day        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2005                                                                   | 5749862        | DIRECT           | Y                  | DE              |                      |                        | 21 YR           | Male         | USA            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Coma; Hypertrophic Cardiomyopathy; Nausea; Toxicity To Various Agents                                               | Lexapro                 |                           |                             | S                        | Oral                          | 45 Mg, Single Dose, Po        |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2005                                                                                                         | 4143267                 | NON-EXPEDITED             | Y                           |                          | US-GLAXOSMITHKLINE-A0500360A  |                               | 82 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Blood Pressure Increased; Decreased Appetite; Drug Ineffective; Energy Increased; Stress; Weight Decreased | Wellbutrin XI           |                           |                             | S                        | Oral                          | 200mg Per Day                 | 2 YR                     | Glaxosmithkline     |                         |
|                                                                                                                     | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                     | Aspirin                 |                           |                             | C                        |                               |                               |                          | Glaxosmithkline     |                         |
|                                                                                                                     | Zocor                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                     | Prilosec                |                           |                             | C                        |                               |                               |                          | Glaxosmithkline     |                         |
|                                                                                                                     | Klonopin                |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2005                                                                                                         | 5752634                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-USA-00704-01              |                               | 22 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypothyroidism                                                                                                      | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2005                                                                                                         | 5719079                 | EXPEDITED (15-DAY)        | N                           | DS                       | S05-USA-08124-01              |                               | 67 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blindness Unilateral; Cerebrovascular Accident; Insomnia; Nightmare                                                 | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                     | Celebrex                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                     | Alprazolam              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2005                                                                                                         | 5722983                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-USA-00077-01              |                               | 7 YR                     | Female              | USA                     |

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| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Intentional Self-Injury;<br>Posturing; Suicidal<br>Ideation                                                         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                     | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                     | Concerta       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Klonopin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Risperdal      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Benadryl       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2005                                                                                                         | 5750434        | DIRECT             | Y                  | RI              |                      |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                                                                                                                | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Q Hs Oral       |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2005                                                                                                         | 4190766        | EXPEDITED (15-DAY) | Y                  | OT              | S04-GER-03331-01     |                      | 54 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                                                                            | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                     | Vioxx          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Propecia       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2005                                                                                                         | 5751423        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00780-01     |                      | 88 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Dyskinesia; Fall;<br>Hip Fracture; Lip<br>Discolouration; Seizure;<br>Swelling Face; Tongue<br>Discolouration | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                     | Lisinopril     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Armour Thyroid |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Norpace        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Digoxin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Antivert       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                     | Zetia          |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                                                                                                                                    |                               |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Lipitor                                                                                                                                            |                               |                    | C                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2005                                                                                                                                        | 5752812                       | DIRECT             | N                  | DE              |                      |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Withdrawal Syndrome; Feeling Abnormal; Hallucination; Hypoaesthesia; Insomnia; Paraesthesia; Product Quality Issue; Tremor | Lexapro                       |                    |                    | S               |                      | 1 A Day              |                 | Not Reported |                |
|                                                                                                                                                    | Paxil Cr                      |                    |                    | S               |                      | 1 A Day              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2005                                                                                                                                        | 5733849                       | EXPEDITED (15-DAY) | Y                  | HO              | S05-DEN-00341-01     |                      | 79 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hiatus Hernia; Nausea; Vomiting                                                                                                                    | Cipraxel                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                    | Lansoprazole                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Primperan                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Novazulid                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Odrik (Trandolapril)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Furosemide                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Keleorid (Potassium Chloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Selozok                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Remeron                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Acetaminophen                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Albyl-Enterosolubile          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                    | Fosamax                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2005                                                                                                                                        | 5753742                       | EXPEDITED (15-DAY) | Y                  | HO              | 2005AC00283          |                      | 74 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Antipsychotic                                                                                                                           | Lisinopril                    |                    |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                          |                      |   |      |                |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|----------------|--------------|
| Drug Level Above Therapeutic; Apathy; Blood Creatinine Increased; Confusional State; Dehydration; Drug Interaction; Drug Level Above Therapeutic; Dysarthria; Nervous System Disorder; Neurotoxicity; Oliguria; Overdose; Somnolence; Toxicity To Various Agents; Tremor | Lisinopril           | S | Oral | 30 Mg Daily Po | Not Reported |
|                                                                                                                                                                                                                                                                          | Irbesartan           | S |      | 300 Mg Daily   | Not Reported |
|                                                                                                                                                                                                                                                                          | Risperidone          | S |      | 0.25 Mg Bid    | Not Reported |
|                                                                                                                                                                                                                                                                          | Lithium              | S |      | 250 Mg Tid     | Not Reported |
|                                                                                                                                                                                                                                                                          | Escitalopram Oxalate | S |      | 10 Mg Daily    | Not Reported |
|                                                                                                                                                                                                                                                                          | Levomepromazine      | S |      | 6.25 Mg Daily  | Not Reported |
|                                                                                                                                                                                                                                                                          | Spironolactone       | S |      | 50 Mg Daily    | Not Reported |
|                                                                                                                                                                                                                                                                          | Furosemide           | S |      | 30 Mg Daily    | Not Reported |
|                                                                                                                                                                                                                                                                          | Dextimide            | C |      |                | Not Reported |
|                                                                                                                                                                                                                                                                          | Lormetazepam         | C |      |                | Not Reported |
|                                                                                                                                                                                                                                                                          | Metformin            | C |      |                | Not Reported |
|                                                                                                                                                                                                                                                                          | Repaglinide          | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2005              | 5753779       | DIRECT           | Y                  |                 |                      |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Insomnia   | Lexapro        |              |            | S           | Oral         | 2.5 Oral           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2005              | 5763742       | NON-EXPEDITED    | Y                  | DE              | 041-163-0276180-00   |                      | 31 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Fat Tissue Increased; Toxicity To Various Agents; Unevaluable Event | Vicodin                       |              |            | S           | Oral         | 30 Mg, 1 In 1 D, Per Oral |                 | Not Reported |
|                                                                     | Lexapro                       |              |            | S           |              |                           |                 | Not Reported |
|                                                                     | Clozapine                     |              |            | S           |              |                           |                 | Not Reported |
|                                                                     | Topiramate                    |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Valproate Semisodium          |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Cyclobenzaprine Hydrochloride |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Promethazine                  |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Doxepin                       |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Propranolol Hydrochloride     |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Gemfibrozil                   |              |            | C           |              |                           |                 | Not Reported |
|                                                                     | Over The Counter Medications  |              |            | C           |              |                           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Feb-2005                                                                                              | 5739757              | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-00352-01     |                      | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Infection; Diabetes Mellitus; Herpes Simplex; Stevens-Johnson Syndrome                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1 Tablet Qd Po       |                 | Not Reported |                |
|                                                                                                          | Tetrazepam           |                    |                    | S               | Oral                 | 1 Qd Po              |                 | Not Reported |                |
|                                                                                                          | Celebrex             |                    |                    | S               |                      | 1 Qd Rc              |                 | Not Reported |                |
|                                                                                                          | Zolpidem             |                    |                    | S               | Oral                 | 1 Q Po               |                 | Not Reported |                |
|                                                                                                          | Acetaminophen        |                    |                    | S               | Oral                 | 2 G Qd Po            |                 | Not Reported |                |
|                                                                                                          | Mopral (Omeprazole)  |                    |                    | S               | Oral                 | 1 Qd Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Feb-2005                                                                                              | 5757139              | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00822-01     |                      | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective; Drug Interaction; Temporal Arteritis; Therapeutic Product Effect Decreased | Lexapro              |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Lexapro              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Prednisone           |                    |                    | S               |                      | 40 Mg Daily          |                 | Not Reported |                |
|                                                                                                          | Prednisone           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Prednisone           |                    |                    | S               |                      | 10 Mg Daily          |                 | Not Reported |                |
|                                                                                                          | Prednisone           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2005                                                                                              | 4127825              | EXPEDITED (15-DAY) | Y                  | OT              | 2004021501           |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Condition Aggravated; Depression; Drug Interaction; Fall; Feeling                      | Neurontin            |                    |                    | S               |                      | 300 Mg (Daily)       |                 | Not Reported |                |
|                                                                                                          | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (Daily)        |                 | Not Reported |                |
|                                                                                                          | Allegra-D            |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                             |   |              |
|--------------------------|-----------------------------|---|--------------|
| Drunk; Gait Disturbance; | Propacet                    | C | Not Reported |
| Gait Disturbance;        | Pantoprazole (Pantoprazole) | C | Not Reported |
| Hallucination, Visual;   | Docusate (Docusate)         | C | Not Reported |
| Migraine; Nightmare      |                             |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2005              | 5723001       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00079-01     |                      | 8 YR       | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Risperdal      |              |            | C           |              |                    |                 | Not Reported |
|                       | Buspar         |              |            | C           |              |                    |                 | Not Reported |
|                       | Benadryl       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2005              | 5757115       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00936-01     |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Generalised Tonic-Clonic | Benicar Hct    |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Inappropriate   |                |              |            |             |              |                    |                 |              |
| Antidiuretic Hormone     |                |              |            |             |              |                    |                 |              |
| Secretion                |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2005              | 5722989       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-USA-00078-01     |                      | 8 YR       | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination; Suicidal | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Ideation                |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2005              | 5750312       | EXPEDITED (15-DAY) | N                  | HO              | A001-002-006386      |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                   |   |      |                         |              |
|----------------------------|-------------------|---|------|-------------------------|--------------|
| Coronary Artery Disease;   | Aricept           | S | Oral | 5 Mg, 1 In 1 D, Oral    | Not Reported |
| Gait Disturbance;          | Aricept           | S | Oral | 150 Mg, 30 In 1 D, Oral | Not Reported |
| Hyperhidrosis; Intentional | Aricept           | S | Oral | 5 Mg, 1 In 1 D, Oral    | Not Reported |
| Self-Injury; Medication    | Lexapro           | S | Oral | 10 Mg, 1 In 1 D, Oral   | Not Reported |
| Error; Suicidal Ideation;  | Lithium (Lithium) | C |      |                         | Not Reported |
| Suicide Attempt; Weight    | Valium            | C |      |                         | Not Reported |
| Decreased                  | Soma              | C |      |                         | Not Reported |
|                            | Percocet          | C |      |                         | Not Reported |
|                            | Prevacid          | C |      |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2005              | 5755936       | DIRECT           | Y                  | OT              |                      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Metrorrhagia | Lexapro        |              |            | S           |              | 5 Mg To 10 Mg      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2005              | 5756292       | DIRECT           | Y                  | DS, HO, LT      |                      |                      | 77 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhage Intracranial | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2005              | 5756323       | DIRECT           | N                  | DS, HO, LT      |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Abnormal Dreams;<br>Anxiety; Burning<br>Sensation; Drug<br>Intolerance; Emotional<br>Distress; Fear; Feelings Of<br>Worthlessness; Intentional<br>Overdose; Suicidal<br>Ideation; Thinking | Lexapro        |              |            | S           | Oral         | 5mg10mg20mg Daily Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Tremor

| <u>FDA Received Date</u>                                                                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2005                                                                                                                                                                                                             | 5756943                         | DIRECT             | Y                  | OT              |                      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual;<br>Product Quality Issue                                                                                                                                                                         | Lexapro                         |                    |                    | S               |                      | 1 Tab Qd             |                 | Forest       |                |
|                                                                                                                                                                                                                         | Synthroid                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                         | Lipitor                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2005                                                                                                                                                                                                             | 5758343                         | EXPEDITED (15-DAY) | Y                  | HO              | T05-GER-00858-01     |                      | 47 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Jaundice                                                                                                                                                                         | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                         | Pegasys (Peginterferon Alfa-2a) |                    |                    | S               | Subcutaneous         | 135 Mg Qw Sc         |                 | Not Reported |                |
|                                                                                                                                                                                                                         | Copegus                         |                    |                    | S               | Oral                 | 1200 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                         | Metoprolol Tartrate             |                    |                    | S               | Oral                 | 35 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2005                                                                                                                                                                                                             | 4140997                         | EXPEDITED (15-DAY) | Y                  | HO              | L04-TUR-01939-01     |                      | 32 YR           | Female       | DZA            |
| <u>Preferred Term</u>                                                                                                                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Electrocardiogram Qt<br>Prolonged; Hyperthermia;<br>Hyporeflexia;<br>Hypotension; Intentional<br>Overdose; Leukocytosis;<br>Nausea; Sinus<br>Tachycardia; Somnolence;<br>Suicide Attempt; Vertigo | Cipralext                       |                    |                    | S               | Oral                 | 190 Mg Once Po       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Mar-2005                                                                                   | 5730738                    | EXPEDITED (15-DAY) | N                  | RI              | S05-USA-00224-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Pain; Drug Ineffective; Intervertebral Disc Protrusion; Myalgia; Pain; Pain In Extremity | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Nexium (Esomeprazole)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Mirapex                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Vivelle                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Estrogel                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2005                                                                                   | 5758273                    | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00988-01     |                      | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenal Ulcer; Stress                                                                        | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Multiple Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2005                                                                                   | 5758426                    | DIRECT             | N                  | OT              |                      |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Diarrhoea; Muscle Spasms                                                              | Lexapro                    |                    |                    | S               |                      | 1 Pill Daily         |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2005                                                                                   | 5732508                    | EXPEDITED (15-DAY) | Y                  | DE              | S05-SWE-00274-01     |                      | 36 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriosclerosis Coronary Artery; Bronchitis Chronic; Cardiomegaly; Cardiopulmonary Failure;  | Ciprallex                  |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Zuclopenthixol Decanoate   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |           |   |      |                |              |
|-------------------------------------------------|-----------|---|------|----------------|--------------|
| Dilatation Atrial; Dilatation Ventricular; Lung | Clozapine | S | Oral | 100 Mg Q4hr Po | Not Reported |
| Hyperinflation; Mucosal Disorder                | Atarax    | C |      |                | Not Reported |
|                                                 | Akineton  | C |      |                | Not Reported |
|                                                 | Stesolid  | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2005              | 5759122       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01033-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2005              | 5759944       | EXPEDITED (15-DAY) | Y                  | HO              | TO5-USA-00286-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Chest Pain;     | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Constipation; Diarrhoea; | Lexapro                 |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Dyspnoea;                | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Electrocardiogram Qt     |                         |              |            |             |              |                    |                 |              |
| Prolonged;               | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Electrocardiogram St-T   | Phenergan               |              |            | C           |              |                    |                 | Not Reported |
| Segment Abnormal;        | Multivitamins           |              |            | C           |              |                    |                 | Not Reported |
| Granulocytopenia;        | Calcium Gluconate       |              |            | C           |              |                    |                 | Not Reported |
| Hyperhidrosis;           | Peginterferon Alfa-2a   |              |            | C           |              |                    |                 | Not Reported |
| Hypokalaemia; Myocardial | Ribavirin               |              |            | C           |              |                    |                 | Not Reported |
| Ischaemia; Pericarditis; | Ibuprofen               |              |            | C           |              |                    |                 | Not Reported |
| Sinus Bradycardia;       | Pepto-Bismol (Bismuth   |              |            | C           |              |                    |                 | Not Reported |
| Supraventricular         | Subsalicylate)          |              |            |             |              |                    |                 |              |
| Extrasystoles;           | Advil                   |              |            | C           |              |                    |                 | Not Reported |
| Tachypnoea; Torsade De   | Lortab                  |              |            | C           |              |                    |                 | Not Reported |
| Pointes; Ventricular     | Otc Antacid             |              |            | C           |              |                    |                 | Not Reported |
| Tachycardia              |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2005              | 5759949       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-01015-01     |                      | 36 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Focal Dyscognitive<br>Seizures; Night Sweats;<br>Simple Partial Seizures | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                   | Lexapro        |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |
|                                                                                                   | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                   | Keppra         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2005              | 5730740       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00268-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Anger;<br>Asthenia; Chills; Circadian<br>Rhythm Sleep Disorder;<br>Depression; Drug<br>Interaction; Feeling Hot;<br>Heart Rate Increased;<br>Hyperhidrosis; Mania;<br>Panic Attack; Paranoia;<br>Pyrexia; Seizure; Suicidal<br>Ideation; Vomiting | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 19 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 17 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Biaxin         |              |            | S           |              | 500 Mg Bid         |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Cedax          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               | Nystatin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                               |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2005              | 4137304       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-02241-01     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mania; Paranoia; Scratch;<br>Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2005              | 5763429       | DIRECT           |                    | RI              |                      |                      | 65 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain; Abnormal Dreams; Animal Scratch; Back Pain; Balance Disorder; Choking; Contusion; Diarrhoea; Dyskinesia; Ecchymosis; Fall; Flatulence; Gastrooesophageal Reflux Disease; Haemorrhage; Hallucination; Headache; Hyperhidrosis; Impaired Healing; Joint Swelling; Oesophagitis; Pain In Extremity; Palpitations; Paraesthesia; Pruritus; Purulent Discharge; Raynaud'S Phenomenon; Restless Legs Syndrome; Serotonin Syndrome; Skin Ulcer; Visual Impairment | Lexapro        |                    |                    | S               |                      | 10 Mg Daily - A.M.   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2005                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 5763665        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01145-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Dyspnoea; Electrocardiogram T Wave Abnormal; Mitral Valve Prolapse                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2005                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 5763904        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01142-01     |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Multiple Sclerosis                                                                                                                                                                                                                                                                                                                                                                                                                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Copaxone       |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------|-----------------------|-----------------|--------------|----------------|
| 11-Mar-2005                                                                                         | 5763905              | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-01148-01            |                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Gout; Seizure;<br>Somnolence; Suicidal<br>Ideation                                         | Lexapro              |                    |                    | S               |                             |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2005                                                                                         | 5764509              | DIRECT             | Y                  | HO              |                             |                       | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness;<br>Encephalitis; Neuroleptic<br>Malignant Syndrome;<br>Seizure | Venlafaxine          |                    |                    | S               | Oral                        | 75 Mg Daily Oral      |                 | Not Reported |                |
|                                                                                                     | Lexapro              |                    |                    | S               | Oral                        | 20 Mg At Bedtime Oral |                 | Not Reported |                |
|                                                                                                     | Risperdal            |                    |                    | C               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Multi-Vitamin        |                    |                    | C               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Alprazolam           |                    |                    | C               |                             |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2005                                                                                         | 5797273              | NON-EXPEDITED      | N                  |                 | 2005-BP-00463BP             |                       | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea                                                                                            | Spiriva              |                    |                    | S               | Respiratory<br>(inhalation) | 18 Mcg (18 Mcg), 1h   |                 | Not Reported |                |
|                                                                                                     | Lexapro              |                    |                    | S               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Albuterol & Atrovent |                    |                    | C               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Enalapril            |                    |                    | C               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Lasix                |                    |                    | C               |                             |                       |                 | Not Reported |                |
|                                                                                                     | Synthroid            |                    |                    | C               |                             |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2005                                                                                         | 4206276              | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-05599-01            |                       | 21 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Foaming At Mouth;<br>Intentional Overdose;<br>Lethargy; Loss Of<br>Consciousness; Mood<br>Altered; Refusal Of<br>Treatment By Patient;<br>Seizure; Suicide Attempt;<br>Tremor | Lexapro        |              |            | S           | Oral         | 40 Mg Once Po      |                 | Not Reported |
|                                                                                                                                                                                     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                     | Gabitril       |              |            | S           | Oral         | 24 Mg Once Po      |                 | Not Reported |
|                                                                                                                                                                                     | Prozac         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                     | Prozac         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2005              | 5743470       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00453-01     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colour Blindness Acquired | Lexapro                                  |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                           | Wellbutrin (Bupropion<br>Hydrochloride)  |              |            | C           |              |                    |                 | Not Reported |
|                           | Minocycline\Minocycline<br>Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2005              | 5746038       | EXPEDITED (15-DAY) | N                  | RI, OT          | S05-USA-00618-01     |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Biliary Dilatation;<br>Depression; Duodenal<br>Stenosis; Melaena; Occult<br>Blood Positive; Pancreatic<br>Neoplasm | Lexapro           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                             | Aspirin           |              |            | S           | Oral         | 81 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                             | Zetia             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Xalatan           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Multi-Vitamin     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Omega3 (Fish Oil) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Potassium         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2005              | 5750576       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00702-01     |                      | 11 DAY     | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Maternal Exposure During Breast Feeding; Selective Eating Disorder; Somnolence Neonatal | Lexapro                          |                    |                    | S               |                              | 10 Mg Qd Bf          |                 | Not Reported |                |
|                                                                                         | Lexapro                          |                    |                    | S               |                              | 15 Mg Qd Bf          |                 | Not Reported |                |
|                                                                                         | Hydrocodone                      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                         | Ibuprofen                        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                         | Stoll Softener (Docusate Sodium) |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2005                                                                             | 5757132                          | EXPEDITED (15-DAY) |                    | OT              | DE-ABBOTT-05I-062-0292831-00 |                      | 38 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Post Procedural Haemorrhage                                                  | Ciprallex                        |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                         | Ciprallex                        |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                         | Heparin                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2005                                                                             | 5760161                          | EXPEDITED (15-DAY) | Y                  | DS, OT          | 2005034830                   |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness Unilateral; Cerebrovascular Accident; Insomnia; Nightmare                     | Celebrex                         |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                         | Escitalopram Oxalate             |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Mar-2005                                                                             | 5763695                          | DIRECT             | Y                  | OT              |                              |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                                                        | Lexapro                          |                    |                    | S               | Oral                         | 10 Mg 1/2 Po Qhs     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2005                                                                             | 5767542                          | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01276-01             |                      |                 | Unknown      | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Akathisia; Tardive Dyskinesia                                                             | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Mar-2005                                                                               | 5701892                 | NON-EXPEDITED             | Y                           | HO                       | S04-USA-07142-01              |                               | 20 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State; Intentional Product Misuse; Suicide Attempt                            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                           | Lexapro                 |                           |                             | S                        | Oral                          | 30 Tablet Once Po             |                          | Not Reported        |                         |
|                                                                                           | Unspecified Ingredient  |                           |                             | S                        | Oral                          | 30 Tablet Once Po             |                          | Not Reported        |                         |
|                                                                                           | Alcohol                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Mar-2005                                                                               | 5734144                 | EXPEDITED (15-DAY)        | N                           |                          | S05-USA-00320-01              |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Crying; Drug Withdrawal Syndrome; Hyperhidrosis; Loss Of Consciousness; Seizure; Vomiting | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                           | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                           | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                           | Nexium (Esomeprazole)   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Mar-2005                                                                               | 5741542                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S05-UKI-00427-01              |                               | 76 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cerebrovascular Accident                                                                  | Ciprallex               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                           | Quinine Sulfate         |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Mar-2005                                                                               | 5745070                 | EXPEDITED (15-DAY)        | Y                           | LT                       | S05-DEN-00492-01              |                               | 41 YR                    | Male                | DNK                     |

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| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Amnesia; Anxiety;<br>Discomfort; Dizziness;<br>Drug Withdrawal<br>Syndrome; Paraesthesia;<br>Road Traffic Accident;<br>Sleep Talking;<br>Somnambulism | Ciprallex      |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Ciprallex      |                    |                    | S               | Oral                                 | 15 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Ciprallex      |                    |                    | C               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Mar-2005                                                                                                                                           | 5757141        | EXPEDITED (15-DAY) | Y                  | HO, LT          | S05-USA-00823-01                     |                      | 52 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Contusion; Pruritus;<br>Purpura;<br>Thrombocytopenia                                                                                                  | Lexapro        |                    |                    | S               | Oral                                 | 30 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Mar-2005                                                                                                                                           | 5759428        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0537918A |                      | 16 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness; Fatigue;<br>Headache; Muscle<br>Spasms; Toxicity To<br>Various Agents                                                                      | Compazine      |                    |                    | S               |                                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                       | Lexapro        |                    |                    | S               | Oral                                 |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Multi-Vitamin  |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-Mar-2005                                                                                                                                           | 5766414        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-01285-01                     |                      | 43 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Intestinal Obstruction;<br>White Blood Cell Count<br>Increased                                                                                        | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qam Po         |                 | Not Reported    |                |
|                                                                                                                                                       | Clozapine      |                    |                    | S               | Oral                                 | 575 Mg Qd Po         |                 | Not Reported    |                |

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|                                                                                          |                | Benztropine Mesylate |                    | S               |                      | 1 Mg Qam             |                 | Not Reported |                |
|------------------------------------------------------------------------------------------|----------------|----------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                          |                | Benztropine Mesylate |                    | S               |                      | 2 Mg Qhs             |                 | Not Reported |                |
|                                                                                          |                | Clonazepam           |                    | S               |                      | 1 Mg Prn             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                              | 5766792        | EXPEDITED (15-DAY)   | Y                  | OT              | S05-UKI-00928-01     |                      | 47 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Clonus;<br>Extensor Plantar<br>Response; Fatigue;<br>Reflexes Abnormal | Ciprallex      |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Atenolol       |                      |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                              | 5766802        | EXPEDITED (15-DAY)   | Y                  | OT              | S05-UKI-00929-01     |                      | 49 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Dysuria;<br>Ejaculation Failure; Urine<br>Flow Decreased                      | Ciprallex      |                      |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                          | Zopiclone      |                      |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                              | 5766815        | EXPEDITED (15-DAY)   | Y                  | DS              | S05-DEN-01000-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia; Osmotic<br>Demyelination Syndrome                   | Ciprallex      |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                              | 5767038        | NON-EXPEDITED        | N                  | OT              | S04-USA-07588-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                               |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|-----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Amnesia; Confusional State; Disorientation; Dizziness; Fatigue                                | Lexapro                 |                           | S                           | Oral                     | 10 Mg Qd Po                   |                               |                             | Not Reported             |                         |
|                                                                                               | Femhrt                  |                           | C                           |                          |                               |                               |                             | Not Reported             |                         |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 16-Mar-2005                                                                                   | 5767040                 | NON-EXPEDITED             | Y                           | OT                       | S04-USA-07589-01              |                               |                             | Unknown                  | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Electrocardiogram Qt Prolonged                                                                | Lexapro                 |                           |                             |                          | S                             |                               |                             |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 16-Mar-2005                                                                                   | 5767043                 | NON-EXPEDITED             | Y                           | HO                       | S04-USA-07563-01              |                               | 16 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Anxiety; Intentional Product Misuse; Migraine; Overdose; Psychiatric Symptom; Suicide Attempt | Lexapro                 |                           |                             |                          | S                             | Oral                          | 10 Mg Qd Po                 |                          | Not Reported            |
|                                                                                               | Ibuprofen               |                           |                             |                          | S                             |                               |                             |                          | Not Reported            |
|                                                                                               | Concerta                |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 16-Mar-2005                                                                                   | 5767046                 | NON-EXPEDITED             | N                           | OT                       | S04-USA-07553-01              |                               | 75 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Suicidal Ideation; Upper Respiratory Tract Infection                                          | Lexapro                 |                           |                             |                          | S                             | Oral                          | 10 Mg Qd Po                 |                          | Not Reported            |
|                                                                                               | Ativan                  |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
|                                                                                               | Atenolol                |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
|                                                                                               | Levoxyl                 |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
|                                                                                               | Zocor                   |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
|                                                                                               | Triamterene             |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
|                                                                                               | Centrum                 |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 16-Mar-2005                                                                                   | 5795200                 | NON-EXPEDITED             | Y                           | HO                       | S05-USA-00318-01              |                               | 43 YR                       | Female                   | USA                     |



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| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain;<br>Flatulence; Nausea;<br>Pancreatitis Acute | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Lorazepam               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Allegra                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Hydrocodone             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Vitamin B12             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Vitamin C               |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                  | 5795202                 | NON-EXPEDITED    | Y                  | HO              | S05-USA-00196-01     |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen False<br>Positive; Overdose                      | Lexapro                 |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                              | Methadone Hydrochloride |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                  | 5795212                 | NON-EXPEDITED    | Y                  | OT              | S05-USA-00042-01     |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                | Lexapro                 |                  |                    | S               | Oral                 | 10 Gm Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                  | 5795217                 | NON-EXPEDITED    | Y                  | HO              | S04-USA-07866-01     |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Oedema;<br>Suicidal Ideation                     | Lexapro                 |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Klonopin                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Zoloft                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Paxil                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Trazodone Hydrochloride |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2005                                                                                                             | 5795218                | NON-EXPEDITED    | Y                  | OT              | S04-USA-07387-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis                                                                                                              | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Unspecified Ingredient |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Unspecified Ingredient |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Neurontin              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Advil                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                                                             | 5795219                | NON-EXPEDITED    | N                  | OT              | S04-USA-07372-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Disturbance In Attention;<br>Headache; Hyperhidrosis;<br>Nausea; Panic Attack;<br>Suicidal Ideation | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Lortab                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Toprol XL              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Interferon Nos         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                                                             | 5795222                | NON-EXPEDITED    | Y                  | HO, LT, RI      | S04-USA-06047-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Joint Injury; Muscle<br>Spasms; Night Sweats;<br>Suicidal Ideation; Suicide<br>Attempt; Upper Limb<br>Fracture          | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Marijuana              |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                                                                                             | 5795241                | NON-EXPEDITED    | Y                  | OT              | S04-USA-06055-01     |                      | 59 YR           | Female       | USA            |

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| <u>Preferred Term</u>                             | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------|---------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acute Kidney Injury;<br>Nephrolithiasis           | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Avandia                         |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Lasix                           |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Synthrod (Levothyroxine Sodium) |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Nexium (Esomeprazole)           |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Percocet                        |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Vioxx                           |                  |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                       | 5795244                         | NON-EXPEDITED    | Y                  | HO              | S05-USA-00524-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Tachycardia                             | Lexapro                         |                  |                    | S               | Oral                 | 750 Mg Once Po       |                 | Not Reported |                |
|                                                   | Lexapro                         |                  |                    | S               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                       | 5795245                         | NON-EXPEDITED    | N                  | OT              | S05-USA-00475-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Suicidal Ideation                         | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Zocor                           |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                   | Zetia                           |                  |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005                                       | 5795246                         | NON-EXPEDITED    | N                  | HO              | S05-USA-00365-01     |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis; Nightmare;<br>Panic Attack; Tremor | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Lexapro                         |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Lipitor                         |                  |                    | C               |                      |                      |                 | Not Reported |                |

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|                          |                                 | Ditropan         |                    | C               |                      |                      |                 |              | Not Reported   |
|--------------------------|---------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                          |                                 | Estradiol        |                    | C               |                      |                      |                 |              | Not Reported   |
|                          |                                 | Vitamins         |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795247                         | NON-EXPEDITED    | N                  | OT              | S05-USA-00333-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Xanax                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Levothyl (Levothyroxine Sodium) |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Estrace                         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795250                         | NON-EXPEDITED    | Y                  | OT              | S04-USA-07841-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                | Lexapro                         |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro                         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lipitor                         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Ultram                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Klonopin                        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Ativan                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795252                         | NON-EXPEDITED    | Y                  | HO              | S04-USA-07774-01     |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncopal                 | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Coumadin                        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lanoxin                         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Miacalcin                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Macrodantin                     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Colace                          |                  |                    | C               |                      |                      |                 | Not Reported |                |

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|                          |                                    |                  |                    |                 |                      |                      |                 |              |                |
|--------------------------|------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Lactulose                |                                    | C                |                    | Not Reported    |                      |                      |                 |              |                |
| Pepcid                   |                                    | C                |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795254                            | NON-EXPEDITED    | Y                  | OT              | S04-USA-07763-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                    | Lexapro                            |                  |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                          | An Unknown Anti-Hypertensive (Nos) |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Prilosec                           |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795255                            | NON-EXPEDITED    | Y                  | HO              | S04-USA-07729-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Lexapro                            |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Multiple Medications (Nos)         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795256                            | NON-EXPEDITED    | Y                  | HO              | S04-USA-07729-02     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Lexapro                            |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Multiple Medications (Nos)         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005              | 5795257                            | NON-EXPEDITED    | Y                  | HO              | S04-USA-07729-03     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia            | Lexapro                            |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Multiple Medications (Nos)         |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2005               | 5795260                    | NON-EXPEDITED      | Y                  | HO              | S04-USA-07729-04     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia             | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                           | Multiple Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2005               | 5795264                    | NON-EXPEDITED      | N                  | OT              | S04-USA-07704-01     |                      | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anxiety;  | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Blood Pressure Increased; | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Drug Ineffective;         | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Dyspnoea; Fatigue;        | Lexapro                    |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
| Headache; Heart Rate      | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Increased; Insomnia;      | Lexapro                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Nausea; Pain; Panic       | Lexapro                    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Reaction; Restlessness;   | Lanoxin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Tremor                    | Xanax                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Valium                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Zoloft                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Coumadin                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2005               | 5767481                    | EXPEDITED (15-DAY) | Y                  | OT              | S05-BRA-00998-01     |                      | 29 YR           | Female       | BRA            |
| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;     | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Foetal Death; Maternal    | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Exposure During           | Alprazolam                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Pregnancy; Pregnancy      |                            |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2005              | 6035462       | EXPEDITED (15-DAY) | Y                  | HO              | S05-GER-01073-01     |                      |            | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrolyte Imbalance | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5694480       | EXPEDITED (15-DAY) | Y                  | DE              | L04-USA-07403-66     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Blood Ph | Diltiazem             |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Cardiac            | Escitalopram Oxalate  |              |            | S           |              |                    |                 | Not Reported |
| Arrest; Coma; Completed       | Lorazepam             |              |            | S           |              |                    |                 | Not Reported |
| Suicide;                      | Benzotropine Mesylate |              |            | S           |              |                    |                 | Not Reported |
| Electrocardiogram Qrs         | Ziprasidone           |              |            | C           |              |                    |                 | Not Reported |
| Complex Prolonged;            | Fexofenadine Hcl      |              |            | C           |              |                    |                 | Not Reported |
| Electrocardiogram Qt          | Oxcarbazepine         |              |            | C           |              |                    |                 | Not Reported |
| Prolonged; Haemodialysis;     |                       |              |            |             |              |                    |                 |              |
| Hypotension; Hypoxia;         |                       |              |            |             |              |                    |                 |              |
| Nodal Rhythm; Overdose;       |                       |              |            |             |              |                    |                 |              |
| Pco2 Decreased;               |                       |              |            |             |              |                    |                 |              |
| Pneumonia Aspiration;         |                       |              |            |             |              |                    |                 |              |
| Po2 Decreased; Renal          |                       |              |            |             |              |                    |                 |              |
| Failure; Supraventricular     |                       |              |            |             |              |                    |                 |              |
| Tachycardia; Therapy          |                       |              |            |             |              |                    |                 |              |
| Non-Responder                 |                       |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5694783       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L04-USA-07403-24     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure             | Lexapro                  |              |            | S           | Oral         | 340 Mg Once Po     |                 | Not Reported |
| Decreased; Cardiac         | Bupropion Hydrochloride  |              |            | S           | Oral         | 2550 Mg Once Po    |                 | Not Reported |
| Arrest; Completed Suicide; | Paroxetine Hydrochloride |              |            | S           | Oral         | 340 Mg Once Po     |                 | Not Reported |
| Ejection Fraction          |                          |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |            |   |      |                |              |
|---------------------------------------------------------------------------------------------------------------------------|------------|---|------|----------------|--------------|
| Decreased; Intentional Overdose; Mental Status Changes; Nausea; Nervous System Disorder; Seizure; Ventricular Dysfunction | Clonazepam | S | Oral | 8.5 Mg Once Po | Not Reported |
|---------------------------------------------------------------------------------------------------------------------------|------------|---|------|----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5694785       | EXPEDITED (15-DAY) | Y                  | DE              | L04-USA-07403-19     |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acidosis; Acute Kidney Injury; Apnoea; Atrial Fibrillation; Brain Death; Coma; Completed Suicide; Dialysis; Hypotension; Intentional Overdose; Pneumonia Aspiration; Vomiting | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                               | Valproic Acid  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5694788       | EXPEDITED (15-DAY) | Y                  | DE              | L04-USA-07403-32     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Aspiration; Blood Bicarbonate                                                                      | Lexapro             |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Ph | Fluoxetine Hcl      |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Coma; Completed Suicide; Drug Screen Positive; Dyskinesia; General Physical Health                  | Liothyronine Sodium |              |            | S           |              |                    |                 | Not Reported |
| Deterioration; Hyperhidrosis; Intentional                                                                      | Lamotrigine         |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Overdose; Muscle  
Twitching; Pco2  
Increased; Petit Mal  
Epilepsy; Po2 Increased;  
Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5694791       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L04-USA-07403-31     |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; Blood Ph        | Lexapro                   |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Blood           | Doxepin                   |              |            | S           |              |                    |                 | Not Reported |
| Pressure Systolic          | Mirtazapine               |              |            | S           |              |                    |                 | Not Reported |
| Increased; Cardiac Arrest; | Ziprasidone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Coma; Completed Suicide;   | Clonazepam                |              |            | S           |              |                    |                 | Not Reported |
| Heart Rate Increased;      |                           |              |            |             |              |                    |                 |              |
| Intentional Overdose;      |                           |              |            |             |              |                    |                 |              |
| Pco2 Decreased; Pupil      |                           |              |            |             |              |                    |                 |              |
| Fixed; Torsade De          |                           |              |            |             |              |                    |                 |              |
| Pointes; Unresponsive To   |                           |              |            |             |              |                    |                 |              |
| Stimuli; Ventricular       |                           |              |            |             |              |                    |                 |              |
| Extrasystoles; Ventricular |                           |              |            |             |              |                    |                 |              |
| Tachycardia                |                           |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2005              | 5696170       | EXPEDITED (15-DAY) | Y                  | DE              | L04-USA-07403-58     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block     | Tiazac                        |              |            | S           |              |                    |                 | Not Reported |
| Second Degree; Blood       | Lexapro                       |              |            | S           |              |                    |                 | Not Reported |
| Pressure Systolic          | Ibuprofen And Pseudoephedrine |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Body            | Hydrochloride                 |              |            |             |              |                    |                 |              |
| Temperature Decreased;     | Calcium Gluconate             |              |            | S           |              |                    |                 | Not Reported |
| Cardio-Respiratory Arrest; | Vitamin C                     |              |            | S           |              |                    |                 | Not Reported |
| Completed Suicide; Heart   | Iron\Vitamins Nos             |              |            | S           |              |                    |                 | Not Reported |
| Rate Increased;            | Benzodiazepine                |              |            | C           |              |                    |                 | Not Reported |
| Intentional Overdose;      |                               |              |            |             |              |                    |                 |              |
| Lethargy; Somnolence;      |                               |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapy Non-Responder

| <a href="#">FDA Received Date</a>                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------|--------------------------|---------------------|-------------------------|
| 18-Mar-2005                                                                          | 5768794                 | DIRECT                    | Y                           | HO                       |                               |                                | 73 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Breast Cancer Female; Lethargy; Mental Status Changes; Metastasis; Urinary Retention | Lexapro                 |                           |                             | S                        | Oral                          | Po [4 Days Prior To Admission] |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2005                                                                | 5663029                 | EXPEDITED (15-DAY)        | N                           | HO                       | S04-USA-07114-01              |                               | 32 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Memory Impairment | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2005                                                                                                    | 5726381                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-NOR-00143-01              |                               | 84 YR                    | Female              | NOR                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Potassium Decreased; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                | Pinex                   |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
|                                                                                                                | Paralgin Forte          |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
|                                                                                                                | Atenolol                |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
|                                                                                                                | Rivotril (Clorazepam)   |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |
|                                                                                                                | Albyl-E                 |                           |                             | C                        |                               |                               | Not Reported             |                     |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Mar-2005                       | 5735601                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-USA-00319-01              |                               | 17 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |                                          |             |      |            |                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------|------|------------|----------------------------------------------|
| Blood Potassium Decreased; Coma;<br>Fatigue; Lethargy; Loss Of Consciousness; Mouth Injury; Seizure; Skin Laceration; Urine Barbiturates; Vomiting | Lexapro<br>Ortho Tri Cyclen<br>Albuterol | S<br>C<br>C | Oral | 5 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------|------|------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2005              | 5752636       | EXPEDITED (15-DAY) | Y                  | DS              | S05-USA-00714-01     |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Impaired Driving Ability;<br>Panic Attack; Tremor | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                   | Valium         |              |            | C           |              |                    |                 | Not Reported |
| Ibuprofen                                         |                |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2005              | 5768276       | EXPEDITED (15-DAY) | Y                  | LT, RI          | S05-USA-01287-01     |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Hyperhidrosis;<br>Hypotension; Loss Of Consciousness; Pallor;<br>Tachycardia; Vision Blurred | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>                                                                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                            | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------|----------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 21-Mar-2005                                                                                                                                                                                                                                                                                                           | 5768854                                                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | HO, OT                                         | S05-GER-01005-01                                                                                        |                      | 55 YR           | Female                                                                                                                                                | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>                                                                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                            |                |
| Confusional State;<br>Disorientation; Fear;<br>Insomnia; Logorrhoea;<br>Paranoia                                                                                                                                                                                                                                      | Ciprallex<br>Insidon (Opipramol)                                                                                                                                                |                    |                    | S<br>C                                         | Oral                                                                                                    | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported                                                                                                                          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>                                                                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                            | <u>Country</u> |
| 21-Mar-2005                                                                                                                                                                                                                                                                                                           | 5768857                                                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | HO                                             | S05-UKI-01006-01                                                                                        |                      |                 | Female                                                                                                                                                | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>                                                                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                            |                |
| Supraventricular<br>Tachycardia; Ventricular<br>Tachycardia                                                                                                                                                                                                                                                           | Ciprallex                                                                                                                                                                       |                    |                    | S                                              |                                                                                                         |                      |                 | Not Reported                                                                                                                                          |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                              | <u>Case #</u>                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>                                                                                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                            | <u>Country</u> |
| 22-Mar-2005                                                                                                                                                                                                                                                                                                           | 5763575                                                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | HO                                             | BE-MERCK-<br>0503USA02984                                                                               |                      | 74 YR           | Female                                                                                                                                                | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                 | <u>Product</u>                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>                                                                                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                            |                |
| Agitation; Apathy; Blood<br>Creatinine Increased;<br>Confusional State;<br>Creatinine Renal<br>Clearance Decreased;<br>Dehydration; Diarrhoea;<br>Drug Interaction;<br>Dysarthria; Lethargy;<br>Motor Dysfunction;<br>Oliguria; Performance<br>Status Decreased;<br>Somnolence; Toxicity To<br>Various Agents; Tremor | Prinivil<br>Lithium Carbonate<br>Escitalopram Oxalate<br>Levomepromazine<br>Irbesartan<br>Furosemide<br>Spironolactone<br>Dexetimide Hydrochloride<br>Lormetazepam<br>Metformin |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>C<br>C | Oral<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown |                      |                 | Merck<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                             |                            |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Repaglinide                                                                                 |                            |                    | C                  |                 | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2005                                                                                 | 5770179                    | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01390-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Enamel Anomaly; Gingival Disorder                                                | Lexapro                    |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Vitamins Nos               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Remeron                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2005                                                                                 | 5699105                    | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07700-01     |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus                                                                                   | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Azithromycin               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Flonase                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Allegra                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Prevacid                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2005                                                                                 | 5761440                    | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-00905-01     |                      | 38 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Haemoglobin Decreased; Post Procedural Complication; Post Procedural Haemorrhage | Cipraxel                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Cipraxel                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Embolex                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Somatostatin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Pantoprazol (Pantoprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Remergil (Mirtazapine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|-----------------------|-----------------|--------------|----------------|
| 23-Mar-2005                                                                             | 5769382        | DIRECT             | Y                  | OT              |                       |                       | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism                                                                                 | Lexapro        |                    |                    | S               | Oral                  | 5mg Qd Oral           |                 | Not Reported |                |
|                                                                                         | Vitamin B12    |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                         | Oscal          |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                         | Multi-Vitamin  |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                         | Synthroid      |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                         | Senokot        |                    |                    | C               |                       |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2005                                                                             | 5770138        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01437-01      |                       | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Female Orgasmic Disorder; Headache; Hypertension                                        | Lexapro        |                    |                    | S               | Oral                  | 10 Mg Qd Po           |                 | Not Reported |                |
|                                                                                         | Atenolol       |                    |                    | C               |                       |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2005                                                                             | 5770537        | DIRECT             | Y                  | RI              |                       |                       | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation; Depression; Feeling Abnormal; Hot Flush; Insomnia; Suicidal Ideation | Lexapro        |                    |                    | S               | Oral                  | One Tab Each Day Oral |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2005                                                                             | 5765235        | EXPEDITED (15-DAY) | Y                  | HO              | US-MERCK-0503USA03019 |                       | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |            |   |      |              |
|--------------------------------------|------------|---|------|--------------|
| Constipation; Intestinal Obstruction | Cogentin   | S | Oral | Merck        |
|                                      | Cogentin   | S | Oral | Merck        |
|                                      | Clozapine  | S | Oral | Not Reported |
|                                      | Clonazepam | S | Oral | Not Reported |
|                                      | Lexapro    | S | Oral | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Mar-2005                       | 5744369                | EXPEDITED (15-DAY)        | Y                           | DE                       | S05-USA-00560-01              |                               | 44 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Antidepressant Drug Level Increased; Blood Alcohol Increased; Carboxyhaemoglobin Increased; Completed Suicide; Intentional Self-Injury; Overdose; Thermal Burn | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                                                                                | Unspecified Ingredient  |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                                                                                                                                | Diphenhydramine         |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Mar-2005                       | 5771865                | EXPEDITED (15-DAY)        | Y                           | DE, DS, LT, OT           | S05-UKI-01168-01              |                               | 37 YR               | Male                | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Completed Suicide              | Ciprallex               |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Mar-2005                       | 5772053                | EXPEDITED (15-DAY)        |                             |                          | 2005-126603-NL                |                               | 57 YR               | Male                | CHE                     |

| <a href="#">Preferred Term</a>                                                        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Blood Creatine Phosphokinase Increased; Hypertension; Serotonin Syndrome; Tachycardia | Mirtazapine             |                       |                     | S                    | Oral                  | 45 Mg                       |                          | Not Reported        |
|                                                                                       | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg Qd                    | 10 DAY                   | Not Reported        |
|                                                                                       | Amisulpride             |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                                                       | Zolpidem Tartrate       |                       |                     | C                    |                       |                             |                          | Not Reported        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                         |                        |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Lorazepam                                                                                               |                        | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2005                                                                                             | 4138850                | EXPEDITED (15-DAY) | Y                  | OT              | S04-PRT-01934-01     |                      | 70 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Decreased Appetite; Dizziness; Drug Interaction; Hypocoagulable State; Tremor                 | Cipralext              |                    |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                                                         | Warfarin Sodium        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                         | Warfarin Sodium        |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                         | Pravocol (Pravastatin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Lasix                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Lopresor               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Vastarel               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Sermion (Nicergoline)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Cordarone              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2005                                                                                             | 5718329                | EXPEDITED (15-DAY) | Y                  | LT              | S04-DEN-08294-01     |                      | 39 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Headache; Loss Of Consciousness                                                       | Cipralext              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Cipralext              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2005                                                                                             | 5728424                | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00293-01     |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Antinuclear Antibody Positive; Cardioliipin Antibody Positive; Gangrene; Vascular Occlusion; Vasculitis | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Inh                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Rifampin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Rifabutin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Pyrazinamide           |                    |                    | C               |                      |                      |                 | Not Reported |                |



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|                                                                                                                                                                                               | Ethambutol          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                               | Vitamin B6          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                               | Bactrim Ds          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                               | Nystatin            |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                               | Ibuprofen           |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2005                                                                                                                                                                                   | 5754494             | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00789-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Stress                                                                                            | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                               | Hydrochlorothiazide |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                               | Lisinopril          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2005                                                                                                                                                                                   | 5773795             | EXPEDITED (15-DAY) | N                  | OT              | SUSI-2005-00203      |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Diplopia; Drug Interaction;<br>Hyperhidrosis; Vision<br>Blurred                                                                                                       | Carbatrol           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                               | Lexapro             |                    |                    | S               |                      | 10 Mg, 1x/Day, Qd    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2005                                                                                                                                                                                   | 5749285             | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00682-01     |                      | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Carotid Artery Aneurysm;<br>Cerebral Haemorrhage;<br>Circulatory Collapse;<br>Confusional State;<br>Dizziness; Fatigue; Loss<br>Of Consciousness; Petit<br>Mal Epilepsy; Suicidal<br>Ideation | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                               | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                                                                                               | Lexapro             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                               | Fentanyl            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                               | Effexor             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                               | Depakote            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                               | Ativan              |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Procrit                                                                                                                                                                    |                         | C                  |                    | Not Reported    |                      |                                             |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2005                                                                                                                                                                | 5773982                 | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00450-01     |                                             | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dissociation; Fall; Focal<br>Dyscognitive Seizures;<br>Hallucinations, Mixed;<br>Incoherent; Mydriasis;<br>Seizure; Somnolence;<br>Staring        | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2005                                                                                                                                                                | 5749283                 | EXPEDITED (15-DAY) | Y                  | LT, OT          | S05-USA-00683-01     |                                             | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Burns Second Degree;<br>Burns Third Degree;<br>Completed Suicide;<br>Depression; Paranoia;<br>Psychotic Disorder;<br>Suicidal Ideation; Suicide<br>Attempt; Suspiciousness | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Klonopin                |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                            | Trazodone Hydrochloride |                    |                    | C               |                      |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2005                                                                                                                                                                | 5769055                 | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-399151      |                                             | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Intestinal<br>Obstruction                                                                                                                                    | Klonopin                |                    |                    | S               | Oral                 | 1mg At Bedtime As<br>Needed.                |                 | Roche        |                |
|                                                                                                                                                                            | Clozapine               |                    |                    | S               | Oral                 |                                             |                 | Not Reported |                |
|                                                                                                                                                                            | Benzatropine            |                    |                    | S               | Unknown              | 1 Mg Taken In The<br>Morning And 2 Mg Taken |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                        |                                                                                                                                                                                                 |                    |                    |                                                     |                                                 |                                      |                 |                                                                                                                                                                                              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------------------------------------|-------------------------------------------------|--------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Lexapro                                                                                                                                                |                                                                                                                                                                                                 | S                  |                    | Oral                                                |                                                 | An Bedtime.<br>Taken In The Morning. |                 | Not Reported                                                                                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                     | <u>Mfr Control #</u>                            | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                   | <u>Country</u> |
| 01-Apr-2005                                                                                                                                            | 5773396                                                                                                                                                                                         | DIRECT             | Y                  | HO, LT, RI                                          |                                                 |                                      | 26 YR           | Female                                                                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                         | <u>Route</u>                                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                   |                |
| Abdominal Pain; Chills;<br>Cough; Dizziness;<br>Headache; Hepatic<br>Enzyme Increased;<br>Nausea; Pyrexia; Vomiting                                    | Lexapro<br>Iron<br>Ambien                                                                                                                                                                       |                    |                    | S<br>C<br>C                                         | Oral                                            | 10 Mg Bid Oral                       |                 | Not Reported<br>Not Reported<br>Not Reported                                                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                     | <u>Mfr Control #</u>                            | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                   | <u>Country</u> |
| 01-Apr-2005                                                                                                                                            | 5773508                                                                                                                                                                                         | DIRECT             | Y                  | OT                                                  |                                                 |                                      | 44 YR           | Female                                                                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                         | <u>Route</u>                                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                   |                |
| Drug Hypersensitivity;<br>Rash Macular                                                                                                                 | Lexapro                                                                                                                                                                                         |                    |                    | S                                                   |                                                 | 10mg Daily                           |                 | Not Reported                                                                                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>                                                                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                     | <u>Mfr Control #</u>                            | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                                                                                                                                                                                   | <u>Country</u> |
| 04-Apr-2005                                                                                                                                            | 5769837                                                                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | HO                                                  | BE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12907242 |                                      | 74 YR           | Female                                                                                                                                                                                       | BEL            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>                                                                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                         | <u>Route</u>                                    | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                   |                |
| Apathy; Confusional State;<br>Dehydration; Diarrhoea;<br>Drug Interaction;<br>Dysarthria; Lethargy;<br>Oliguria; Toxicity To<br>Various Agents; Tremor | Lithium Carbonate<br>Levomepromazine<br>Furosemide<br>Spironolactone<br>Escitalopram Oxalate<br>Lormetazepam<br>Metformin Hydrochloride<br>Repaglinide<br>Irbesartan<br>Prinivil<br>Risperidone |                    |                    | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C<br>S<br>S<br>S | Oral                                            |                                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Bristol Myers Squibb<br>Not Reported<br>Bristol Myers Squibb<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Apr-2005                                                                                     | 5758156                  | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-01016-01     |                      | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crohn'S Disease                                                                                 | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2005                                                                                     | 5763103                  | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07520-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Complication Of Delivery; Maternal Exposure During Pregnancy; Postpartum Haemorrhage; Pregnancy | Lexapro                  |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2005                                                                                     | 5763104                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01134-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                         | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                 | Demerol                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2005                                                                                     | 5776131                  | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-07942-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;                                                                               | Lexapro                  |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Condition Aggravated;                                                                           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Dissociative Disorder;                                                                          | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Schizoaffective Disorder;                                                                       | Risperdal                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Stress; Syncope                                                                                 | Trileptal                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                 | Depakote Er (Divalproex) |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 05-Apr-2005                                                                                                                                                                                                                                                                                                                     | 5808745                    | NON-EXPEDITED      | Y                  | OT              | 2004023507           |                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Body Temperature Increased; Bruxism; Drug Interaction; Dyskinesia; Seizure                                                                                                                                                                                                                                           | Geodon                     |                    |                    | S               | Oral                 | 60 Mg (Daily), Oral          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate       |                    |                    | S               |                      | Unk (Daily), Unknown         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2005                                                                                                                                                                                                                                                                                                                     | 5808965                    | NON-EXPEDITED      | Y                  | OT              | 2004076507           |                              |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder                                                                                                                                                                                                                                                                                                         | Geodon                     |                    |                    | S               | Oral                 | 160 Mg (80 Mg,2 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate       |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                        | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2005                                                                                                                                                                                                                                                                                                                     | 3880031                    | EXPEDITED (15-DAY) | N                  | HO              | 2001070033US         |                              | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                           | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Abdominal Pain Upper; Asthenia; Blood Glucose Fluctuation; Constipation; Decreased Appetite; Depression; Discomfort; Drug Dependence; Drug Tolerance Increased; Drug Withdrawal Syndrome; Dysphagia; Dyspnoea; Family Stress; Feeling Abnormal; Feeling Jittery; Gait Disturbance; Hepatocellular Injury; | Xanax                      |                    |                    | S               | Oral                 | 2 Mg (3 In 1 D), Oral        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate       |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Unspecified Ingredient     |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Nefazodone Hydrochloride   |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Fluoxetine Hydrochloride   |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | (Fluoxetine Hydrochloride) |                    |                    |                 |                      |                              |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                 | Hydrochlorothiazide        |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | (Hydrochlorothiazide)      |                    |                    |                 |                      |                              |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                 | Estradiol                  |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                 | Paroxetine Hydrochloride   |                    |                    | C               |                      |                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperventilation;  
Hypophagia; Impaired  
Driving Ability; Loss Of  
Personal Independence In  
Daily Activities; Muscle  
Spasms; Myalgia; Panic  
Attack; Product Quality  
Issue; Tension Headache;  
Therapeutic Product Effect  
Decreased; Treatment  
Noncompliance; Vision  
Blurred; Visual Acuity  
Reduced; Weight  
Decreased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2005              | 5703309       | EXPEDITED (15-DAY) | Y                  | HO              | L04-TUR-08102-01     |                      | 53 YR      | Male       | TUR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Deep Vein Thrombosis;     | Ciprallex      |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
| Irritability; Major       | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depression; Persecutory   |                |              |            |             |              |                    |                 |              |
| Delusion; Suicide Attempt |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2005              | 5770832       | EXPEDITED (15-DAY) | Y                  | OT              | L05-ITA-01092-01     |                      | 60 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;     | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Epistaxis; Rectal     | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Haemorrhage           | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Venlafaxine          |              |            | S           | Oral         | 150 Mg Qd Po       |                 | Not Reported |
|                       | Venlafaxine          |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
|                       | Venlafaxine          |              |            | S           | Oral         | 37.5 Mg Qd Po      |                 | Not Reported |
|                       | Mirtazapine          |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |              |              |
|-------------|---|------|--------------|--------------|
| Mirtazapine | S | Oral | 7.5 Mg Qd Po | Not Reported |
| Omeprazole  | C |      |              | Not Reported |
| Irbesartan  | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2005              | 5659089       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-04P-163-0279298-00 |                      | 56 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acidosis; Acute Kidney Injury; Apnoea; Atrial Fibrillation; Brain Death; Cardio-Respiratory Arrest; Coma; Completed Suicide; Hypotension; Overdose; Overdose; Pneumonia Aspiration; Unresponsive To Stimuli; Vomiting | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2005              | 5778534       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01686-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Blood Bilirubin Increased; Hepatic Enzyme Increased; Jaundice; Nausea | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                       | Actos          |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2005              | 5778833       | DIRECT           | N                  | RI              |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide; Condition Aggravated; Disorientation; Insomnia | Lexapro        |              |            | S           | Oral         | 10 Mg A Day Oral   |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2005              | 5749525       | EXPEDITED (15-DAY) | N                  | OT              | 2005026789           |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Abnormal Behaviour;      | Gabapentin (Gabapentin)  |              |            | S           | Oral         | 2400 Mg (3 In 1 D), Oral |                 | Not Reported |
| Adverse Event; Anxiety;  | Nefazodone Hydrochloride |              |            | S           | Oral         | Oral                     |                 | Not Reported |
| Back Pain; Balance       | Escitalopram Oxalate     |              |            | S           |              |                          |                 | Not Reported |
| Disorder; Choking;       | Clonazepam               |              |            | C           |              |                          |                 | Not Reported |
| Coordination Abnormal;   | Unspecified Ingredient   |              |            | C           |              |                          |                 | Not Reported |
| Drug Ineffective;        |                          |              |            |             |              |                          |                 |              |
| Dysphonia; Dystonia;     |                          |              |            |             |              |                          |                 |              |
| Feeling Abnormal; Gait   |                          |              |            |             |              |                          |                 |              |
| Disturbance; Headache;   |                          |              |            |             |              |                          |                 |              |
| Memory Impairment; Neck  |                          |              |            |             |              |                          |                 |              |
| Pain; Nuclear Magnetic   |                          |              |            |             |              |                          |                 |              |
| Resonance Imaging Brain  |                          |              |            |             |              |                          |                 |              |
| Abnormal; Opisthotonus;  |                          |              |            |             |              |                          |                 |              |
| Oropharyngeal Pain; Road |                          |              |            |             |              |                          |                 |              |
| Traffic Accident;        |                          |              |            |             |              |                          |                 |              |
| Somnolence; Speech       |                          |              |            |             |              |                          |                 |              |
| Disorder; Thinking       |                          |              |            |             |              |                          |                 |              |
| Abnormal; Tremor; Vision |                          |              |            |             |              |                          |                 |              |
| Blurred                  |                          |              |            |             |              |                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2005              | 5727164       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00167-01     |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysphagia; Eating     | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Disorder; Myopathy;   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Oesophageal Disorder; |                |              |            |             |              |                    |                 |              |
| Paralysis; Speech     |                |              |            |             |              |                    |                 |              |
| Disorder; Weight      |                |              |            |             |              |                    |                 |              |
| Decreased             |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2005              | 5781950       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S05-USA-01758-01     |                      | 38 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| Abortion Induced;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Skeletal Dysplasia;<br>Ultrasound Antenatal<br>Screen Abnormal | Lexapro                |                    |                    | S               | Oral                 | 15 Mg Qd Po                  |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2005                                                                                                                              | 5780350                | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01760-01     |                              | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Corneal Scar;<br>Eye Pain; Facial Pain;<br>Stevens-Johnson<br>Syndrome                                                        | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd; Po                 |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                |                    |                    | S               | Oral                 | 15 Mg Qd; Po                 |                 | Not Reported |                |
|                                                                                                                                          | Unspecified Ingredient |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2005                                                                                                                              | 5780647                | EXPEDITED (15-DAY) | Y                  | OT              | GBWYE554604APR05     |                              | 32 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Visual Acuity Reduced                                                                                                                    | Minocin                |                    |                    | S               | Oral                 | 100mg (Frequency<br>Unknown) | 29 DAY          | Not Reported |                |
|                                                                                                                                          | Cipralext              |                    |                    | S               | Oral                 | 20 Mg                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2005                                                                                                                              | 5782342                | DIRECT             |                    | OT              |                      |                              | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence; Drug<br>Withdrawal Syndrome;<br>Therapeutic Response<br>Decreased                                                       | Effexor                |                    |                    | S               |                      | 75-150 Every Day             |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                |                    |                    | S               |                      | 10 Mg Everyday               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Apr-2005                                                                                                                                                                                                                                          | 5781658                                | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-00006-01     |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;<br>Diarrhoea; Dysgeusia;<br>Feeling Abnormal; Feeling<br>Hot; Nasal Congestion                                                                                                                                                     | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Lexapro                                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Zyrtec                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Bactrim                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2005                                                                                                                                                                                                                                          | 5783612                                | EXPEDITED (15-DAY) | Y                  | HO              | KII-2005-0016028     |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Abnormal;<br>Confusional State;<br>Hypercapnia;<br>Hyponatraemia; Mental<br>Status Changes; Miosis;<br>Opiates Positive; Therapy<br>Non-Responder                                                                                      | Morphine Sulfate                       |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Lexapro                                |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Prednisone                             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                             | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2005                                                                                                                                                                                                                                          | 5703329                                | EXPEDITED (15-DAY) | Y                  | DS, HO, LT      | S04-GER-08030-01     |                      | 48 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Affect<br>Lability; Device Related<br>Sepsis; Dialysis;<br>Enterococcal Infection;<br>Escherichia Urinary Tract<br>Infection;<br>Glomerulonephritis<br>Proliferative; Henoch-<br>Schonlein Purpura; Mental<br>Disorder Due To A | Cipraxel                               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                      | Carnigen (Oxilofrine<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

General Medical  
Condition; Normochromic  
Normocytic Anaemia;  
Thrombocytopenia;  
Vasculitis

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
| 20-Apr-2005                                                                                | 5789037                                   | DIRECT             | N                  | HO               |                      |                      | 49 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hallucination                                                                              | Lexapro<br>Synthroid<br>Inderal           |                    |                    | S<br>C<br>C      |                      |                      |                 | Forest<br>Not Reported<br>Not Reported                       |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 21-Apr-2005                                                                                | 5784479                                   | EXPEDITED (15-DAY) | Y                  | OT               | S05-USA-01868-01     |                      | 31 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Aggression; Alcohol Use;<br>Anger; Physical Assault;<br>Screaming                          | Lexapro<br>Lexapro<br>Alcohol<br>Klonopin |                    |                    | S<br>S<br>S<br>C |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 22-Apr-2005                                                                                | 5719100                                   | EXPEDITED (15-DAY) | N                  | OT               | S04-USA-08018-01     |                      | 54 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Erectile Dysfunction;<br>Premature Ejaculation;<br>Prostatic Specific Antigen<br>Increased | Lexapro                                   |                    |                    | S                | Oral                 | 10 Mg Qd Po          |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 22-Apr-2005                                                                                | 5781949                                   | EXPEDITED (15-DAY) | Y                  | HO, OT           | S05-USA-00632-01     |                      | 76 YR           | Female                                                       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dyspnoea; Eating Disorder; Hyponatraemia; Mental Status Changes                                                                                                                                                                                                                                                              | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Pamelor                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Lorazepam                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Accupril                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Protonix                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Ultracet                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Detrol La                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2005                                                                                                                                                                                                                                                                                                                  | 4167391                    | EXPEDITED (15-DAY) | N                  | DE              | S04-USA-03514-01     |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                                                                                                                                                                                                                                                                                  | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2005                                                                                                                                                                                                                                                                                                                  | 5745790                    | EXPEDITED (15-DAY) | Y                  | RI              | S05-USA-00537-01     |                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Antinuclear Antibody Positive; Blood Creatine Phosphokinase Decreased; Blood Creatinine Increased; Blood Urea Increased; Bursitis; Cerebrovascular Accident; Confusional State; Contusion; Diarrhoea; Facial Bones Fracture; Fall; Fatigue; Haematoma; Hallucination, Visual; Hypertrophy; Inflammation; Intervertebral Disc | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Imuran                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Lopresor                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Prednisone                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Plavix                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Lasix                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Potassium                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Baby Aspirin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Tylenol (Paracetamol)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Citracal (Calcium Citrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                              | Centrum Silver             |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protrusion; Intervertebral  
Disc Space Narrowing;  
Intracranial Aneurysm;  
Loss Of Consciousness;  
Muscle Atrophy; Muscle  
Rupture; Muscular  
Weakness; Nausea; Nerve  
Conduction Studies  
Abnormal; Neuropathy  
Peripheral; Osteoarthritis;  
Osteopenia; Pain; Red  
Blood Cell Sedimentation  
Rate Increased; Renal  
Artery Stenosis; Skin  
Laceration; Somnolence;  
Spinal Fracture; Spinal  
Osteoarthritis; Swelling  
Face; Tri-Iodothyronine  
Uptake Increased; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2005              | 5788750       | EXPEDITED (15-DAY) |                    | DE              | S05-USA-01997-01     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun<br>Shot Wound; Head Injury;<br>Skin Laceration | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2005              | 5788454       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-01983-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Fatigue; Intentional<br>Self-Injury; Skin<br>Laceration | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                | Seroquel       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|------------------------|-----------------|--------------|----------------|
| 27-Apr-2005                                                                                                         | 5791330        | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | S05-UKI-01491-01      |                        | 37 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Obsessive-Compulsive Disorder                                                                                       | Cipralext      |                    |                    | S               | Oral                  | 10 Mg Qd Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2005                                                                                                         | 5791333        | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | S05-UKI-01493-01      |                        | 49 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Obsessive-Compulsive Disorder                                                                                       | Cipralext      |                    |                    | S               | Oral                  | 10 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                     | Atenolol       |                    |                    | C               |                       |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2005                                                                                                         | 5791862        | DIRECT             | N                  | OT              |                       |                        |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation; Chills; Fear; Heart Rate Increased; Hyperhidrosis; Mydriasis; Night Sweats; Palpitations; Tremor | Cipralext      |                    |                    | S               | Oral                  | 1x 20mg Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2005                                                                                                         | 5811501        | NON-EXPEDITED      | Y                  | OT              | US-JNJFOC-20041008443 |                        | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                  | Ultram         |                    |                    | S               | Oral                  | 400 Mg, In 1 Day, Oral |                 | Not Reported |                |
|                                                                                                                     | Lexapro        |                    |                    | S               | Oral                  | 8 Mg, In 1 Day, Oral   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                                                                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|--------------------------------------|------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| 27-Apr-2005                                                                                                                             | 5811656                                                                                                                     | NON-EXPEDITED      | Y                  | OT                         | US-JNJFOC-20041207311                |                                                                        |                 | Unknown                                                                                      | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                                                                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Seizure                                                                                                                                 | Ultram<br>Lexapro                                                                                                           |                    |                    | S<br>S                     | Oral                                 | See Image                                                              |                 | Not Reported<br>Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                                                                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 28-Apr-2005                                                                                                                             | 5811462                                                                                                                     | NON-EXPEDITED      | Y                  | OT                         | 2004111059                           |                                                                        | 52 YR           | Male                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                                                                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Myoclonus                                                                                                                               | Azithromycin<br>Escitalopram Oxalate<br>Fluticasone Propionate<br>Fexofenadine Hydrochloride<br>Lansoprazole (Lansoprazole) |                    |                    | S<br>S<br>C<br>C<br>C      |                                      |                                                                        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                                                                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 02-May-2005                                                                                                                             | 5768281                                                                                                                     | EXPEDITED (15-DAY) | Y                  | HO                         | S05-USA-01342-01                     |                                                                        | 45 YR           | Male                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                                                                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Anxiety; Concussion;<br>Confusional State; Fall;<br>Hyponatraemia;<br>Perseveration; Personality<br>Change; Seizure; Skin<br>Laceration | Lexapro<br>Lexapro<br>Lexapro<br>Lexapro<br>Lexapro<br>Mellaril                                                             |                    |                    | S<br>S<br>S<br>S<br>S<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral | 20 Mg Qd Po<br>10 Mg Qd Po<br>20 Mg Qd Po<br>5 Mg Qd Po<br>10 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                                                                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 02-May-2005                                                                                                                             | 5783688                                                                                                                     | EXPEDITED (15-DAY) | N                  | HO                         | 2005055158                           |                                                                        | 31 YR           | Female                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                                                                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                      |   |      |  |                          |  |  |              |
|-----------------------------|----------------------|---|------|--|--------------------------|--|--|--------------|
| Abdominal Pain Upper;       | Flagyl               | S |      |  |                          |  |  | Not Reported |
| Drug Interaction;           | Escitalopram Oxalate | S | Oral |  | 30 Mg (30 Mg, 1 In 1 D), |  |  | Not Reported |
| Hypoaesthesia; Panic Attack | Ciprofloxacin        | S |      |  | Oral                     |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2005              | 5789300       | EXPEDITED (15-DAY) | N                  | HO              | 2005059988           |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Depression;                          | Geodon                  |              |            | S           |              |                    |                 | Not Reported |
| Drug Interaction; Drug                            | Lithium (Lithium)       |              |            | S           |              |                    |                 | Not Reported |
| Level Decreased; Fatigue;                         | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| General Physical Health                           | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
| Deterioration; Malaise;                           | Topiramate              |              |            | S           |              |                    |                 | Not Reported |
| Product Quality Issue;                            | Lorazepam               |              |            | C           |              |                    |                 | Not Reported |
| Self-Medication; Sleep Disorder; Weight Increased |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2005              | 5792229       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S05-USA-02156-01     |                      | 66 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bronchitis; Fall;                     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Hypertension;                         | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Hyponatraemia; Loss Of Consciousness; | Flomax         |              |            | C           |              |                    |                 | Not Reported |
| Pneumothorax; Pyrexia;                |                |              |            |             |              |                    |                 |              |
| Rib Fracture; Seizure;                |                |              |            |             |              |                    |                 |              |
| Skin Abrasion                         |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2005              | 5792750       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02075-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine Increased | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                            |                             |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hydrochlorothiazide                                                                                                                        |                             | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2005                                                                                                                                | 5794796                     | EXPEDITED (15-DAY) | Y                  | DE              | 2005-127760-NL       |                      | 89 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Atrial Fibrillation; Blood Pressure Fluctuation; Coma; Heart Rate Irregular; Hemiparesis; Hypertension; Salivary Hypersecretion | Mirtazapine                 |                    |                    | S               | Oral                 | 15 Mg, Oral          |                 | Not Reported |                |
|                                                                                                                                            | Risperidone                 |                    |                    | S               | Oral                 | Mg, Oral             | 144 DAY         | Not Reported |                |
|                                                                                                                                            | Buspirone Hydrochloride     |                    |                    | S               | Oral                 | 15 Mg, Oral          | 131 DAY         | Not Reported |                |
|                                                                                                                                            | Galantamine Hydrobromide    |                    |                    | S               | Oral                 | Mg/24 Mg, Oral       | 13 DAY          | Not Reported |                |
|                                                                                                                                            |                             |                    |                    |                 | Oral                 | Mg/24 Mg, Oral       | 124 DAY         |              |                |
|                                                                                                                                            | Valproate Sodium            |                    |                    | S               | Oral                 | Mg, Oral             | 127 DAY         | Not Reported |                |
|                                                                                                                                            | Mineral Oil\Phenolphthalein |                    |                    | S               |                      | 10 Mg                | 6 MTH           | Not Reported |                |
|                                                                                                                                            | Escitalopram Oxalate        |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2005                                                                                                                                | 5758275                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00987-01     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foaming At Mouth; Lethargy; Loss Of Consciousness; Road Traffic Accident; Seizure; Self-Medication                                         | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                            | Ultram                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2005                                                                                                                                | 5776213                     | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-01620-01     |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychiatric Symptom; Self-Injurious Ideation                                                                                               | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                            | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-May-2005                                                                                                                                                                         | 5794671              | DIRECT             | N                  | DE              |                      |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                   | Lexapro              |                    |                    | S               |                      | 10 Mg 2x Day         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2005                                                                                                                                                                         | 5796740              | DIRECT             | Y                  | HO              |                      |                      | 4 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage Neonatal; Intraventricular Haemorrhage; Maternal Exposure During Pregnancy; Neonatal Seizure; Subarachnoid Haemorrhage Neonatal; Subdural Haemorrhage Neonatal | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2005                                                                                                                                                                         | 5788738              | EXPEDITED (15-DAY) | Y                  | OT              | L05-USA-01419-01     |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Condition Aggravated; Crying; Drug Interaction; Panic Attack; Therapeutic Product Effect Decreased; Treatment Noncompliance                                   | Citalopram           |                    |                    | S               |                      | 20 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                                     | Citalopram           |                    |                    | S               |                      | 40 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                                     | Citalopram           |                    |                    | S               |                      | 60 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                                     | Citalopram           |                    |                    | S               |                      | 60 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                                     | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Rifampin             |                    |                    | S               | Oral                 | 600 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                                                                                                     | Bupropion            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Lorazepam            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Clonazepam           |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                 |   |              |
|---------------------------------|---|--------------|
| Clindamycin                     | C | Not Reported |
| Vancomycin                      | C | Not Reported |
| Sulfamethoxazole & Trimethoprim | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2005              | 4042368       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S03-USA-04774-01     |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;                                                              | Lexapro              |              |            | S           |              |                    |                 | Not Reported |
| Abnormal Behaviour;                                                                | Elavil               |              |            | S           |              | 150 Mg Qd          |                 | Not Reported |
| Activated Partial Thromboplastin Time                                              | Elavil               |              |            | S           |              | 75 Mg Qd           |                 | Not Reported |
| Prolonged; Acute Kidney Injury; Areflexia;                                         | Topamax              |              |            | C           |              |                    |                 | Not Reported |
| Arrhythmia; Balance Disorder; Blood Sodium Decreased; Confusional State; Cyanosis; | Klonopin             |              |            | C           |              |                    |                 | Not Reported |
| Demyelination; Depressed Level Of Consciousness;                                   | Ativan               |              |            | C           |              |                    |                 | Not Reported |
| Dialysis; Drug Abuser;                                                             | Neurontin            |              |            | C           |              |                    |                 | Not Reported |
| Drug Level Decreased;                                                              | Tambocor             |              |            | C           |              |                    |                 | Not Reported |
| Drug Withdrawal                                                                    | Percocet             |              |            | C           |              |                    |                 | Not Reported |
| Syndrome; Dyspnoea;                                                                | Oxycontin            |              |            | C           |              |                    |                 | Not Reported |
| Encephalitis;                                                                      | Zanaflex             |              |            | C           |              |                    |                 | Not Reported |
| Encephalopathy; Fall;                                                              | Lasix                |              |            | C           |              |                    |                 | Not Reported |
| Haematocrit Increased;                                                             | K-Dur                |              |            | C           |              |                    |                 | Not Reported |
| Haemoconcentration;                                                                | Allopurinol          |              |            | C           |              |                    |                 | Not Reported |
| Haemodynamic Instability;                                                          | Lidoderm (Lidocaine) |              |            | C           |              |                    |                 | Not Reported |
| Haemoglobin Increased;                                                             | Nitroglycerin        |              |            | C           |              |                    |                 | Not Reported |
| Herpes Simplex; Herpes Zoster; Hypocalcaemia;                                      | Risperdal            |              |            | C           |              |                    |                 | Not Reported |
| Hypotension; Loss Of Consciousness;                                                | Lithium (Lithium)    |              |            | C           |              |                    |                 | Not Reported |
| Meningitis;                                                                        | Ambien               |              |            | C           |              |                    |                 | Not Reported |
| Meningoencephalitis                                                                |                      |              |            |             |              |                    |                 |              |
| Herpetic; Metabolic Acidosis; Mydriasis; Nausea; Neuroleptic                       |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malignant Syndrome;  
Nuchal Rigidity; Oliguria;  
Palpitations; Paraplegia;  
Polymyositis; Pupillary  
Reflex Impaired;  
Rhabdomyolysis;  
Serotonin Syndrome;  
Shock; Sinus Tachycardia;  
Urine Abnormality;  
Vulvovaginal Mycotic  
Infection

| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-May-2005                                                                                                                          | 5796099                  | EXPEDITED (15-DAY) | Y                  | OT              | DSA_26337_2005       |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug<br>Interaction; Memory<br>Impairment                                                                         | Ativan                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Q Day Po       |                 | Not Reported |                |
|                                                                                                                                      | Lexapro                  |                    |                    | S               | Oral                 | 5 Mg Q Day Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2005                                                                                                                          | 5796565                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02236-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                                                                                                   | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2005                                                                                                                          | 5797001                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-SWI-01568-01     |                      | 33 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation;<br>Condition Aggravated;<br>Dizziness; Dyspnoea;<br>Fatigue; Muscular<br>Weakness; Somnolence;<br>Tongue Disorder | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                      | Tizanidine Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Feldene                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Mefenamic Acid           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                      | Xefo (Lornoxicam)        |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|------------------------------|----------------|
| 05-May-2005                    | 5797005                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-ESP-01633-01     |                            | 49 YR           | Male                         | ESP            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Haematuria                     | Cipralelex<br>Acenocoumarol |                    |                    | S<br>C          |                      |                            |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-May-2005                    | 5797660                     | DIRECT             | Y                  | OT              |                      |                            | 49 YR           | Male                         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Blood Pressure Increased       | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po                |                 | Not Reported                 |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-May-2005                    | 5798318                     | DIRECT             | N                  |                 |                      |                            | 66 YR           | Female                       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Malaise                        | Lexapro                     |                    |                    | S               |                      | 10 Mg Daily                |                 | Not Reported                 |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 06-May-2005                    | 5775035                     | EXPEDITED (15-DAY) | Y                  | DE              | S05-NOR-01249-01     |                            | 50 YR           | Female                       | NOR            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Asphyxia; Completed<br>Suicide | Cipralelex<br>Cipralelex    |                    |                    | S<br>S          | Oral<br>Oral         | 10 Mg Qd Po<br>20 Mg Qd Po |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 06-May-2005                    | 5796719                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-01647-01     |                            |                 | Female                       | GBR            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|-------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Self-Injurious Ideation;<br>Suicidal Ideation                                                         |                         | Cipralelex                | S                           | Oral                     | 10 Mg Qd Po                   |                               | Not Reported             |                     |                         |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-May-2005                                                                                           | 5796809                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-GER-00504-01              |                               | 48 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Fall; Loss Of Consciousness;<br>Orthostatic Hypotension;<br>Subdural Haematoma;<br>Syncope | Cipralelex              |                           |                             | S                        |                               | 10 Mg Qd                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-May-2005                                                                                           | 5796838                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-UKI-01571-01              |                               | 27 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal;<br>Psychomotor<br>Hyperactivity; Sleep<br>Disorder                                  | Cipralelex              |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-May-2005                                                                                           | 5798018                 | DIRECT                    | N                           | DS, OT                   |                               |                               | 21 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dysphemia; Muscle<br>Twitching; Weight<br>Increased                                                   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-May-2005                                                                                           | 5746209                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 2005024283                    |                               | 60 YR                    | Male                | NOR                     |
| <a href="#">Preferred Term</a>                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                            |                                        |   |      |                                    |              |
|--------------------------------------------------------------------------------------------|----------------------------------------|---|------|------------------------------------|--------------|
| Anaemia; Gastric Ulcer<br>Haemorrhage;<br>Gastrointestinal<br>Haemorrhage;<br>Haematemesis | Celebrex                               | S | Oral | 200 Mg (200 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                            | Escitalopram Oxalate                   | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   | Not Reported |
|                                                                                            | Chlorprothixene Hydrochloride          | C |      |                                    | Not Reported |
|                                                                                            | Symbicort Turbuhaler                   | C |      |                                    | Not Reported |
|                                                                                            | Acetaminophen And Codeine<br>Phosphate | C |      |                                    | Not Reported |
|                                                                                            | Metoprolol Succinate                   | C |      |                                    | Not Reported |
|                                                                                            | Tramadol Hydrochloride                 | C |      |                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-May-2005              | 5773965       | EXPEDITED (15-DAY) | N                  | HO, RI          | S05-USA-01466-01     |                      | 79 YR      | Male       | USA            |

  

| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Balance<br>Disorder; Blood Pressure<br>Increased; Dizziness;<br>Drug Interaction; Fall;<br>Hypertension; Rib<br>Fracture; Seborrhoeic<br>Dermatitis; Urinary<br>Incontinence; Urinary<br>Retention | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                              | Erythromycin          |              |            | S           |              | 250 Mg Tid         |                 | Not Reported |
|                                                                                                                                                                                                              | Namenda               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                              | Atenolol              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                              | Synthroid             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                              | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                              | Aspirin               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-May-2005              | 5798879       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-02325-01     |                      | 49 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Breast Mass;<br>Increased Tendency To<br>Bruise; Menorrhagia;<br>Nasopharyngitis;<br>Thrombosis | Lexapro           |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                          | Lexapro           |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                          | Calcium Gluconate |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-May-2005              | 5793279       | EXPEDITED (15-DAY) | Y                  | DE              | CH-JNJFOC-20050501114 |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Agitation; Atrial Fibrillation; Blood Pressure Fluctuation; Cerebrovascular Accident; Coma; Depression; Hemiparesis; Salivary Hypersecretion; Sleep Disorder | Risperdal                   |              |            | S           | Oropharyngeal | 1.5 - 2.5 Mg       |                 | Not Reported |
|                                                                                                                                                              | Buspar                      |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Reminyl                     |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Reminyl                     |              |            | S           | Oropharyngeal | 8-16 Mg            |                 | Not Reported |
|                                                                                                                                                              | Convulex (Valproate Sodium) |              |            | S           | Oropharyngeal | 100-200 Mg         |                 | Not Reported |
|                                                                                                                                                              | Remeron                     |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Remeron                     |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Cipralext                   |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Agar                        |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Agar                        |              |            | S           | Oropharyngeal |                    |                 | Not Reported |
|                                                                                                                                                              | Phenolphthalein             |              |            | S           | Oropharyngeal |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-May-2005              | 5803724       | DIRECT           | N                  | DS, HO, LT      |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|------------|
| Agitation; Anxiety; Drug Intolerance; Dysarthria; Dysgraphia; Economic Problem; Fear; Feeling Abnormal; Feelings Of Worthlessness; Hypersensitivity; Impaired Work Ability; Inappropriate Schedule Of Product Administration; Injury; Intentional Product Misuse; Tension; Tremor | Lexapro        |              |            | S           | Oral         | 5 Mg - 20mg/Day, Orally |                 | Forest     |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2005              | 5787801       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00972-01     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Drug Screen Positive; Fatigue; Feeling Abnormal; Intentional Product Misuse; Maternal Exposure During Pregnancy; Maternal Use Of Illicit Drugs; Nausea; Overdose; Palpitations; Pharyngitis Streptococcal; Sensory Disturbance; Suicide Attempt; Treatment Noncompliance; Tremor; Vaginal Infection | Lexapro                |              |            | S           | Oral         | 220 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Amphetamine            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                         | Albuterol              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2005              | 5654664       | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06698-01     |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematocrit Decreased; Haematuria; Haemoglobin Decreased; Platelet Count Decreased; Rectal Haemorrhage; Victim Of Abuse; White Blood Cell Count Decreased | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2005              | 5795195       | EXPEDITED (15-DAY) | N                  | HO, LT          | 2005UW07199          |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                      |                                                                                  |                            |              |      |                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------|--------------|------|----------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Depression; Drug<br>Ineffective; Intentional<br>Product Misuse; Mania;<br>Overdose; Personality<br>Change; Social Avoidant<br>Behaviour; Suicide<br>Attempt; Weight Increased | Seroquel<br>Lexapro<br>Lithium<br>Lamictal<br>Abilify<br>Trazodone Hydrochloride | S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral | 3 YR | Zeneca<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------|--------------|------|----------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2005              | 5801872       | EXPEDITED (15-DAY) | Y                  | HO              | S05-UKI-01725-01     |                      | 58 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------------------------|
| Confusional State;<br>Hallucination, Auditory;<br>Hallucination, Visual;<br>Hyponatraemia; Paranoia | Ciprallex<br>Bendrofluazide |              |            | S<br>S      | Oral<br>Oral | 10 Mg Qd Po<br>2.5 Mg Qd Po |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2005              | 5802918       | EXPEDITED (15-DAY) | N                  | HO              | 2005-127881-NL       |                      | 90 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                                   |
|------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|----------------------------------------------|
| Cerebrovascular Accident;<br>Nervousness | Remeron<br>Lexapro<br>Unspecified Ingredient |              |            | S<br>S<br>C | Oral<br>Oral | Oral<br>10 Mg Daily Oral | 10 YR           | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2005              | 5892222       | EXPEDITED (15-DAY) | Y                  | OT              | ACO_0144_2005        |                      | 33 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                                                                   |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-----------------------|--------------|-----------------------------------|-----------------|------------------------------------------------------------------------------|
| Burning Sensation;<br>Dizziness; Dyspnoea;<br>Muscular Weakness;<br>Somnolence; Sudden<br>Onset Of Sleep; Tongue<br>Disorder | Tizanidine<br>Ciprallex<br>Felden<br>Ponstan<br>Xefo |              |            | S<br>S<br>C<br>C<br>C | Oral<br>Oral | 4 Tab Qday Po<br>10 Mg Nightly Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-May-2005                                                                                                                                              | 5909823        | EXPEDITED (15-DAY) | Y                  | HO              | 2005AP02618          |                      | 59 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenal Ulcer;<br>Gastrointestinal<br>Haemorrhage; Melaena;<br>Overdose                                                                                 | Atacand        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                          | Lexapro        |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                          | Minipress      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                          | Zocor          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                          | Daonil         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2005                                                                                                                                              | 5803418        | DIRECT             |                    |                 |                      |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Suicidal<br>Ideation                                                                                                                   | Lexapro        |                    |                    | S               |                      | 1 Dose - One Time    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2005                                                                                                                                              | 5703491        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-07716-01     |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Gait Inability; Guillain-<br>Barre Syndrome;<br>Headache; Myalgia;<br>Nausea; Speech Disorder;<br>Vomiting | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2005                                                                                                                                              | 5743491        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00523-01     |                      | 60 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Preferred Term                                                                                                                 | Product                              | Comp. | OTC | Role | Route | Dosage Text  | Duration | Mfr          |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-------|-----|------|-------|--------------|----------|--------------|
| Acute Kidney Injury; Acute Sinusitis; Anaemia Of Chronic Disease;                                                              | Lexapro                              |       |     | S    | Oral  | 20 Mg Qd Po  |          | Not Reported |
| Asthenia; Back Pain;                                                                                                           | Lexapro                              |       |     | S    | Oral  | 30 Mg Qd Po  |          | Not Reported |
| Bacterial Sepsis; Blood Glucose Increased; Chest Pain; Clostridium Colitis;                                                    | Lexapro                              |       |     | S    | Oral  | 10 Mg Qd Po  |          | Not Reported |
| Coma; Confusional State; Depression; Device                                                                                    | Lexapro                              |       |     | S    | Oral  | 20 Mg Qd Po  |          | Not Reported |
| Related Sepsis; Disease Recurrence; Drug Interaction; Electrolyte Imbalance; Fall; Fluid Overload; Hypercapnia; Hyperkalaemia; | Lexapro                              |       |     | S    | Oral  | 30 Mg Qd Po  |          | Not Reported |
| Hypotension; Hypoxia; Metabolic Acidosis;                                                                                      | Wellbutrin (Bupropion Hydrochloride) |       |     | S    | Oral  | 300 Mg Qd Po |          | Not Reported |
| Musculoskeletal Chest Pain; Musculoskeletal Discomfort; Neuropathy                                                             | Wellbutrin (Bupropion Hydrochloride) |       |     | S    |       | 150 Mg Bid   |          | Not Reported |
| Peripheral; Pneumonia                                                                                                          | Wellbutrin (Bupropion Hydrochloride) |       |     | S    | Oral  | 300 Mg Qd Po |          | Not Reported |
| Bacterial; Pulmonary                                                                                                           | Wellbutrin (Bupropion Hydrochloride) |       |     | S    | Oral  | 150 Mg Qd Po |          | Not Reported |
| Hypertension; Respiratory Failure; Staphylococcal Infection;                                                                   | Atenolol                             |       |     | C    |       |              |          | Not Reported |
| Stenotrophomonas                                                                                                               | Potassium                            |       |     | C    |       |              |          | Not Reported |
| Infection; Syncope;                                                                                                            | Zocor                                |       |     | C    |       |              |          | Not Reported |
| Tremor; Urinary Tract Infection                                                                                                | Aspirin                              |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Nexium                               |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Aricept                              |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Duragesic                            |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Hydrocodone                          |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Centrum Silver                       |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Magnesium                            |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Vitamin B12                          |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Diazepam                             |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Altace                               |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Demadex                              |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Skelaxin                             |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Isordil(Isosorside Dinitrate)        |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Glucophage                           |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Acetazolamide                        |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Xalatan                              |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Oxycontin                            |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Miconazole                           |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Humulin R                            |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Astelin                              |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Meclizine                            |       |     | C    |       |              |          | Not Reported |
|                                                                                                                                | Norvasc                              |       |     | C    |       |              |          | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |              |
|---------------------------------|---|--------------|
| Rocephin                        | C | Not Reported |
| Tobramycin                      | C | Not Reported |
| Hydralazine                     | C | Not Reported |
| Protonix                        | C | Not Reported |
| Valium                          | C | Not Reported |
| Lorcet Plus                     | C | Not Reported |
| Diamox Sequels                  | C | Not Reported |
| Avandia (Rosiglitazone Maleate) | C | Not Reported |
| Nitrol                          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-May-2005              | 5797206       | EXPEDITED (15-DAY) | N                  | HO              | US-GLAXOSMITHKLINE-A0558030A |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Antisocial Behaviour;<br>Depression; Drug<br>Ineffective; Intentional<br>Product Misuse; Mania;<br>Overdose; Personality<br>Change; Suicidal Ideation;<br>Suicide Attempt; Weight<br>Increased | Lamictal                |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                | Lithium                 |              |            | S           | Unknown      | 600mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                                                                | Lexapro                 |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |
|                                                                                                                                                                                                | Abilify                 |              |            | S           | Unknown      | 15mg Per Day       |                 | Not Reported    |
|                                                                                                                                                                                                | Seroquel                |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                                                                                                                                                | Trazodone Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2005              | 5798789       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-02258-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure<br>Decreased; Dry Skin;<br>Fatigue; Feeling<br>Abnormal; Gait<br>Disturbance; Heart Rate<br>Decreased; Incoherent;<br>Nausea | Lexapro                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                             | Metadate (Methylphenidate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Protonix                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Nasacort                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                             | Zyrtec-D                   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|-----------------|--------------|----------------|
| 17-May-2005                                                                                                                | 5800702        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02263-01                        |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hydrocephalus;<br>Papilloedema                                                                                             | Lexapro        |                    |                    | S               | Oral                                    | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Lexapro        |                    |                    | S               | Oral                                    | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Lexapro        |                    |                    | S               | Oral                                    | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Diovan         |                    |                    | C               |                                         |                      |                 | Not Reported |                |
|                                                                                                                            | Celebrex       |                    |                    | C               |                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2005                                                                                                                | 5818377        | NON-EXPEDITED      | N                  | HO              | S05-USA-00335-01                        |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Drug Interaction;<br>Fall; Hypersomnia; Loss<br>Of Consciousness; Pelvic<br>Fracture; Tremor                     | Namenda        |                    |                    | S               | Oral                                    | 50 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Namenda        |                    |                    | S               | Oral                                    | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                                                                            | Namenda        |                    |                    | S               | Oral                                    | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Namenda        |                    |                    | S               | Oral                                    | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Namenda        |                    |                    | S               | Oral                                    | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                                                                            | Lexapro        |                    |                    | S               |                                         |                      |                 | Not Reported |                |
|                                                                                                                            | Aricept        |                    |                    | C               |                                         |                      |                 | Not Reported |                |
|                                                                                                                            | Synthroid      |                    |                    | C               |                                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2005                                                                                                                | 5887774        | EXPEDITED (15-DAY) | N                  | HO              | US-<br>KINGPHARMUSA00001<br>-K200500576 |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Autoimmune<br>Thyroiditis; Blood<br>Pressure Decreased; Drug<br>Interaction; Heart Rate<br>Increased; Irritability; | Cytomel        |                    |                    | S               | Oral                                    | 12.5 Mcg, Qd         |                 | King         |                |
|                                                                                                                            | Cytomel        |                    |                    | S               | Oral                                    | 25 Mcg, Qd           |                 | King         |                |
|                                                                                                                            | Cytomel        |                    |                    | S               | Oral                                    | 37.5 Mcg, 1.5        |                 | King         |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |           |   |      |                 |              |
|----------------------------------------------------------|-----------|---|------|-----------------|--------------|
| Lethargy; Mood Swings;<br>Overdose; Suicidal<br>Ideation | Cytomel   | S | Oral | Tablet/25mcg Qd | King         |
|                                                          | Cytomel   | S | Oral | 25 Mcg, Qd      | King         |
|                                                          | Abilify   | S | Oral | 12.5 Mcg, Qd    | Not Reported |
|                                                          | Strattera | S | Oral | 10 Mg, Qd       | Not Reported |
|                                                          | Lexapro   | S | Oral | 18 Mg, 2qd      | Not Reported |
|                                                          | Lexapro   | S | Oral | 30 Mg, Qd       | Not Reported |
|                                                          | Lexapro   | S | Oral | 2.5 Mg, Qd      | Not Reported |
|                                                          | Lexapro   | S | Oral | 5 Mg, Qd        | Not Reported |
|                                                          | Lexapro   | S | Oral | 2.5 Mg, Qd      | Not Reported |
|                                                          | Klonopin  | S | Oral | Unk, Unk        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2005              | 5781932       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-01768-01     |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Alcohol Use;<br>Amnesia; Drug Interaction;<br>Loss Of Consciousness | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Herbal Nos     |              |            | S           | Oral         | 2 Tablet Once Po   |                 | Not Reported |
|                                                                                 | Alcohol        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 18-May-2005              | 5798047       | EXPEDITED (15-DAY) | Y                  | DS, OT          | GB-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12948212 |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Depression; Drug<br>Interaction; Gait<br>Disturbance; Movement<br>Disorder; Muscle Rigidity;<br>Tremor | Abilify                |              |            | S           | Oral         | 15 Mg/Day 16-Mar-05;<br>Reduced To 10 Mg/Day |                 | Not Reported |
|                                                                                                        | Amisulpride            |              |            | C           | Oral         |                                              |                 | Not Reported |
|                                                                                                        | Unspecified Ingredient |              |            | C           | Oral         |                                              |                 | Not Reported |
|                                                                                                        | Escitalopram Oxalate   |              |            | S           | Oral         |                                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 18-May-2005                                                | 5804653                 | EXPEDITED (15-DAY)        | N                           | DE                       | S05-USA-02494-01              |                               | 55 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide; Gun Shot Wound; Nervous System Disorder | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>                                                                                                                                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 18-May-2005                                                                                                                                                                                                  | 5805043                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-UKI-01792-01              |                               | 47 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Akathisia; Blood Creatine Phosphokinase Increased; Coordination Abnormal; Dyskinesia; Fatigue; Headache; Hyperreflexia; Injury; Muscle Rigidity; Muscle Tightness; Muscle Twitching; Myoclonus; Restlessness | Cipralex                |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-May-2005                                                       | 5804638                 | DIRECT                    | N                           | OT                       |                               |                               | 32 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Alcohol Use; Condition Aggravated; Psychotic Disorder | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Daily Oral              |                          |                     | Forest                  |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-May-2005                       | 5804642                 | DIRECT                    | Y                           |                          |                               |                               | 40 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                     |          |   |      |                  |              |
|-------------------------------------------------------------------------------------|----------|---|------|------------------|--------------|
| Abscess; Acute Kidney Injury; Diverticular Perforation; Granulomatous Liver Disease | Lexapro  | S | Oral | 10 Mg Daily Oral | Not Reported |
|                                                                                     | Altace   | S | Oral | 2.5 Daily Oral   | Not Reported |
|                                                                                     | Prevacid | C |      |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2005              | 6278137       | EXPEDITED (15-DAY) | N                  | HO, RI, OT      | 2005-01660           |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>     |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|----------------|
| Depression; Drug Ineffective; Intentional Product Misuse; Mania; Off Label Use; Overdose; Personality Change; Suicide Attempt; Weight Increased | Trazodone Hydrochloride |              |            | S           | Oral         | Oral                |                 | Watson         |
|                                                                                                                                                 | Lexapro                 |              |            | S           | Oral         | 20 Mg, Daily, Oral  |                 | Not Reported   |
|                                                                                                                                                 | Lithium                 |              |            | S           | Oral         | 600 Mg, Daily, Oral |                 | Not Reported   |
|                                                                                                                                                 | Lamictal                |              |            | S           | Oral         | 50 Mg, Bid, Oral    |                 | Glaxo Wellcome |
|                                                                                                                                                 | Aripiprazole            |              |            | S           | Oral         | 15 Mg, Daily, Oral  |                 | Not Reported   |
|                                                                                                                                                 | Seroquel                |              |            | S           | Oral         | Oral                |                 | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 20-May-2005              | 5800669       | EXPEDITED (15-DAY) | Y                  | OT              | US-KINGPHARMUSA00001-K200500633 |                      |            | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Granulomatous Liver Disease | Altace         |              |            | S           |              |                    |                 | King         |
|                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                             | Prevacid       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2005              | 5719092       | EXPEDITED (15-DAY) | Y                  | OT              | S04-USA-08048-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Condition Aggravated; Hallucination, Auditory; Homicide; Nervousness; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thinking Abnormal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2005              | 5771195       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01454-01     |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Disorientation; Fall; Head Injury; Hypersomnia; Seizure; Tongue Biting; Tremor | Lexapro                 |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                  | Bupropion Hydrochloride |              |            | S           |              | 300 Mg Qam         |                 | Not Reported |
|                                                                                                                  | Lexapro                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 23-May-2005              | 5801839       | EXPEDITED (15-DAY) | Y                  | HO              | AU-MERCK-0505AUS00102 |                      | 59 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Duodenal Ulcer; Gastrointestinal Haemorrhage; Melaena; Overdose | Zocor                  |              |            | S           | Oral         |                    |                 | Merck        |
|                                                                 | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                 | Prazosin Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                 | Candesartan Cilexetil  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                 | Glyburide              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2005              | 5751253       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-00778-01     |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antinuclear Antibody Positive | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2005              | 5803825       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-01759-01     |                      | 36 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Diplopia; Drug Interaction;<br>Facial Paralysis; Nausea;<br>Vertigo; Vomiting | Wellbutrin     |                    |                    | S               | Oral                                 | 150mg Per Day        |                 | Glaxosmithkline |                |
|                                                                               | Lexapro        |                    |                    | S               | Oral                                 | 40mg Per Day         | 357 DAY         | Not Reported    |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-May-2005                                                                   | 5792752        | NON-EXPEDITED      | Y                  | OT              | S05-USA-02072-01                     |                      | 20 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Generalised Tonic-Clonic<br>Seizure                                           | Wellbutrin     |                    |                    | S               | Oral                                 | 450mg Per Day        | 3 WEEK          | Glaxosmithkline |                |
|                                                                               | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-May-2005                                                                   | 5806281        | NON-EXPEDITED      | Y                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0550253A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Disorientation; Visual<br>Impairment                                          | Wellbutrin XI  |                    |                    | S               | Oral                                 | 150mg Per Day        | 3 DAY           | Glaxosmithkline |                |
|                                                                               | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-May-2005                                                                   | 5806423        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0553620A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Drug Ineffective;<br>Drug Interaction;<br>Hyperhidrosis; Tremor     | Wellbutrin XI  |                    |                    | S               | Oral                                 |                      | 3 DAY           | Glaxosmithkline |                |
|                                                                               | Lexapro        |                    |                    | S               | Unknown                              |                      | 1 YR            | Not Reported    |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-May-2005                                                                   | 5811875        | EXPEDITED (15-DAY) | Y                  | OT              | S05-NOR-01883-01                     |                      | 42 YR           | Female          | NOR            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                               |                |                    |                    |                 |              |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------|----------------------|----------------------|-----------------|--------------|----------------|
| Keratitis                                                                                                                                                                                                                                                                                                                                                     | Ciprallex      |                    |                    | S               | Oral         | 5 Mg Qd Po           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2005                                                                                                                                                                                                                                                                                                                                                   | 5811876        | EXPEDITED (15-DAY) | Y                  | DS, OT          |              | S05-UKI-01892-01     |                      | 21 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   |                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Hot; Malaise;<br>Myalgia; Seizure; Syncope                                                                                                                                                                                                                                                                                                            | Ciprallex      |                    |                    | S               | Oral         | 20 Mg Qd Po          |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               | Evra           |                    |                    | C               |              |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2005                                                                                                                                                                                                                                                                                                                                                   | 5816204        | EXPEDITED (15-DAY) | N                  | DE              |              | 142209USA            |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   |                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                                                                                                                                                                                             | Fluoxetine     |                    |                    | S               |              |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               | Lexapro        |                    |                    | S               |              |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2005                                                                                                                                                                                                                                                                                                                                                   | 5776118        | EXPEDITED (15-DAY) | Y                  | OT              |              | S05-UKI-01324-01     |                      | 78 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   |                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Adams-Stokes Syndrome;<br>Amnesia; Aphasia;<br>Arrhythmia;<br>Atrioventricular Block First<br>Degree; Balance Disorder;<br>Blood Potassium<br>Decreased; Blood Thyroid<br>Stimulating Hormone<br>Increased; Bundle Branch<br>Block Right; Dysarthria;<br>Dyspnoea; Fall;<br>Gastroenteritis; Malaise;<br>Treatment<br>Noncompliance; Vitamin<br>B12 Decreased | Ciprallex      |                    |                    | S               | Oral         | 10 Mg Qd Po          |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               | Adalat         |                    |                    | C               |              |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               | Haloperidol    |                    |                    | C               |              |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               | Bendrofluazide |                    |                    | C               |              |                      |                      |                 |              | Not Reported   |
|                                                                                                                                                                                                                                                                                                                                                               |                |                    |                    |                 |              |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jun-2005                                                                                                                                                  | 5804455                      | EXPEDITED (15-DAY) | N                  | DS              | S05-USA-02405-01     |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Connective Tissue<br>Disorder; Depression;<br>Paraesthesia; Post-<br>Traumatic Neck<br>Syndrome; Road Traffic<br>Accident; Tinnitus | Lexapro                      |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               | Oral                 | 5mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Levoxyl                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Premarin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2005                                                                                                                                                  | 5805038                      | EXPEDITED (15-DAY) | Y                  | HO              | S05-ITA-01739-01     |                      | 69 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradyarrhythmia;<br>Electrocardiogram<br>Abnormal                                                                                                            | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Esomeprazole                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Colimicin (Colistin Sulfate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Indoxen (Indometacin)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Polase                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Aminomal (Aminophylline)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2005                                                                                                                                                  | 5817199                      | DIRECT             | Y                  | RI              |                      |                      | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parosmia                                                                                                                                                     | Lexapro                      |                    |                    | S               |                      | 10mg Qd              | 8 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2005                                                                                                                                                  | 5818059                      | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-01969-01     |                      | 23 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                                  |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Amylase Increased; Back Pain; Lipase Increased                                 |                                  | Ciprallex          |                    | S               | Oral                 | 15 Mg Qd Po          | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2005                                                                    | 5792754                          | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-02019-01     |                      | 90 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Pressure Systolic Increased;                                    | Lexapro                          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Cerebrovascular Accident;                                                      | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Confusional State; Dry Mouth; Feeling Hot;                                     | Remeron                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Nervousness; Syncope                                                           | Blood Pressure Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2005                                                                    | 5818338                          | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-02719-01     |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;                                                       | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Dizziness; Drug Hypersensitivity; Fall; Gait Disturbance                       | Prinivil                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Glucophage                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Albuterol                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2005                                                                    | 5818362                          | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-02256-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Fall; Hypotension; Loss Of Consciousness; Nausea; Nervousness; Tremor | Lexapro                          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                | Risperdal                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                | Lipitor                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Lasix                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Tenormin                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Prevacid                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Humalog                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Lantus                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                | Iron                             |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>                    | <u>Sex</u>                                                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------|------------------------------|--------------------------------------------|-------------------------------|------------------------------------------------------------------------------|----------------|
| 06-Jun-2005                                                                                                                                                                                              | 5809415                                                                                               | EXPEDITED (15-DAY) | Y                  | HO                    | S05-USA-02499-01             |                                            | 40 YR                         | Male                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u>               | <u>Mfr</u>                                                                   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Diverticulitis; Granulomatous Liver Disease; Intestinal Perforation | Lexapro<br>Prevacid<br>Altace                                                                         |                    |                    | S<br>C<br>C           |                              |                                            |                               | Not Reported<br>Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>                    | <u>Sex</u>                                                                   | <u>Country</u> |
| 06-Jun-2005                                                                                                                                                                                              | 5821717                                                                                               | EXPEDITED (15-DAY) | Y                  | HO                    | S05-UKI-01977-01             |                                            | 59 YR                         | Female                                                                       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u>               | <u>Mfr</u>                                                                   |                |
| Drug Interaction; Hyponatraemia                                                                                                                                                                          | Cipralext<br>Bendrofluazide<br>Atorvastatin<br>Aspirin (Acetylsalicylic Acid)<br>Levothyroxine Sodium |                    |                    | S<br>S<br>S<br>C<br>C | Oral<br>Oral<br>Oral         | 10 Mg Qd Po<br>2.5 Mg Qd Po<br>10 Mg Qd Po |                               | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>                    | <u>Sex</u>                                                                   | <u>Country</u> |
| 07-Jun-2005                                                                                                                                                                                              | 5813307                                                                                               | EXPEDITED (15-DAY) | Y                  | OT                    | 2005PK00950                  |                                            | 31 YR                         | Female                                                                       | AUT            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u>               | <u>Mfr</u>                                                                   |                |
| Dyskinesia; Psychotic Disorder; Serum Serotonin Increased; Sleep Disorder                                                                                                                                | Seroquel<br>Seroquel<br>Seroquel<br>Cipralext                                                         |                    |                    | S<br>S<br>S<br>S      | Oral<br>Oral<br>Oral<br>Oral |                                            | 24 DAY<br>4 DAY<br><br>18 DAY | Zeneca<br>Zeneca<br>Zeneca<br>Not Reported                                   |                |

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|                         |   |      |        |              |
|-------------------------|---|------|--------|--------------|
| Cipralex                | S | Oral |        | Not Reported |
| Trazodone Hydrochloride | C | Oral |        | Not Reported |
| Zolpidem                | C | Oral | 15 DAY | Not Reported |
| Diazepam                | C | Oral | 18 DAY | Not Reported |
| Diazepam                | C | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2005              | 5744361       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-00558-01     |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coronary Artery Disease; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Feeling Cold; Gait       | Aricept        |              |            | S           |              | 5 Mg Qd            |                 | Not Reported |
| Disturbance;             | Lithium        |              |            | C           |              |                    |                 | Not Reported |
| Hyperhidrosis; Marital   | Valium         |              |            | C           |              |                    |                 | Not Reported |
| Problem; Overdose;       | Soma           |              |            | C           |              |                    |                 | Not Reported |
| Personality Change;      | Percocet       |              |            | C           |              |                    |                 | Not Reported |
| Suicide Attempt; Weight  | Prevacid       |              |            | C           |              |                    |                 | Not Reported |
| Decreased                | Remeron        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2005              | 5819419       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-02744-01     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Asthenia; Blood   | Lexapro          |              |            | S           | Oral         | 40 Mg Once Po      |                 | Not Reported |
| Cholesterol Increased;     | Lexapro          |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Dizziness; Dyspnoea; Fall; | Lexapro          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Irritable Bowel Syndrome;  | Lexapro          |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Lethargy; Sinus            | Estraderm        |              |            | C           |              |                    |                 | Not Reported |
| Bradycardia; Syncope;      | Actonel          |              |            | C           |              |                    |                 | Not Reported |
| Weight Increased           | Nasalcrom        |              |            | C           |              |                    |                 | Not Reported |
|                            | Os-Cal (Calcium) |              |            | C           |              |                    |                 | Not Reported |
|                            | Diazepam         |              |            | C           |              |                    |                 | Not Reported |
|                            | Aspirin          |              |            | C           |              |                    |                 | Not Reported |
|                            | Vitamin E        |              |            | C           |              |                    |                 | Not Reported |



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| <u>FDA Received Date</u>                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jun-2005                                                         | 5821349             | NON-EXPEDITED      | Y                  | OT              | 370649               |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                             | Accutane            |                    |                    | S               |                      | 20 Mg Daily          |                 | Not Reported |                |
|                                                                     | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2005                                                         | 5820673             | DIRECT             | Y                  | HO, RI          |                      |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mental Status Changes                                               | Prozac              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Lexapro             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2005                                                         | 5820679             | DIRECT             | Y                  | HO              |                      |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Nausea; Sedation; Vomiting                                    | Risperdal           |                    |                    | S               | Oral                 | 0.5 Mg Orally Hs     | 4 WEEK          | Not Reported |                |
|                                                                     | Lexapro             |                    |                    | S               | Oral                 | 5 Mg Orally Daily    | 4 WEEK          | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2005                                                         | 5822587             | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-02869-01     |                      | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion; Mental Status Changes | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                     | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                     | Hydrochlorothiazide |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Lisinoril           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Norvasc             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Aspirin             |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|------------------|----------------------|-------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 09-Jun-2005                                                                                      | 5823293                                   | EXPEDITED (15-DAY) | Y                  | OT               | S05-SAF-02038-01     |                               | 84 YR           | Male                                                         | ZAF            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hepatitis                                                                                        | Cipralext<br>Exelon                       |                    |                    | S<br>C           | Oral                 | 10 Mg Qd Po                   |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 10-Jun-2005                                                                                      | 5821337                                   | DIRECT             | N                  | OT               |                      |                               | 53 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Neck Pain; Pain In Extremity                                                                     | Lexapro                                   |                    |                    | S                | Oral                 | 1 Day Oral                    |                 | Forest                                                       |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 10-Jun-2005                                                                                      | 5823695                                   | EXPEDITED (15-DAY) | Y                  | HO               | 2005081856           |                               | 48 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Ankle Fracture; Anxiety; Arthralgia; Depression; Drug Hypersensitivity; Fall; Rash; Rash Papular | Bextra<br>Lexapro<br>Morphine<br>Zonegran |                    |                    | S<br>S<br>S<br>S | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 13-Jun-2005                                                                                      | 4162920                                   | NON-EXPEDITED      | Y                  | HO               | S04-USA-01891-01     |                               | 30 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Abdominal Distension; Abdominal Pain; Diarrhoea; Flatulence                                      | Lexapro<br>Celexa                         |                    |                    | S<br>C           | Oral                 | 10 Mg Qd Po                   |                 | Not Reported<br>Not Reported                                 |                |

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| <u>FDA Received Date</u>                              | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jun-2005                                           | 5729844                              | NON-EXPEDITED    | Y                  | HO              | S05-USA-00304-01     |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis Acute                                    | Lexapro                              |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Wellbutrin (Bupropion Hydrochloride) |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                           | 5795203                              | NON-EXPEDITED    | Y                  | OT              | S05-USA-00175-01     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged                        | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                       | Norvasc                              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Zaroxolyn                            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                       | Protonix                             |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                           | 5795214                              | NON-EXPEDITED    | Y                  | HO              | S04-USA-08046-01     |                      | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematochezia                                         | Lexapro                              |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                           | 5795215                              | NON-EXPEDITED    | Y                  | OT              | S04-USA-07990-01     |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea; Hot Flush; Panic Attack; Vomiting | Lexapro                              |                  |                    | S               | Oral                 | 10 Mg Qhs Po         |                 | Not Reported |                |
|                                                       | Unspecified Ingredient               |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jun-2005                                                                                               | 5795216        | NON-EXPEDITED    | Y                  | OT              | S04-USA-07975-01     |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Loss Of Libido; Suicidal Ideation                                                             | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Lipitor        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Atenolol       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Tricor         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Cymbalta       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Flomax         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Effexor Xr     |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                                               | 5795251        | NON-EXPEDITED    | N                  | OT              | S04-USA-07779-01     |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Electrocardiogram Qt Prolonged; Heart Rate Increased; Supraventricular Extrasystoles | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Tikosyn        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Tikosyn        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Zetia          |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                                               | 5795269        | NON-EXPEDITED    | Y                  | HO              | S04-USA-07648-01     |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional Product Misuse; Suicide Attempt                                                   | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                           | Xanax Xr       |                  |                    | S               | Oral                 | 16 Tablet Once Po    |                 | Not Reported |                |

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|                                                                         |                |                  |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                         | Xanax Xr       |                  | S                  | Oral            |                      | 1 Mg Prn Po          |                 | Not Reported |                |
|                                                                         | Alcohol        |                  | S                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                             | 5822508        | NON-EXPEDITED    | N                  | OT              | S05-USA-02391-01     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Amnesia;<br>Crying; Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                         | Xanax          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Singulair      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Folic Acid     |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                             | 5822509        | NON-EXPEDITED    | N                  | OT              | S05-USA-02338-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Feelings Of<br>Worthlessness                         | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                             | 5822512        | NON-EXPEDITED    | N                  | OT              | S05-USA-02170-01     |                      | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Muscle Strain                              | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                             | 5822515        | NON-EXPEDITED    | Y                  | HO              | S05-USA-02074-01     |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                         | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                         | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 13-Jun-2005                                                                                                                                                            | 5822519                 | NON-EXPEDITED             | Y                           | OT                       | S05-USA-01382-01              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Suicidal Ideation                                                                                                                                    | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                                                                                                                                            | 5822524                 | NON-EXPEDITED             | Y                           | OT                       | S04-USA-02747-01              |                               | 23 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Derealisation; Disturbance In Attention; Dystonia; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Monocyte Count Increased; Nightmare; Vision Blurred | Lexapro                 |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |
|                                                                                                                                                                        | Folic Acid              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                                        | Thiamine                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                                        | Multi-Vitamin           |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                                                                                                                                            | 5822527                 | NON-EXPEDITED             | N                           | DS                       | S05-USA-00708-01              |                               | 30 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Insomnia; Migraine                                                                                                                                                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                                                                                                                                            | 5822536                 | NON-EXPEDITED             | Y                           | OT                       | S05-USA-02502-01              |                               | 14 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Tic                                                                                                                                                  | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                        | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|-----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jun-2005                                                           | 5822541               | NON-EXPEDITED    | N                  | OT              | S05-USA-01602-01     |                      | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Heart Rate Decreased                                         | Lexapro               |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                       | Lopresor              |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Klonopin              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Altace                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Hytrin                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Norvasc               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Water Pills (2) (Nos) |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                           | 5822542               | NON-EXPEDITED    | N                  | OT              | S05-USA-01594-01     |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression; Mental Impairment; Suicidal Ideation; Tinnitus | Lexapro               |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                           | 5822543               | NON-EXPEDITED    | Y                  | DE              | S05-USA-01986-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                 | Lexapro               |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                           | 5822545               | NON-EXPEDITED    | Y                  | OT              | S05-USA-01948-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>        | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Suicide Attempt                           | Lexapro               |                  |                    | S               | Oral                 | 800 Mg Once Po       |                 | Not Reported |                |
|                                                                       | Lexapro               |                  |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jun-2005                                                                     | 5822547             | NON-EXPEDITED    | N                  | OT              | S05-USA-01917-01     |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective; Erectile Dysfunction; Insomnia; Suicidal Ideation | Lexapro             |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Risperdal           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Accupril            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Hydrochlorothiazide |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                     | 5822548             | NON-EXPEDITED    | Y                  | HO              | S05-USA-01869-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual                                                           | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                     | 5822555             | NON-EXPEDITED    | Y                  | HO, RI          | S05-USA-01825-01     |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Suicide Attempt                                     | Lexapro             |                  |                    | S               | Oral                 | 800 Mg Once Po       |                 | Not Reported |                |
|                                                                                 | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                     | 5822575             | NON-EXPEDITED    | Y                  | OT              | S05-USA-00971-01     |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                                                                       | Lexapro             |                  |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Allegra-D           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Prevacid            |                  |                    | C               |                      |                      |                 | Not Reported |                |



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| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 13-Jun-2005                                        | 5822579                 | NON-EXPEDITED             | Y                           | OT                       | S05-USA-00964-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastrointestinal<br>Haemorrhage                    | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                        | 5822581                 | NON-EXPEDITED             | Y                           | OT                       | S05-USA-00824-01              |                               | 17 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Apathy; Flat<br>Affect; Suicidal Ideation | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                        | 5822584                 | NON-EXPEDITED             | Y                           | OT                       | S05-USA-00781-01              |                               | 67 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradycardia                                        | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                    | Inderal La              |                           |                             | S                        |                               | 80 Mg Qd                      |                          | Not Reported        |                         |
|                                                    | Captopril               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                    | Hydrochlorothiazide     |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                        | 5822585                 | NON-EXPEDITED             | N                           | OT                       | S05-USA-01359-01              |                               | 34 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Platelet Count Decreased                           | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                    | Motrin                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jun-2005                                        | 5822588                 | NON-EXPEDITED             | N                           | OT                       | S05-USA-01343-01              |                               | 45 YR                    | Male                | USA                     |

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| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------|------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Chills; Mania                                                                          | Lexapro                                  |                  |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                            | 5822592                                  | NON-EXPEDITED    | N                  | HO, LT          | S05-USA-01055-01     |                      | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Hyperhidrosis; Road<br>Traffic Accident; Suicidal<br>Ideation | Lexapro                                  |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                        | Zyrtec                                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                            | 5822593                                  | NON-EXPEDITED    | Y                  | LT              | S05-USA-01024-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                                                       | Lexapro                                  |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                            | 5822596                                  | NON-EXPEDITED    | Y                  | OT              | S05-USA-01021-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme<br>Increased                                                            | Lexapro                                  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                        | Provigil                                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Advicor                                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Minocycline\Minocycline<br>Hydrochloride |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Flovent                                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                            | 5822597                                  | NON-EXPEDITED    | N                  | OT              | S05-USA-01666-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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|                                                             |                                     |                  |                    |                 |                      |                      |                    |                 |                |
|-------------------------------------------------------------|-------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Gastroesophageal Reflux Disease                             | Lexapro                             |                  | S                  | Oral            | 5 Mg Qd Po           |                      |                    | Not Reported    |                |
|                                                             | Risperdal                           |                  | C                  |                 |                      |                      |                    | Not Reported    |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Jun-2005                                                 | 5822598                             | NON-EXPEDITED    | Y                  | OT              | S05-USA-01624-02     |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hyponatraemia                                               | Lexapro                             |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Jun-2005                                                 | 5822600                             | NON-EXPEDITED    | Y                  | HO              | S05-USA-01624-01     |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hyponatraemia                                               | Lexapro                             |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Jun-2005                                                 | 5822603                             | NON-EXPEDITED    | N                  | OT              | S05-USA-01611-01     |                      | 87 YR              | Female          | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Amnesia; Contusion; Fall; Loss Of Consciousness; Somnolence | Lexapro                             |                  |                    |                 | S                    | Oral                 | 5 Mg Qd Po         |                 | Not Reported   |
|                                                             | Micardis                            |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                             | Triamterene And Hydrochlorothiazide |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                             | Synthroid                           |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
|                                                             | Actonel                             |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Jun-2005                                                 | 5822718                             | NON-EXPEDITED    | Y                  | OT              | S04-USA-06983-01     |                      | 58 YR              | Female          | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Dystonia                                                    | Lexapro                             |                  |                    |                 | S                    | Oral                 | 20 Mg Qd Po        |                 | Not Reported   |
|                                                             | Lexapro                             |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
|                                                             | Clonazepam                          |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |

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| Serevent Diskus<br>Advair                                                                                       |                                          |                  | C<br>C             |                 | Not Reported<br>Not Reported |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                                                     | 5822723                                  | NON-EXPEDITED    | Y                  | OT              | S04-USA-05972-01             |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Epistaxis; Insomnia; Panic<br>Attack; Psychiatric<br>Symptom; Suicidal<br>Ideation | Lexapro                                  |                  |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Lexapro                                  |                  |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Lexapro                                  |                  |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Folic Acid                               |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                 | Vitamin B Complex (Vitamin B<br>Complex) |                  |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                                                     | 5822743                                  | NON-EXPEDITED    | N                  | HO              | S05-USA-02549-01             |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ankle Fracture; Fall;<br>Hypersensitivity; Rash                                                                 | Lexapro                                  |                  |                    | S               | Oral                         | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Morphine                                 |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                 | Bextra                                   |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                 | Zonegran                                 |                  |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2005                                                                                                     | 5822745                                  | NON-EXPEDITED    | N                  | OT              | S05-USA-02505-01             |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Feeling<br>Abnormal; Suicidal<br>Ideation; Thinking<br>Abnormal                              | Lexapro                                  |                  |                    | S               | Oral                         | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                                 | Gemzar                                   |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                 | Taxotere                                 |                  |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                 | Aleve                                    |                  |                    | C               |                              |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2005                                                                                                                    | 5783676        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01901-01     |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Drunk;<br>Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Postictal<br>State; Tonic Clonic<br>Movements | Lexapro        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2005                                                                                                                    | 5800523        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-02309-01     |                      | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                        | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                | Diovan         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Sular          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                | Diclofenac     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2005                                                                                                                    | 5823313        | DIRECT             | Y                  | DE              |                      |                      | 71 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotension; Hypoxia;<br>Pulmonary Embolism                                                                                    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                | Nexium         |                    |                    | S               | Oral                 | 40 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                | Avodart        |                    |                    | S               | Oral                 | 0.5 Mg Daily Po      |                 | Not Reported |                |
|                                                                                                                                | Aricept        |                    |                    | S               | Oral                 | 5 Mg Daily Po        |                 | Not Reported |                |
|                                                                                                                                | Norvasc        |                    |                    | S               |                      | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                | Lipitor        |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                | Cardura        |                    |                    | S               | Oral                 | 4 Mg Daily Po        |                 | Not Reported |                |
|                                                                                                                                | Iressa         |                    |                    | S               | Oral                 | 250 Mg Daily Po      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|----------------------------------------------|----------------|
| 14-Jun-2005                                                                                                                                                        | 5823855                        | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-02111-01     |                           | 63 YR           | Male                                         | GBR            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Blood Glucose Decreased;<br>Memory Impairment;<br>Somnolence; Thirst                                                                                               | Cipralex<br>Zopiclone          |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po               |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Jun-2005                                                                                                                                                        | 5823861                        | DIRECT             | N                  | OT              |                      |                           | 59 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abdominal Distension;<br>Dysuria; Flatulence;<br>Hyperhidrosis; Impaired<br>Work Ability; Irritability;<br>Loss Of Libido; Muscle<br>Spasms; Prostatic<br>Disorder | Lexapro                        |                    |                    | S               |                      |                           |                 | Forest                                       |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Jun-2005                                                                                                                                                        | 5825631                        | EXPEDITED (15-DAY) |                    | OT              | S05-USA-02895-01     |                           | 41 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Asthenia; Blood Pressure<br>Systolic Increased;<br>Dizziness; Muscle Spasms                                                                                        | Lexapro<br>Lexapro<br>Vitamins |                    |                    | S<br>S<br>C     | Oral<br>Oral         | 10 Mg Qd Po<br>5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Jun-2005                                                                                                                                                        | 5804662                        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02386-01     |                           | 49 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Eye Haemorrhage;                                                                                                                                                   | Lexapro                        |                    |                    | S               | Oral                 | 15 Mg Qd Po               |                 | Not Reported                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |           |   |      |             |              |
|--------------|-----------|---|------|-------------|--------------|
| Hypertension | Lexapro   | S | Oral | 10 Mg Qd Po | Not Reported |
|              | Lexapro   | S | Oral | 10 Mg Qd Po | Not Reported |
|              | Aspirin   | C |      |             | Not Reported |
|              | Calcium-D | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2005              | 5826361       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-02978-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Level Increased  | Celexa         |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2005              | 5823939       | DIRECT           | N                  | RI              |                      |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Menorrhagia           | Lexapro        |              |            | S           | Oral         | 20mg 1x/Day Oral   |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2005              | 5824497       | DIRECT           | Y                  | OT              |                      |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Seizure | Lexapro        |              |            | S           |              | 10 Mg Daily        | 1 WEEK          | Not Reported |
|                                  | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
|                                  | Tegretol       |              |            | C           |              |                    |                 | Not Reported |
|                                  | Depakote       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2005              | 5824389       | DIRECT           | Y                  | HO              |                      |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disinhibition; Suicidal<br>Ideation | Lexapro        |              |            | S           | Oral         | 20 Mg Po Q Am      | 1 MTH           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |              |
|-------------|---|--------------|
| Doxycycline | C | Not Reported |
| Metoprolol  | C | Not Reported |
| Risperdal   | C | Not Reported |
| Clonidine   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2005              | 5771652       | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-01523-01     |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Apathy;        | Lexapro                      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Asphyxia; Asthenia;       | Lexapro                      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Cardiomyopathy;           | Fluoxetine                   |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |
| Completed Suicide;        | Librax                       |              |            | C           |              |                    |                 | Not Reported |
| Conjunctival Hyperaemia;  | Xanax                        |              |            | C           |              |                    |                 | Not Reported |
| Disease Recurrence; Drug  | Hydrocodone                  |              |            | C           |              |                    |                 | Not Reported |
| Ineffective; Fatigue;     | Vicodin                      |              |            | C           |              |                    |                 | Not Reported |
| Hepatomegaly; Insomnia;   | Hydromet Syrup (Hydrocodone) |              |            | C           |              |                    |                 | Not Reported |
| Intervertebral Disc       | Lanoxin                      |              |            | C           |              |                    |                 | Not Reported |
| Protrusion; Irritability; | Accupril                     |              |            | C           |              |                    |                 | Not Reported |
| Lymphadenopathy; Non-     | Quinidine Hydrochloride      |              |            | C           |              |                    |                 | Not Reported |
| Hodgkin'S Lymphoma;       | Lomotil (Diphenoxylate And   |              |            | C           |              |                    |                 | Not Reported |
| Petechiae; Restlessness;  | Atropine)                    |              |            |             |              |                    |                 |              |
| Skin Abrasion; Skin       | Coumadin                     |              |            | C           |              |                    |                 | Not Reported |
| Discolouration; Social    | Guaibid (Guaifenesin)        |              |            | C           |              |                    |                 | Not Reported |
| Avoidant Behaviour;       | Ambien                       |              |            | C           |              |                    |                 | Not Reported |
| Spinal Stenosis;          |                              |              |            |             |              |                    |                 |              |
| Splenomegaly; Ventricular |                              |              |            |             |              |                    |                 |              |
| Hypertrophy; Weight       |                              |              |            |             |              |                    |                 |              |
| Decreased                 |                              |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2005              | 5791335       | EXPEDITED (15-DAY) | Y                  | DE              | S05-ISR-01560-01     |                      |            | Male       | ISR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Cipralext      |              |            | S           |              |                    |                 | Not Reported |
|                       | Risperidone    |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------------|-----------------|--------------|----------------|
| 21-Jun-2005                                                     | 5825602                      | DIRECT             | Y                  | OT              |                           |                                  | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Psychomotor<br>Hyperactivity; Thinking<br>Abnormal    | Lexapro                      |                    |                    | S               | Oral                      | 10mg 1 Q Hs Oral                 |                 | Not Reported |                |
|                                                                 | Caffeine\Phenylpropanolamine |                    |                    | S               | Oral                      | 1 Tab 1 Q Am Oral                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2005                                                     | 5832453                      | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-03134-01          |                                  | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anger;<br>Asphyxia; Completed<br>Suicide; Hostility | Lexapro                      |                    |                    | S               | Oral                      | 10 Mg Qd Po                      |                 | Not Reported |                |
|                                                                 | Lexapro                      |                    |                    | S               | Oral                      | 20 Mg, Qd, Po                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2005                                                     | 5824372                      | EXPEDITED (15-DAY) | Y                  | OT              | DE-JNJFOC-<br>20050603246 |                                  |                 | Male         | DEU            |
| <u>Preferred Term</u>                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis;<br>Depression                                  | Haloperidol                  |                    |                    | S               | Unknown                   |                                  |                 | Not Reported |                |
|                                                                 | Risperdal Consta             |                    |                    | S               | Intramuscular             |                                  |                 | Not Reported |                |
|                                                                 | Seroquel                     |                    |                    | S               |                           |                                  |                 | Not Reported |                |
|                                                                 | Amisulpride                  |                    |                    | S               |                           |                                  |                 | Not Reported |                |
|                                                                 | Cipralext                    |                    |                    | S               | Oropharyngeal             | Start Date = End Of Apr-<br>2005 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2005                                                     | 5826937                      | DIRECT             | Y                  |                 |                           |                                  | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Confusional<br>State; Depressed Level Of              | Wellbutrin Sr                |                    |                    | S               |                           |                                  |                 | Not Reported |                |
|                                                                 | Lexapro                      |                    |                    | S               |                           |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Consciousness;  
Disorientation; Road  
Traffic Accident; Status  
Epilepticus

| <u>FDA Received Date</u>                                                               | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Jun-2005                                                                            | 5830425                                | EXPEDITED (15-DAY) | Y                  | DS              | S05-CAN-02203-01     |                      | 60 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia;<br>Dizziness; Nausea;<br>Paranoia; Somnolence;<br>Vertigo; Vomiting | Cipralelex                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                        | Mirtazapine                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Mirapex                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Fosamax                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Cyanocobalamin                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Rabeprazole Sodium                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Duragesic                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                        | Tylenol With Codeine                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2005                                                                            | 5830521                                | EXPEDITED (15-DAY) | Y                  | HO              | S05-SWI-02210-01     |                      | 44 YR           | Unknown      | CHE            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash Maculo-<br>Papular                                                      | Cipralelex                             |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                        | Cipralelex                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                        | Cipralelex                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                        | Cipralelex                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                        | Cipralelex                             |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                        | Deroxate (Paroxetine<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2005                                                                            | 5832034                                | EXPEDITED (15-DAY) | Y                  | HO              | L05-BEL-02196-01     |                      | 74 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                   |                      |   |      |             |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|-------------|--------------|
| Agitation; Apathy; Blood Creatinine Increased; Dehydration; Drug Interaction; Dysarthria; Neurotoxicity; Oliguria; Somnolence; Toxicity To Various Agents; Tremor | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                                                                                   | Lithium              | S |      | 250 Mg Tid  | Not Reported |
|                                                                                                                                                                   | Levomepromazine      | S |      | 6.25 Mg Qd  | Not Reported |
|                                                                                                                                                                   | Lisinopril           | S |      | 30 Mg Qd    | Not Reported |
|                                                                                                                                                                   | Lisinopril           | S |      | 20 Mg Qd    | Not Reported |
|                                                                                                                                                                   | Irbesartan           | S |      | 300 Mg Qd   | Not Reported |
|                                                                                                                                                                   | Spironolactone       | S |      | 50 Mg Qd    | Not Reported |
|                                                                                                                                                                   | Risperidone          | S |      | 0.25 Mg Qd  | Not Reported |
|                                                                                                                                                                   | Furosemide           | C |      |             | Not Reported |
|                                                                                                                                                                   | Repaglinide          | C |      |             | Not Reported |
|                                                                                                                                                                   | Metformin            | C |      |             | Not Reported |
|                                                                                                                                                                   | Lormetazepam         | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2005              | 5830385       | DIRECT           | Y                  | OT              |                      |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Hypertension; Tremor  | Lexapro        |              |            | S           | Oral<br>Oral | 10 Mg Po Daily<br>10 Mg Po Daily |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2005              | 7495034       | EXPEDITED (15-DAY) | Y                  | LT              | 2005PK01088          |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;                                                                                                                                        | Ciprallex                   |              |            | S           | Oral         |                    |                 | Not Reported |
| Cardiac Tamponade;                                                                                                                                          | Nadroparin Calcium          |              |            | S           | Subcutaneous |                    | 21 DAY          | Not Reported |
| Cardiogenic Shock;                                                                                                                                          | Daflon (Diosmin/Hesperidin) |              |            | C           | Oral         |                    |                 | Not Reported |
| Coagulopathy; Drug Interaction; Intestinal Ischaemia; Ischaemic Hepatitis; Lung Infiltration; Multiple Organ Dysfunction Syndrome; Pericardial Haemorrhage; | Xanax                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                             | Detrol                      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                             | Rivotril                    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                             | Thiamine Hydrochloride      |              |            | C           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                                                                  |   |              |        |              |
|---------------------------------------------------|------------------------------------------------------------------|---|--------------|--------|--------------|
| Pulseless Electrical Activity; Seroma; Skin Graft | Ascorbic Acid\Biotin\Dexpanthenol\Pyridoxine\Riboflavin\Thiamine | C | Oral         |        | Not Reported |
|                                                   | Madopar                                                          | C | Oral         |        | Not Reported |
|                                                   | Pyridoxine                                                       | C | Oral         |        | Not Reported |
|                                                   | Flunitrazepam                                                    | C | Oral         |        | Not Reported |
|                                                   | Dhea                                                             | C | Oral         |        | Not Reported |
|                                                   | Etilefrine Hydrochloride                                         | C | Oral         |        | Not Reported |
|                                                   | Mebeverine Hydrochloride                                         | C | Oral         |        | Not Reported |
|                                                   | Acemetacin                                                       | C | Oral         |        | Not Reported |
|                                                   | Morphine Sulfate                                                 | C | Oral         |        | Not Reported |
|                                                   | Morphine                                                         | C | Oral         |        | Not Reported |
|                                                   | Omeprazole                                                       | S | Oral         |        | Not Reported |
|                                                   | Nadroparin Calcium                                               | S | Subcutaneous | 18 DAY | Not Reported |
|                                                   | Sintrom                                                          | S | Oral         |        | Not Reported |
|                                                   | Aspirin Cardio                                                   | S | Oral         |        | Not Reported |
|                                                   | Zocor                                                            | S | Oral         |        | Not Reported |
|                                                   | Xenical                                                          | S | Oral         |        | Not Reported |

| <u>FDA Received Date</u>                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2005                                    | 5835193                               | EXPEDITED (15-DAY) | Y                  | HO              | 2005-BP-10433RO      |                      | 74 YR           | Female       |                |
| <u>Preferred Term</u>                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Apathy; Blood Creatinine Increased; | Lithium Carbonate (Lithium Carbonate) |                    |                    | S               | Oral                 | 250 Mg Tid, Po       |                 | Not Reported |                |
| Confusional State;                             | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 10 Mg/Day, Po        |                 | Not Reported |                |
| Dehydration; Diarrhoea;                        | Levomepromazine                       |                    |                    | S               | Oral                 | 6.25 Mg/Day, Po      |                 | Not Reported |                |
| Drug Interaction;                              | Lisinopril (Lisinopril)               |                    |                    | S               |                      | 30 Mg/Day            |                 | Not Reported |                |
| Dysarthria; Lethargy;                          | Irbesartan                            |                    |                    | S               |                      | 300 Mg/Day           |                 | Not Reported |                |
| Oliguria; Somnolence;                          | Furosemide (Furosemide)               |                    |                    | S               |                      | 30 Mg/Day            |                 | Not Reported |                |
| Toxicity To Various Agents; Tremor             | Spironolactone                        |                    |                    | S               |                      | 50 Mg/Day            |                 | Not Reported |                |

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|  |                             |   |                        |              |
|--|-----------------------------|---|------------------------|--------------|
|  | Risperidone (Risperidone)   | S | 0.25 Mg Bid (2 In 1 D) | Not Reported |
|  | Lormetazepam (Lormetazepam) | C |                        | Not Reported |
|  | Metformin (Metformin)       | C |                        | Not Reported |
|  | Rapaglinide (Repaglinide)   | C |                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jun-2005              | 5835208       | EXPEDITED (15-DAY) | Y                  | OT              | 2005-BP-10595RO      |                      | 60 YR      | Male       |                |

| <u>Preferred Term</u>                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Epistaxis; Platelet<br>Aggregation; Rectal<br>Haemorrhage | Mirtazapine (Mirtazapine) |              |            | S           | Oral         | 15 Mg Daily, Po    |                 | Not Reported |
|                                                                                | Escitalopram Oxalate      |              |            | S           | Oral         | 20 Mg Daily, Po    |                 | Not Reported |
|                                                                                | Venlafaxine               |              |            | S           | Oral         | 150 Mg Daily, Po   |                 | Not Reported |
|                                                                                | Omeprazole                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Irbesartan                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2005              | 5828954       | EXPEDITED (15-DAY) | Y                  | LT              | CH-MERCK-0506CHE00030 |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Tamponade;<br>Cardiogenic Shock;<br>Intestinal Ischaemia;<br>Multiple Organ<br>Dysfunction Syndrome | Zocor                    |              |            | S           | Oral         |                    |                 | Merck        |
|                                                                                                             | Nadroparin Calcium       |              |            | S           | Subcutaneous |                    | 18 DAY          | Not Reported |
|                                                                                                             | Nadroparin Calcium       |              |            | S           | Subcutaneous |                    | 21 DAY          | Not Reported |
|                                                                                                             | Acenocoumarol            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Acenocoumarol            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Aspirin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Escitalopram Oxalate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Omeprazole               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Orlistat                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Mebeverine Hydrochloride |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Acemetacin               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                             | Morphine Sulfate         |              |            | C           | Oral         |                    |                 | Not Reported |

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|                                   |   |         |              |
|-----------------------------------|---|---------|--------------|
| Morphine                          | C | Unknown | Not Reported |
| Diosmin                           | C | Oral    | Not Reported |
| Alprazolam                        | C | Oral    | Not Reported |
| Tolterodine Tartrate              | C | Oral    | Not Reported |
| Clonazepam                        | C | Oral    | Not Reported |
| Thiamine Hydrochloride            | C | Oral    | Not Reported |
| Ascorbic Acid                     | C | Oral    | Not Reported |
| Benserazide                       | C | Oral    | Not Reported |
| Hydrochloride\Levodopa            |   |         |              |
| Pyridoxine Hydrochloride          | C | Oral    | Not Reported |
| Flunitrazepam                     | C | Oral    | Not Reported |
| Prasterone                        | C | Oral    | Not Reported |
| Dihydroergotamine                 | C | Oral    | Not Reported |
| Mesylate\Etilefrine Hydrochloride |   |         |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2005              | 5831426       | DIRECT           | Y                  | OT              |                      |                      | 17 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression            | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Abilify        |              |            | C           |              |                    |                 | Not Reported |
|                       | Depakote       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2005              | 5831439       | DIRECT           | Y                  | OT              |                      |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression            | Lexapro        |              |            | S           | Oral         | 10 Mg Po Qd        |                 | Not Reported |
|                       | Adderall       |              |            | C           |              |                    |                 | Not Reported |
|                       | Depakote       |              |            | C           |              |                    |                 | Not Reported |
|                       | Clonidine      |              |            | C           |              |                    |                 | Not Reported |
|                       | Abilify        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jun-2005              | 5831452        | DIRECT           | Y                  | OT              |                      |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Risperdal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tetracycline   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trileptal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Strattera      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5831464        | DIRECT           | Y                  | OT              |                      |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Po Qd           |                 | Not Reported |                |
|                          | Trileptal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5832628        | DIRECT           | Y                  | OT              |                      |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro        |                  |                    | S               | Oral                 | Po 5 Mg Qd           |                 | Not Reported |                |
|                          | Risperdal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trileptal      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5832634        | DIRECT           | Y                  | OT              |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Lithium        |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Jun-2005              | 5832641              | DIRECT           | Y                  | OT              |                      |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Depakote Er          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tetracycline         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5832653              | DIRECT           | Y                  | OT              |                      |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Clonidine            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trileptal            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Risperdal            |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5832657              | DIRECT           | Y                  | OT              |                      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Lithium Carbonate Er |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Trileptal            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Wellbutrin           |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005              | 5832662              | DIRECT           | Y                  | OT              |                      |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Lexapro              |                  |                    | S               | Oral                 | 10 Mg Po Qd          |                 | Not Reported |                |
|                          | Depakote Er          |                  |                    | C               |                      |                      |                 | Not Reported |                |



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|                                                                                           |                                           |                  |                    |                 |                      |                           |                 |              |                |
|-------------------------------------------------------------------------------------------|-------------------------------------------|------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| Seroquel                                                                                  |                                           | C                |                    |                 |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005                                                                               | 5832670                                   | DIRECT           | Y                  | OT              |                      |                           | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression                                                                                | Lexapro                                   |                  |                    | S               |                      |                           |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005                                                                               | 5838608                                   | NON-EXPEDITED    | N                  | HO              | 385651               |                           | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Chills; Disorientation; Hypotension; Myalgia; Nausea; Pyrexia; Vomiting | Klonopin                                  |                  |                    | S               | Oral                 | 2.25 Mg Daily Oral        |                 |              | Not Reported   |
|                                                                                           | Provigil                                  |                  |                    | S               | Oral                 | 50 Mg 1 Per One Dose Oral |                 |              | Not Reported   |
|                                                                                           | Neurontin                                 |                  |                    | S               | Oral                 | 1200 Mg Daily Oral        |                 |              | Not Reported   |
|                                                                                           | Aciphex                                   |                  |                    | S               | Oral                 | 60 Mg Daily Oral          |                 |              | Not Reported   |
|                                                                                           | Hydrochlorothiazide (Hydrochlorothiazide) |                  |                    | S               | Oral                 | 100 Mg Daily Oral         |                 |              | Not Reported   |
|                                                                                           | Doryx                                     |                  |                    | S               | Oral                 | 100 Mg Daily Oral         |                 |              | Not Reported   |
|                                                                                           | Lexapro                                   |                  |                    | S               | Oral                 | 10 Mg Daily Oral          |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2005                                                                               | 5838609                                   | NON-EXPEDITED    | N                  | OT              | 385724               |                           | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis                                                                      | Klonopin                                  |                  |                    | S               | Oral                 | 8 Mg Daily Oral           |                 |              | Not Reported   |
|                                                                                           | Abilify                                   |                  |                    | S               | Oral                 | 5 Mg Daily Oral           |                 |              | Not Reported   |
|                                                                                           | Lexapro                                   |                  |                    | S               | Oral                 | 15 Mg Daily Oral          |                 |              | Not Reported   |
|                                                                                           | Trileptal                                 |                  |                    | S               |                      | 900 Mg Daily              |                 |              | Not Reported   |
|                                                                                           | Zocor                                     |                  |                    | C               |                      |                           |                 |              | Not Reported   |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Jul-2005                                                    | 5792271        | EXPEDITED (15-DAY) | Y                  | HO              | S05-GER-01552-01     |                      | 61 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Syncope                        | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Cipralext      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2005                                                    | 5830518        | EXPEDITED (15-DAY) | Y                  | LT              | S05-UKI-02208-01     |                      | 39 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Impulsive Behaviour; Overdose; Personality Change | Cipralext      |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Cipralext      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Diazepam       |                    |                    | S               | Oral                 | 70 Mg Once Po        |                 | Not Reported |                |
|                                                                | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2005                                                    | 5836040        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-03216-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Ocular Icterus                                   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2005                                                    | 5837336        | NON-EXPEDITED      | N                  | OT              | 2004033534           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affective Disorder; Anxiety; Drug Ineffective;                 | Zoloft         |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                          |   |         |              |
|--------------------------|--------------------------|---|---------|--------------|
| Haematoma;               | Paroxetine Hydrochloride | S | Unknown | Not Reported |
| Haemorrhage; Insomnia;   | Escitalopram Oxalate     | S | Unknown | Not Reported |
| Maternal Exposure During | Unspecified Ingredient   | C |         | Not Reported |
| Pregnancy; Panic Attack; | Unspecified Ingredient   | C |         | Not Reported |
| Weight Increased         | Vitamins Nos             | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2005              | 5837895       | NON-EXPEDITED    | Y                  | HO              | 2005044707           |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood Sodium     | Zolof                         |              |            | S           | Unknown      |                    |                 | Not Reported |
| Decreased; Depression;     | Fluoxetine Hydrochloride      |              |            | S           | Unknown      |                    |                 | Not Reported |
| Inappropriate Antidiuretic | (Fluoxetine Hydrochloride)    |              |            |             |              |                    |                 |              |
| Hormone Secretion          | Escitalopram Oxalate          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Diazepam (Diazepam)           |              |            | C           |              |                    |                 | Not Reported |
|                            | Clonazepam (Cloazepam)        |              |            | C           |              |                    |                 | Not Reported |
|                            | Metoprolol Tartrate           |              |            | C           |              |                    |                 | Not Reported |
|                            | Hydrochlorothiazide           |              |            | C           |              |                    |                 | Not Reported |
|                            | (Hydrochlorothiazide)         |              |            |             |              |                    |                 |              |
|                            | Lisinopril (Lisinopril)       |              |            | C           |              |                    |                 | Not Reported |
|                            | Oxybuprocaine Hydrochloride   |              |            | C           |              |                    |                 | Not Reported |
|                            | (Oxybuprocaine Hydrochloride) |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2005              | 5754496       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-00818-01     |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;        | Lexapro              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depression; Feeling       | Tylenol With Codeine |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Self-Medication | Ambien               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2005              | 5788758       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01991-01     |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                  |            |   |      |             |              |
|----------------------------------------------------------------------------------------------------------------------------------|------------|---|------|-------------|--------------|
| Apnoea; Confusional State; Cyanosis;                                                                                             | Lexapro    | S | Oral | 10 Mg Qd Po | Not Reported |
| Depressed Level Of Consciousness;                                                                                                | Lexapro    | S | Oral | 5 Mg Qd Po  | Not Reported |
| Depression; Emotional Disorder; Feeling Abnormal; Generalised Tonic-Clonic Seizure; Memory Impairment; Muscle Twitching; Seizure | Lexapro    | S | Oral | 5 Mg Qd Po  | Not Reported |
|                                                                                                                                  | Ativan     | C |      |             | Not Reported |
|                                                                                                                                  | Ortho Evra | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2005              | 5809414       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-02503-01     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Fluctuation; Hypertension; Sinusitis | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                     | Ativan         |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Protonix       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2005              | 5830575       | EXPEDITED (15-DAY) | N                  | LT              | CH-ROCHE-408911      |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------------------|-----------------|--------------|
| Acute Kidney Injury; Blood Disorder; Cardiac Perforation; Cardiac Tamponade; Cardiogenic Shock; Drug Interaction; Hepatic Necrosis; Intestinal Ischaemia; Multiple Organ Dysfunction Syndrome; Pericardial Haemorrhage; Pulseless Electrical Activity | Xenical        |              |            | S           | Oral         | Therapy Duration Reported As 'Long Term'                                        |                 | Roche        |
|                                                                                                                                                                                                                                                       | Omeprazole     |              |            | S           | Oral         | Therapy Duration Reported As Long Term Trade Name Was Reported As Antra 20      |                 | Not Reported |
|                                                                                                                                                                                                                                                       | Zocor          |              |            | S           | Oral         | Therapy Duration Of Use Reported As Long Term Trade Name Reported As Zocor 20mg |                 | Not Reported |
|                                                                                                                                                                                                                                                       | Cipralext      |              |            | S           | Oral         | Therapy Duration Reported As Long Term                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                       | Aspirin        |              |            | S           | Oral         | Therapy Duration                                                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |   |              |                                                                                        |                        |
|----------------------------------------------------------------|---|--------------|----------------------------------------------------------------------------------------|------------------------|
|                                                                |   |              | Reported As Long Term<br>Doseform Reported As<br>Film Coated Tablets                   |                        |
| Acenocoumarol                                                  | S | Oral         |                                                                                        | Not Reported           |
| Acenocoumarol                                                  | S | Oral         | Therapy Duration<br>Reported As Long Term<br>Trade Name Reported As<br>Sintrom 1 Mitis | Not Reported           |
| Acenocoumarol                                                  | S | Oral         | Dose Decreased                                                                         | Not Reported           |
| Nadroparin Calcium                                             | S | Subcutaneous | Dose Increased Total<br>Therapy Duration<br>Reported As 39 Days                        | 21 DAY<br>Not Reported |
| Nadroparin Calcium                                             | S | Subcutaneous |                                                                                        | 18 DAY<br>Not Reported |
| Daflon (Diosmin/Hesperidin)                                    | C | Oral         |                                                                                        | Not Reported           |
| Xanax                                                          | C | Oral         |                                                                                        | Not Reported           |
| Detrol                                                         | C | Oral         | Doseform Reported As<br>Film Coated Tablets                                            | Not Reported           |
| Rivotril                                                       | C | Oral         |                                                                                        | Not Reported           |
| Benerva                                                        | C | Oral         |                                                                                        | Not Reported           |
| Ascorbic<br>Acid\Biotin\Cyanocobalamin\Rib<br>oflavin\Thiamine | C | Oral         |                                                                                        | Not Reported           |
| Madopar                                                        | C | Oral         | Strength Reported As<br>100mg/25mg                                                     | Not Reported           |
| Pyridoxine                                                     | C | Oral         |                                                                                        | Not Reported           |
| Flunitrazepam                                                  | C | Oral         | Doseform Reported As<br>Film Coated Tablets                                            | Not Reported           |
| Dhea                                                           | C | Oral         |                                                                                        | Not Reported           |
| Effortil Plus                                                  | C | Oral         |                                                                                        | Not Reported           |
| Duspatalin                                                     | C | Oral         |                                                                                        | Not Reported           |
| Acemetacin                                                     | C | Oral         | Doseform Reported As<br>Membrane Capsules                                              | Not Reported           |
| Morphine                                                       | C | Oral         | Doseform Reported As<br>Membrane Capsules                                              | Not Reported           |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                |                |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Morphine                                                                                       |                |                    | C                  |                 | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                    | 5834109        | DIRECT             | N                  | DE              |                      |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose                                                                 | Amitriptyline  |                    |                    | S               | Oral                 | 3 Tabs @Bedt Oral    |                 | Not Reported |                |
|                                                                                                | Lexapro        |                    |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                    | 5834167        | DIRECT             | N                  | DE              |                      |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide                                                                 | Lexapro        |                    |                    | S               | Oral                 | 1 Daily Oral         |                 | Not Reported |                |
|                                                                                                | Xanax          |                    |                    | S               | Oral                 | 1-2 Bedtime Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                    | 5834243        | DIRECT             | N                  | DE              |                      |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Asphyxia;<br>Completed Suicide; Social<br>Avoidant Behaviour | Lexapro        |                    |                    | S               | Oral                 | 1 Pill 1 A Day Oral  |                 | Not Reported |                |
|                                                                                                | Norvasc        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Relafen        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                | Flomax         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                    | 5835698        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03279-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                        | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Jul-2005                                                                                                                                                                                                              | 5837620                      | EXPEDITED (15-DAY) | Y                  | OT              | S05-SAF-02198-01     |                      | 27 YR           | Male         | ZAF            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Cold Sweat;<br>Confusional State;<br>Dissociation; Eye<br>Movement Disorder; Fall;<br>Flat Affect; Hallucination,<br>Auditory; Hallucination,<br>Visual; Palpitations;<br>Seizure; Speech Disorder;<br>Vomiting | Cipralext                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Cipralext                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Purata (Oxazepam)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                                                                                                                                              | 5837623                      | EXPEDITED (15-DAY) | Y                  | DS              | S05-DEN-02282-01     |                      | 56 YR           | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Burning<br>Sensation; Condition<br>Aggravated; Eye Pain;<br>Eyelid Disorder;<br>Musculoskeletal Stiffness;<br>Myopia; Pain; Sensory<br>Disturbance; Vision<br>Blurred                                           | Cipralext                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Alopam (Oxazepam)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Stilnoct (Zolpidem Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2005                                                                                                                                                                                                              | 5837871                      | EXPEDITED (15-DAY) | Y                  | RI              | S05-USA-02311-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Breech<br>Presentation; Caesarean<br>Section; Maternal<br>Exposure During<br>Pregnancy                                                                                                                      | Lexapro                      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Prenatal Vitamins            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Synthroid                    |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2005                                                                                                   | 5835104                  | DIRECT             | Y                  | LT              |                      |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Disorder;<br>Neutropenia                                                                     | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Forest       |                |
|                                                                                                               | Lasix                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | Norvasc                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | K-Dur                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | Prevacid                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | Toprol XL                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | Coumadin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2005                                                                                                   | 5835116                  | DIRECT             | N                  | LT, RI          |                      |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Condition<br>Aggravated; Depression;<br>Disorientation;<br>Nervousness; Suicidal<br>Ideation; Tremor | Lexapro                  |                    |                    | S               | Oral                 | 75 Mg Daily Oral     |                 | Forest       |                |
|                                                                                                               | Diovan                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                               | Wellbutrin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2005                                                                                                   | 5838319                  | EXPEDITED (15-DAY) | Y                  | HO              | S05-DEN-02284-01     |                      | 51 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hypokalaemia;<br>Hypomagnesaemia;<br>Hyponatraemia;<br>Hypophosphataemia;<br>Seizure    | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
|                                                                                                               | Fluoxetine Hydrochloride |                    |                    | S               | Oral                 | 20 Mg Qd; Po         |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 07-Jul-2005                                                                                           | 5803842        | EXPEDITED (15-DAY) | Y                  | OT              | PK-GLAXOSMITHKLINE-B0380854A |                      | 43 YR           | Female          | PAK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Dizziness; Drug Hypersensitivity; Headache; Hypertension; Insomnia; Palpitations; Urticaria | Lamictal       |                    |                    | S               | Oral                         | 50mg Per Day         | 23 DAY          | Glaxosmithkline |                |
|                                                                                                       | Ciprallex      |                    |                    | S               | Oral                         | 10mg Twice Per Day   |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------|-----------------|--------------|----------------|
| 07-Jul-2005                                                                                                                                                                                                                                                                                                                                                    | 5820131                     | EXPEDITED (15-DAY) | Y                  | HO              | 2005079018           |                            | 74 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Apathy; Blood Creatinine Increased; Coma Scale Abnormal; Confusional State; Creatinine Renal Clearance Decreased; Dehydration; Diarrhoea; Drug Interaction; Dysarthria; General Physical Health Deterioration; Lethargy; Neurotoxicity; Oliguria; Overdose; Renal Impairment; Somnolence; Therapy Non-Responder; Toxicity To Various Agents; Tremor | Lithium (Lithium)           |                    |                    | S               |                      | 750 Mg (250 Mg, 3 In 1 D)  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Levomepromazine             |                    |                    | S               |                      | 6.25 Mg                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Lisinopril (Lisinopril)     |                    |                    | S               |                      | 30 Mg                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Risperidone (Risperidone)   |                    |                    | S               |                      | 0.5 Mg (0.25 Mg, 2 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Escitalopram Oxalate        |                    |                    | S               |                      | 10 Mg                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Irbesartan                  |                    |                    | S               |                      | 300 Mg                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Lormetazepam (Lormetazepam) |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Metformin Hydrochloride     |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Furosemide (Furosemide)     |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Repaglinide (Repaglinide)   |                    |                    | C               |                      |                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                | Spironolactone              |                    |                    | C               |                      |                            |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Jul-2005              | 5834478        | DIRECT           | Y                  | OT              |                      |                      | 17 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                                |                    |                    |                 |                      |                           |                 |              |                |
|------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| Contusion                    | Lexapro                        |                    | S                  | Oral            | 1q.Day Po            |                           | Not Reported    |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2005                  | 5839784                        | EXPEDITED (15-DAY) | Y                  | OT              | T05-GER-02286-01     |                           | 39 YR           | Female       | DEU            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;              | Cipraxel                       |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
| Circulatory Collapse;        | Paroxetine Hydrochloride       |                    |                    | S               | Oral                 | 10 Mg Qd Po               |                 | Not Reported |                |
| Dizziness; Nausea;           |                                |                    |                    |                 |                      |                           |                 |              |                |
| Treatment Noncompliance      |                                |                    |                    |                 |                      |                           |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2005                  | 5836932                        | DIRECT             | Y                  | HO              |                      |                           | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Mental        | Lexapro                        |                    |                    | S               | Oral                 | 20mg Qday Oral            |                 | Not Reported |                |
| Status Changes               | Mirapex                        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Cardura                        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Vasotec                        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Lexapro                        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Depakote                       |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Trazodone Hydrochloride        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                              | Ultram                         |                    |                    | C               |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2005                  | 5837570                        | EXPEDITED (15-DAY) | Y                  | LT              | 200511978GDS         |                           | 59 YR           | Female       | CHE            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Blood   | Aspirin (Acetylsalicylic Acid) |                    | Y                  | S               | Oral                 | 300 Mg, Total Daily, Oral |                 | Not Reported |                |
| Disorder; Cardiac            | Nadroparin Calcium             |                    |                    | S               | Subcutaneous         | 0.4 Mg, Total Daily,      |                 | Not Reported |                |
| Perforation; Cardiac         |                                |                    |                    |                 | Subcutaneous         | Subcutane; See Image      |                 |              |                |
| Tamponade; Cardiogenic       |                                |                    |                    |                 | Subcutaneous         | 0.4 Mg, Total Daily,      |                 |              |                |
| Shock; Drug Interaction;     |                                |                    |                    |                 | Subcutaneous         | Subcutane; See Image      |                 |              |                |
| Intestinal Ischaemia;        |                                |                    |                    |                 | Subcutaneous         | 0.4 Mg, Total Daily,      |                 |              |                |
| Ischaemic Hepatitis; Lung    |                                |                    |                    |                 | Subcutaneous         | Subcutane; See Image      |                 |              |                |
| Infiltration; Multiple Organ |                                |                    |                    |                 |                      |                           |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                      |                             |   |      |                                       |              |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------|---|------|---------------------------------------|--------------|
| Dysfunction Syndrome;<br>Pericardial Haemorrhage;<br>Pulseless Electrical<br>Activity; Skin Ulcer;<br>Superinfection | Acenocoumarol               | S | Oral | 1 Mg, Total Daily, Oral;<br>See Image | Not Reported |
|                                                                                                                      |                             |   | Oral | 1 Mg, Total Daily, Oral;<br>See Image |              |
|                                                                                                                      | Escitalopram Oxalate        | S | Oral | 20 Mg, Total Daily, Oral              | Not Reported |
|                                                                                                                      | Simvastatin                 | S | Oral | 20 Mg, Total Daily, Oral              | Not Reported |
|                                                                                                                      | Omeprazole                  | S | Oral | 20 Mg, Total Daily, Oral              | Not Reported |
|                                                                                                                      | Orlistat                    | C |      |                                       | Not Reported |
|                                                                                                                      | Daflon (Diosmin/Hesperidin) | C |      |                                       | Not Reported |
|                                                                                                                      | Xanax                       | C |      |                                       | Not Reported |
|                                                                                                                      | Detruaitol                  | C |      |                                       | Not Reported |
|                                                                                                                      | Rivotril                    | C |      |                                       | Not Reported |
|                                                                                                                      | Benerva                     | C |      |                                       | Not Reported |
|                                                                                                                      | Becozyme C                  | C |      |                                       | Not Reported |
|                                                                                                                      | Madopar                     | C |      |                                       | Not Reported |
|                                                                                                                      | Vitamine B6                 | C |      |                                       | Not Reported |
|                                                                                                                      | Rohypnol                    | C |      |                                       | Not Reported |
|                                                                                                                      | Dhea                        | C |      |                                       | Not Reported |
|                                                                                                                      | Effortil Plus /Gfr/         | C |      |                                       | Not Reported |
|                                                                                                                      | Duspatalin                  | C |      |                                       | Not Reported |
|                                                                                                                      | Tilur                       | C |      |                                       | Not Reported |
|                                                                                                                      | Kapanol                     | C |      |                                       | Not Reported |
|                                                                                                                      | Morphine                    | C |      |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2005              | 8291105       | EXPEDITED (15-DAY) | Y                  | LT              | S05-SWI-02300-01     |                      | 59 YR      | Female     | CHE            |

| <u>Preferred Term</u>        | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Perforation;         | Cipralax           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Cardiac Tamponade;           | Nadroparin Calcium |              |            | S           | Subcutaneous | 0.4 MI Qd Sc       |                 | Not Reported |
| Cardiogenic Shock;           | Nadroparin Calcium |              |            | S           | Subcutaneous | 0.6 MI Qd Sc       |                 | Not Reported |
| Coagulation Time             | Sintrom            |              |            | S           | Oral         | Mg Qd Po           |                 | Not Reported |
| Abnormal; Infection;         | Sintrom            |              |            | S           | Oral         | Mg Qd Po           |                 | Not Reported |
| Intestinal Ischaemia;        | Aspirin            |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |
| Ischaemic Hepatitis; Lung    | Zocor              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Infiltration; Multiple Organ |                    |              |            |             |              |                    |                 |              |
| Dysfunction Syndrome;        |                    |              |            |             |              |                    |                 |              |
| Pericardial Haemorrhage;     |                    |              |            |             |              |                    |                 |              |
| Pulseless Electrical         |                    |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |                                  |   |      |               |              |
|----------------------------------------|----------------------------------|---|------|---------------|--------------|
| Activity; Renal Failure;<br>Skin Ulcer | Omeprazole                       | S | Oral | 20 Mg Bid Po  | Not Reported |
|                                        | Xenical                          | S | Oral | 120 Mg Bid Po | Not Reported |
|                                        | Daflon (Diosmin)                 | C |      |               | Not Reported |
|                                        | Xanax                            | C |      |               | Not Reported |
|                                        | Rivotril (Clonazepam)            | C |      |               | Not Reported |
|                                        | Benerva (Thiamine Hydrochloride) | C |      |               | Not Reported |
|                                        | Becozyme C                       | C |      |               | Not Reported |
|                                        | Madopar                          | C |      |               | Not Reported |
|                                        | Vitamin B6                       | C |      |               | Not Reported |
|                                        | Rohypnol (Flunitrazepam)         | C |      |               | Not Reported |
|                                        | Dhea                             | C |      |               | Not Reported |
|                                        | Effortil Plus                    | C |      |               | Not Reported |
|                                        | Duspatalin (Mebeverine)          | C |      |               | Not Reported |
|                                        | Tilue (Acemetacin)               | C |      |               | Not Reported |
|                                        | Kapanol (Morphine Sulfate)       | C |      |               | Not Reported |
|                                        | Morphine                         | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2005              | 5762623       | EXPEDITED (15-DAY) | Y                  | DS, OT          | S05-GER-00904-01     |                      | 45 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colon Adenoma; Lactose Intolerance; Large Intestine Polyp; Retroperitoneal Fibrosis | Citalopram Hydrobromide |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                     | Ciprallex               |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2005              | 5804494       | EXPEDITED (15-DAY) | Y                  | OT              | S05-SWE-01740-01     |                      | 24 YR      | Male       | SWE            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper; Hepatocellular Injury; Nervousness | Ciprallex      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                          | Valproic Acid  |              |            | S           | Oral         | 500 Mg Bid Po      |                 | Not Reported |
|                                                          | Mirtazapine    |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                          | Olanzapine     |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Effexor        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 11-Jul-2005                                                                                                                                               | 5828933                                      | EXPEDITED (15-DAY) | Y                  | OT              | 2005087479           |                                   | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Breast Cyst;<br>Gynaecomastia                                                                                               | Geodon                                       |                    |                    | S               | Oral                 | 120 Mg (60 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                           | Lexapro                                      |                    |                    | S               |                      | (30 Mg)                           |                 | Not Reported |                |
|                                                                                                                                                           | Norvasc                                      |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Hydrochlorothiazide<br>(Hydrochlorothiazide) |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Flonase                                      |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2005                                                                                                                                               | 5674622                                      | EXPEDITED (15-DAY) | Y                  | HO              | T04-NLD-07228-01     |                                   | 77 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Cirrhosis; Serum<br>Ferritin Increased                                                                                                            | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | 10 Mg Qd Po                       |                 | Not Reported |                |
|                                                                                                                                                           | Amaryl                                       |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Metformin                                    |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Ascal (Acetylsalicylate Calcium)             |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Legendal (Lactulose)                         |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Duratears                                    |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Nortrilen Filmtabletten                      |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                                                           | Tranxene T-Tab                               |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jul-2005                                                                                                                                               | 5787304                                      | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-USA-01947-01     |                                   | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Agitation;<br>Alcohol Interaction;<br>Alcoholism; Anger;<br>Anxiety; Apathy; Attention<br>Deficit/Hyperactivity<br>Disorder; Bipolar Disorder; | Lexapro                                      |                    |                    | S               | Oral                 | 10 Mg Qd Po                       |                 | Not Reported |                |
|                                                                                                                                                           | Lexapro                                      |                    |                    | S               | Oral                 | 10 Mg Qd Po                       |                 | Not Reported |                |
|                                                                                                                                                           | Alcohol                                      |                    |                    | S               |                      |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Borderline Personality  
Disorder; Delusion;  
Diarrhoea; Drug  
Dependence; Drug  
Ineffective; Erectile  
Dysfunction; Generalised  
Anxiety Disorder;  
Hallucination; Headache;  
Homicidal Ideation;  
Insomnia; Irritability;  
Judgement Impaired;  
Malaise; Memory  
Impairment; Mood Swings;  
Nervousness;  
Restlessness; Sexual  
Abuse; Sluggishness;  
Somnolence; Suicidal  
Ideation; Toxicity To  
Various Agents; Treatment  
Noncompliance

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2005              | 5798780       | EXPEDITED (15-DAY) | N                  | HO, LT          | S05-USA-02250-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;    | Lexapro                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Depression; Drug         | Lithium                 |              |            | S           |              | 600 Mg Qd          |                 | Not Reported |
| Ineffective; Mania;      | Lamictal                |              |            | S           |              | 50 Mg Bid          |                 | Not Reported |
| Overdose; Personality    | Abilify                 |              |            | S           |              | 15 Mg Qd           |                 | Not Reported |
| Change; Suicide Attempt; | Seroquel                |              |            | S           |              |                    |                 | Not Reported |
| Weight Increased         | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2005              | 5820724       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02782-01     |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                                      |   |      |             |              |
|--------------|--------------------------------------|---|------|-------------|--------------|
| Parkinsonism | Lexapro                              | S | Oral | 10 Mg Qd Po | Not Reported |
|              | Lexapro                              | S | Oral | 20 Mg Qd Po | Not Reported |
|              | Lexapro                              | S |      |             | Not Reported |
|              | Prozac                               | S | Oral | 80 Mg Qd Po | Not Reported |
|              | Prozac                               | S | Oral | 20 Mg Qd Po | Not Reported |
|              | Prozac                               | S | Oral | 40 Mg Qd Po | Not Reported |
|              | Abilify                              | S |      | 30 Mg Qhs   | Not Reported |
|              | Depakote                             | C |      |             | Not Reported |
|              | Lisinopril                           | C |      |             | Not Reported |
|              | Diovan                               | C |      |             | Not Reported |
|              | Coreg                                | C |      |             | Not Reported |
|              | Wellbutrin (Bupropion Hydrochloride) | C |      |             | Not Reported |
|              | Hydrocodone/Apap                     | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2005              | 5844337       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03438-01     |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hyperhidrosis; Loss Of Consciousness; Seizure; Vomiting | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Pegintron      |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Ribavirin      |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Buspar         |              |            | C           |              |                    |                 | Not Reported |
|                                                               | Protonix       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Jul-2005              | 5793334       | EXPEDITED (15-DAY) | N                  | HO              | US-GLAXOSMITHKLINE-A0556917A |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anxiety; Discomfort; Fatigue; Heart Rate Increased; Hypoaesthesia; Intentional Product Misuse; Muscle | Wellbutrin XI          |              |            | S           | Oral         | 900mg Single Dose  |                 | Glaxosmithkline |
|                                                                                                       | Lexapro                |              |            | S           | Oral         |                    | 15 DAY          | Not Reported    |
|                                                                                                       | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Contracture; Paraesthesia;  
Posture Abnormal;  
Seizure; Suicide Attempt;  
Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2005              | 5802710       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-02393-01     |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Discomfort; Fatigue;<br>Hypoaesthesia; Ill-Defined<br>Disorder; Intentional<br>Product Misuse; Muscle<br>Contractions Involuntary;<br>Paraesthesia; Seizure;<br>Tremor | Wellbutrin XI  |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                                                                                                        | Lexapro        |              |            | S           | Oral         | 20mg Per Day       | 15 DAY          | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2005              | 5838923       | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-410336      |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose;<br>Agitation; Drug Screen<br>False Positive; Gait<br>Disturbance; Irritability;<br>Overdose; Psychomotor<br>Retardation; Sedation;<br>Stupor | Klonopin                     |              |            | S           | Oral         |                    | 1 DAY           | Roche        |
|                                                                                                                                                                   | Soma                         |              |            | S           | Unknown      |                    | 1 DAY           | Not Reported |
|                                                                                                                                                                   | Lexapro                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                   | Lexapro                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                   | Relafen                      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                   | Cyproheptadine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Claritin                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Inderal                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Doxycycline                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Melatonin                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Hydroxyzine                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2005              | 5791128       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01761-01     |                      | 54 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>       | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypoacusis; Viral Infection | Lexapro           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                             | Calcium Gluconate |              |            | C           |              |                    |                 | Not Reported |
|                             | Vitamin C         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2005              | 5812772       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-02675-01     |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Condition Aggravated;<br>Depression; Drug<br>Ineffective; Hallucination;<br>Intentional Product<br>Misuse; Overdose; Post-Traumatic Stress Disorder;<br>Suicidal Ideation; Suicide<br>Attempt; Treatment<br>Noncompliance | Lexapro        |              |            | S           | Oral         | 50 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 50 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Elavil         |              |            | S           |              | 50 Mg Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Klonopin       |              |            | S           |              | 1 Mg Qd            |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Ritalin        |              |            | S           |              | 30 Mg Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Abilify        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                  | Geodon         |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2005              | 5822539       | EXPEDITED (15-DAY) | N                  | HO, OT          | S05-USA-02498-01     |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Delusion; Depression;<br>Gastroesophageal Reflux<br>Disease; Gun Shot<br>Wound; Headache;<br>Serratia Infection; Suicide | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 60 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                   | Klonopin       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Attempt; Thinking  
Abnormal; Urinary Tract  
Infection; Vision Blurred;  
Weight Decreased

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| 19-Jul-2005                                                                                          | 5847861               | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-03510-01                                |                      | 40 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aggression; Alcohol<br>Interaction; Alcohol Use;<br>Paranoia                                         | Lexapro<br>Alcohol    |                    |                    | S<br>S          | Oral                                            | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-Jul-2005                                                                                          | 5847785               | DIRECT             | N                  | DE              |                                                 |                      | 53 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anaphylactic Shock;<br>Obstructive Airways<br>Disorder; Swelling                                     | Lexapro<br>Wellbutrin |                    |                    | S<br>S          |                                                 |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Jul-2005                                                                                          | 5802758               | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-02406-01                                |                      | 56 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Exercise<br>Electrocardiogram<br>Abnormal; Fall; Loss Of<br>Consciousness;<br>Resuscitation; Syncope | Lexapro<br>Geodon     |                    |                    | S<br>C          |                                                 |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Jul-2005                                                                                          | 5842630               | NON-EXPEDITED      | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12797510 |                      | 90 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                         |        |      |                                                                                   |                              |
|----------------------------------------------------|-------------------------|--------|------|-----------------------------------------------------------------------------------|------------------------------|
| Abdominal Pain;<br>Gastrointestinal<br>Haemorrhage | Coumadin                | S      | Oral | Dose Unk, But Kept At<br>Approx 3.5 (Units Not<br>Given); Commenced<br>Years Ago. | Bristol Myers Squibb         |
|                                                    | Lexapro                 | S      | Oral |                                                                                   | Not Reported                 |
|                                                    | Ambien<br>Multi-Vitamin | C<br>C |      |                                                                                   | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Jul-2005              | 5842646       | NON-EXPEDITED    | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12808283 |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| International Normalised<br>Ratio Decreased | Coumadin       |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported         |
|                                             | Paclitaxel     |              |            | C           |              |                    |                 | Bristol Myers Squibb |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 21-Jul-2005              | 5842806       | NON-EXPEDITED    | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12925921 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| International Normalised<br>Ratio Increased | Coumadin       |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2005              | 5845358       | EXPEDITED (15-DAY) | Y                  | LT              | S05-NLD-02364-02     |                      | 1 DAY      | Female     | NLD            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Apgar Score Low;<br>Asphyxia; Maternal<br>Exposure During<br>Pregnancy; Meconium | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
|                                                                                  | Oxazepam             |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Neonatal  
Respiratory Depression

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2005              | 5770905       | EXPEDITED (15-DAY) | Y                  | DE, DS          | US-ROCHE-400261      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Ammonia Increased;<br>Colon Cancer Metastatic;<br>Mental Status Changes;<br>Metastases To Liver | Xeloda                  |              |            | S           | Oral         |                                           | 2 DAY           | Roche        |
|                                                                                                 | Lexapro                 |              |            | S           | Oral         | Dosage Regimen<br>Reported As Every Day   |                 | Not Reported |
|                                                                                                 | Seroquel                |              |            | S           | Oral         | Dosage Regimen<br>Reported As Every Night |                 | Not Reported |
|                                                                                                 | Methadone Hydrochloride |              |            | S           | Oral         |                                           |                 | Not Reported |
|                                                                                                 | Oxaliplatin             |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                 | Avastin                 |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                 | Megace                  |              |            | C           | Oral         |                                           |                 | Not Reported |
|                                                                                                 | Protonix                |              |            | C           |              | Dosage Regimen<br>Reported As Daily       |                 | Not Reported |
|                                                                                                 | Senokot                 |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                 | Colace                  |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                 | Combivent               |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                 | Prochlorperazine        |              |            | C           |              | Dosage Regimen<br>Reported As Prn         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2005              | 5849875       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Restless Legs Syndrome | Lexapro        |              |            | S           | Oral         | 10mg 1x/Day Oral   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2005              | 5816266       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | PHEH2005US06346      |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |          |   |      |           |           |  |              |
|---------------------------------------------------------------------------------------------------------------------------|----------|---|------|-----------|-----------|--|--------------|
| Depression; Drug Ineffective; Hallucination; Overdose; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt | Ritalin  | S | Oral | 30 Mg, Qd |           |  | Novartis     |
|                                                                                                                           | Lexapro  | S | Oral | 10 Mg, Qd | 10080 MIN |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 20 Mg, Qd | 10080 MIN |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 30 Mg, Qd | 10080 MIN |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 40 Mg, Qd | 10080 MIN |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 50 Mg, Qd |           |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 30 Mg, Qd |           |  | Not Reported |
|                                                                                                                           | Lexapro  | S | Oral | 50 Mg, Qd |           |  | Not Reported |
|                                                                                                                           | Elavil   | S | Oral | 50 Mg, Qd |           |  | Not Reported |
|                                                                                                                           | Klonopin | S | Oral | 1 Mg, Qd  | 341 DAY   |  | Not Reported |
|                                                                                                                           | Abilify  | S | Oral | Unk, Unk  | 135 DAY   |  | Not Reported |
|                                                                                                                           | Geodon   | S | Oral | 40 Mg, Qd | 46080 MIN |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2005              | 5844722       | NON-EXPEDITED    | N                  |                 | US013232             |                      |            | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Flushing | Dyazide        |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                            | Provigil       |              |            | S           |              |                    |                 | Not Reported    |
|                            | Estraderm      |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                            | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                            | Lipitor        |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2005              | 5851086       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03548-02     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2005              | 5776226       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01603-01     |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                                                                                                                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                                                             | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------------------------------------------------------------------|----------------------|------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Activated Partial Thromboplastin Time Prolonged; Alanine Aminotransferase Decreased; Anion Gap Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Chloride Increased; Blood Creatine Phosphokinase Increased; Blood Creatine Phosphokinase Mb Increased; Blood Creatinine Increased; Blood Fibrinogen Decreased; Blood Glucose Increased; Blood Phosphorus Decreased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Sodium Decreased; Blood Sodium Increased; Blood Urea Increased; Haematocrit Decreased; Haemoglobin Decreased; International Normalised Ratio Increased; Lymphocyte Count Decreased; Mitral Valve Repair; Neutrophil Count | Lexapro<br>Warfarin Sodium<br>Warfarin Sodium<br>Trazodone Hydrochloride<br>Restoril<br>Quinapril<br>Prednisone<br>Lopressor XI (Metoprolol)<br>Megestrol<br>Losartan Potassium<br>Loratadine<br>Insulin Nos<br>Pepcid<br>Epogen<br>Clonidine |              |            | S<br>S<br>S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral | 5 Mg Qd Po<br>5 Mg Qd Po<br>2.5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Increased; Pco2  
Decreased; Platelet Count  
Decreased; Protein Total  
Decreased; Prothrombin  
Time Prolonged; Red  
Blood Cell Count  
Decreased; Tricuspid  
Valve Repair; Troponin  
Increased; White Blood  
Cell Count Increased

| <u>FDA Received Date</u>                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 26-Jul-2005                                                    | 5811849               | EXPEDITED (15-DAY) | Y                  | HO, RI          | S05-USA-01774-01     |                          | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Calcium Increased;<br>Parathyroid Gland<br>Operation     | Lexapro               |                    |                    | S               | Oral                 | 30 Mg Qd Po              |                 | Not Reported |                |
|                                                                | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                | Nexium (Esomeprazole) |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                | Fosamax               |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2005                                                    | 5838395               | EXPEDITED (15-DAY) | Y                  | DE              | S05-GER-02285-01     |                          | 19 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Incorrect Dose<br>Administered; Insomnia | Ciprallex             |                    |                    | S               | Oral                 | 10 Mg Qd; Po             |                 | Not Reported |                |
|                                                                | Zopiclone             |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jul-2005                                                    | 5850898               | DIRECT             | N                  | RI              |                      |                          | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Energy                       | Lexapro               |                    |                    | S               | Oral                 | 20 Mg 1/Day-Morning Oral |                 | Not Reported |                |
|                                                                | Oxazepam              |                    |                    | C               |                      |                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                               |            |   |              |
|-------------------------------------------------------------------------------------------------------------------------------|------------|---|--------------|
| Increased; Insomnia;<br>Muscle Tightness;<br>Nicotine Dependence;<br>Restlessness; Serotonin<br>Syndrome; Trismus;<br>Yawning | Alprazolam | C | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------|------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2005              | 5851702       | EXPEDITED (15-DAY) | Y                  | HO, LT          | T05-FIN-02514-01     |                      | 44 YR      | Female     | FIN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Poisoning; Blood<br>Pressure Diastolic<br>Decreased; Depression;<br>Dizziness; Injury;<br>Intentional Product<br>Misuse; Joint Swelling;<br>Loss Of Consciousness;<br>Overdose; Poisoning;<br>Seizure; Suicide Attempt;<br>Wheezing | Escitalopram Oxalate |              |            | S           |              | 800 Mg Once        |                 | Not Reported |
|                                                                                                                                                                                                                                             | Escitalopram Oxalate |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                             | Alcohol              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                             | Diazepam             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                             | Lanexat (Flumazenil) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2005              | 4215859       | EXPEDITED (15-DAY) | N                  | OT              | 2004063520           |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Alopecia; Anxiety; Body<br>Height Decreased; Chest<br>Discomfort; Depression;<br>Disturbance In Attention;<br>Divorced; Drug Ineffective;<br>Drug Interaction;<br>Dyspnoea; Feeling<br>Abnormal; Headache;<br>Heart Rate Increased;<br>Mood Altered; Myocardial<br>Infarction; Neck Pain;<br>Panic Attack; | Neurontin      |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Zoloft         |              |            | S           | Oral         | (1 In 1 D), Oral                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Xanax          |              |            | S           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Lexapro        |              |            | S           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Gabapentin     |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Claritin       |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Buspar         |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Prozac         |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Zyprexa        |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Zyrtec         |              |            | C           |              |                                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Psychomotor  
Hyperactivity; Road Traffic  
Accident; Stress; Suicidal  
Ideation; Therapeutic  
Product Effect Decreased

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 28-Jul-2005                       | 5707932                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S04-GER-08106-01              |                               | 80 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aplastic Anaemia                  | Ciprallex               |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>                                                                                                                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>        | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>             | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------------|-------------------------------|--------------------------|---------------------------------|-------------------------|
| 28-Jul-2005                                                                                                                                                                                  | 5847245                 | EXPEDITED (15-DAY)        | N                           | OT                       | US-<br>GLAXOSMITHKLINE-<br>A0566775A |                               |                          | Male                            | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>             |                         |
| Aggression; Dysgraphia;<br>Fear; Impaired Driving<br>Ability; Malaise; Memory<br>Impairment; Self-Injurious<br>Ideation; Thinking<br>Abnormal; Visual Acuity<br>Reduced; Weight<br>Increased | Paxil<br>Lexapro        |                           |                             | S<br>S                   | Oral                                 |                               | 3 YR                     | Glaxosmithkline<br>Not Reported |                         |

| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 28-Jul-2005                                                          | 5853653                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-CAN-02530-01              |                               | 53 YR                    | Male                | CAN                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic<br>Seizure; Liver Function<br>Test Abnormal | Ciprallex               |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Jul-2005                       | 5854220                | DIRECT                    | Y                           | HO, LT                   |                               |                               | 55 YR               | Male                | USA                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;<br>Dehydration; Hypotension;<br>Nausea; Oxygen<br>Saturation Decreased;<br>Pulmonary Embolism;<br>Vomiting | Iressa         |              |            | S           | Oral         | 250 Mg Daily Po    |                 | Not Reported |
|                                                                                                                            | Xanax          |              |            | S           | Oral         | 0.25 Mg Q6h Po     |                 | Not Reported |
|                                                                                                                            | Phenergan      |              |            | S           | Oral         | 12.5 Mg Q6h Prn Po |                 | Not Reported |
|                                                                                                                            | Protonix       |              |            | S           | Oral         | 40 Mg Bid Po       |                 | Not Reported |
|                                                                                                                            | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |
|                                                                                                                            | Colace         |              |            | S           | Oral         | 100 Mg Tid Po      |                 | Not Reported |
|                                                                                                                            | Percocet       |              |            | S           | Oral         | 5 Mg Q4h Prn Po    |                 | Not Reported |
|                                                                                                                            | Duragesic      |              |            | S           | Transdermal  | 50 Mcg Q3days Derm |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2005              | 5854475       | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-02534-01     |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure; Tremor       | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Ebixa                |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2005              | 5854478       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S05-FRA-02533-01     |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Confusional<br>State; Gastrointestinal<br>Haemorrhage;<br>Hypokalaemia;<br>International Normalised<br>Ratio Increased | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                    | Levothyroxine Sodium |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Flecainide Acetate   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2005              | 5850018       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-03547-01     |                      | 54 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Alcohol Use; Homicide                                                                                                                 |                      | Lexapro                       |                    | S               |                      |                      |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                       |                      | Cholesterol Medications (Nos) |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                       |                      | Unspecified Ingredient        |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>              | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2005                                                                                                                           | 5853192              | DIRECT                        | N                  | OT              |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>                  | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disturbance In Attention; Fear; Feeling Abnormal; Hallucination, Auditory; Hyperhidrosis; Muscle Twitching; Paranoia; Tremor | Lexapro              |                               |                    | S               | Oral                 | 5mg Per Day Oral     |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>              | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2005                                                                                                                           | 5855185              | EXPEDITED (15-DAY)            | Y                  | LT              | S05-UKI-02525-01     |                      | 45 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>                  | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Shock; Asthma                                                                                                            | Ciprallex            |                               |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                       | Levothyroxine Sodium |                               |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Liothyronine Sodium  |                               |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>              | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2005                                                                                                                           | 5858686              | EXPEDITED (15-DAY)            | Y                  | DE              | S05-USA-03655-01     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>                  | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colon Cancer; Hepatic Failure; Hepatomegaly; Mental Status Changes; Metastases To Liver                                               | Lexapro              |                               |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                       | Seroquel             |                               |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                       | Combivent            |                               |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>              | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2005                                                                                                                           | 5858688              | EXPEDITED (15-DAY)            | Y                  | OT              | S05-USA-03667-01     |                      |                 | Unknown      | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Seizure                                                                          | Lexapro                        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2005                                                                      | 5860434                        | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-02622-01                                |                      | 51 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder;<br>Movement Disorder                                    | Ciprallex                      |                    |                    | S               |                                                 | 10 Mg Qd             |                 | Not Reported |                |
|                                                                                  | Ciprallex                      |                    |                    | S               |                                                 | 20 Mg Qd             |                 | Not Reported |                |
|                                                                                  | Mareen (Doxepin Hydrochloride) |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2005                                                                      | 5860892                        | EXPEDITED (15-DAY) | Y                  | LT              | S05-SAF-02624-01                                |                      | 39 YR           | Male         | ZAF            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Haemorrhage;<br>International Normalised<br>Ratio Increased | Ciprallex                      |                    |                    | S               | Oral                                            | 5 Mg Qd, Po          |                 | Not Reported |                |
|                                                                                  | Warfarin Sodium                |                    |                    | S               | Oral                                            | 5 Mg Qd, Po          |                 | Not Reported |                |
|                                                                                  | Prednisone                     |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2005                                                                      | 5855434                        | DIRECT             | Y                  | OT              |                                                 |                      | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Hallucination, Visual;<br>Palpitations                      | Lexapro                        |                    |                    | S               | Oral                                            | Po 15 -> 20mg        |                 | Forest       |                |
|                                                                                  |                                |                    |                    |                 | Oral                                            | Po 15 -> 20mg        |                 |              |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2005                                                                      | 5821767                        | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12998167 |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                                             |                                                               |                            |              |  |  |  |                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----------------------------|--------------|--|--|--|----------------------------------------------------------------------------------------------|
| Depression; Drug Ineffective; Hallucination; Intentional Product Misuse; Post-Traumatic Stress Disorder; Suicidal Ideation; Suicide Attempt | Abilify<br>Lexapro<br>Elavil<br>Klonopin<br>Ritalin<br>Geodon | S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral |  |  |  | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----------------------------|--------------|--|--|--|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Aug-2005              | 5857609       | DIRECT           | Y                  | HO, LT          |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|----------------------------------------------|
| Abdominal Pain; Chromaturia; Faeces Discoloured; Nausea; Scleral Discolouration | Lexapro<br>Synthroid<br>Femhrt |              |            | S<br>C<br>C | Oral         | 60mg Once Daily Oral |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Aug-2005              | 5857870       | DIRECT           | N                  | HO, OT          |                      |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Anger; Anxiety; Crying; Depression; Dysphagia; Feeling Abnormal; Headache; Hostility; Hypoaesthesia; Malaise; Mania; Muscle Tightness; Nightmare; Pain; Psychotic Disorder; Suicidal Ideation | Neurontin<br>Lexapro |              |            | S<br>S      | Oral<br>Oral | Oral<br>Oral       |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Aug-2005              | 5862028       | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-02692-01     |                      | 27 YR      | Female     | GBR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Epilepsy; Loss | Ciprallex      |              |            | S           | Oral         | 5 Mg Qs Po         |                 | Not Reported |

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|                                                            |                            |                          |                    |                 |                       |                      |                 |              |                |
|------------------------------------------------------------|----------------------------|--------------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Of Consciousness                                           |                            | Sertraline Hydrochloride |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>              | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2005                                                | 5862416                    | EXPEDITED (15-DAY)       | Y                  | DE              | S05-USA-03721-01      |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>             | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Exsanguination; Skin<br>Laceration   | Lexapro                    |                          |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                            | Xanax                      |                          |                    | C               |                       |                      |                 | Not Reported |                |
|                                                            | Aspirin                    |                          |                    | C               |                       |                      |                 | Not Reported |                |
|                                                            | Tylenol (Paracetamol)      |                          |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>              | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2005                                                | 4218537                    | EXPEDITED (15-DAY)       | Y                  | HO              | DE-MERCK-0409DEU00158 |                      | 90 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u>             | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Duodenal Ulcer<br>Haemorrhage         | Vioxx                      |                          |                    | S               | Oral                  |                      |                 | Merck        |                |
|                                                            | Escitalopram Oxalate       |                          |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                            | Enoxaparin Sodium          |                          |                    | S               | Subcutaneous          |                      |                 | Not Reported |                |
|                                                            | Clopidogrel Bisulfate      |                          |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                            | Moxifloxacin Hydrochloride |                          |                    | C               | Oral                  |                      | 11 DAY          | Not Reported |                |
|                                                            | Hydrochlorothiazide        |                          |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                            | Pantoprazole Sodium        |                          |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                            | Simvastatin                |                          |                    | C               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>              | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2005                                                | 5788457                    | EXPEDITED (15-DAY)       | Y                  | HO              | S05-USA-01998-01      |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>             | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Serotonin<br>Syndrome | Lexapro                    |                          |                    | S               | Oral                  | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                            | Lexapro                    |                          |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                            | Buspar                     |                          |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 09-Aug-2005                                                                                 | 5836977        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-03346-01             |                      | 56 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Akathisia; Condition Aggravated; Fatigue                                                    | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Lexapro        |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Lexapro        |                    |                    | S               | Oral                         | 15 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Navane         |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Anafranil      |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Aug-2005                                                                                 | 5863278        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-03739-01             |                      | 18 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams; Condition Aggravated; Focal Dyscognitive Seizures; Hallucination; Insomnia | Lexapro        |                    |                    | S               | Oral                         | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                                                             | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Lamictal       |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                             | Depakote       |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2005                                                                                 | 5855605        | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0554040A |                      | 36 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Drug Withdrawal Syndrome; Fear; Vomiting                                        | Paxil Cr       |                    |                    | S               | Oral                         | 25mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                             | Lexapro        |                    |                    | S               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2005                                                                                 | 5857076        | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0560134A |                      | 49 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                              |                |                                     |                    |                 |                      |                      |                 |                 |                |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|-------------------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Amnesia; Drug Ineffective;<br>Nervousness; Panic<br>Attack                                                                                   |                | Paroxetine Hydrochloride<br>Lexapro |                    | S               | Oral                 | 30mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                                              |                |                                     |                    | S               | Oral                 | 10mg Per Day         |                 | 6 WEEK          | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>                    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Aug-2005                                                                                                                                  | 5795210        | EXPEDITED (15-DAY)                  | Y                  | OT              | S05-USA-00052-01     |                      | 52 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>                        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Impaired Driving<br>Ability; Nervous System<br>Disorder; Vascular<br>Dementia                                                       | Lexapro        |                                     |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                              | Atenolol       |                                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                              | Inderal        |                                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                              | Lipitor        |                                     |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>                    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Aug-2005                                                                                                                                  | 5831739        | EXPEDITED (15-DAY)                  | N                  | HO              | S05-USA-03181-01     |                      | 48 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>                        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Aggression; Feeling<br>Jittery; Refusal Of<br>Treatment By Patient;<br>Suicidal Ideation                                                     | Lexapro        |                                     |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported    |                |
|                                                                                                                                              | Risperdal      |                                     |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>                    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Aug-2005                                                                                                                                  | 5845729        | EXPEDITED (15-DAY)                  | N                  | HO              | US-ROCHE-410971      |                      | 17 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u> | <u>Comp.</u>                        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depression; Hallucination;<br>Intentional Self-Injury;<br>Overdose; Post-Traumatic<br>Stress Disorder; Suicidal<br>Ideation; Suicide Attempt | Klonopin       |                                     |                    | S               | Unknown              | Overdose Therapy.    | 341 DAY         | Roche           |                |
|                                                                                                                                              | Klonopin       |                                     |                    | S               | Unknown              |                      |                 | Roche           |                |
|                                                                                                                                              | Lexapro        |                                     |                    | S               | Oral                 |                      | 7 DAY           | Not Reported    |                |
|                                                                                                                                              | Lexapro        |                                     |                    | S               | Oral                 |                      | 7 DAY           | Not Reported    |                |
|                                                                                                                                              | Lexapro        |                                     |                    | S               | Oral                 |                      | 7 DAY           | Not Reported    |                |
|                                                                                                                                              | Lexapro        |                                     |                    | S               | Oral                 |                      | 7 DAY           | Not Reported    |                |
|                                                                                                                                              | Lexapro        |                                     |                    | S               | Oral                 |                      | 7 DAY           | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                              |                        |                    |                    |                 |                                      |                      |                    |                 |                 |
|------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|--------------------|-----------------|-----------------|
|                                                                                                                              | Lexapro                |                    | S                  | Oral            |                                      |                      |                    | Not Reported    |                 |
|                                                                                                                              | Lexapro                |                    | S                  | Oral            |                                      |                      |                    | Not Reported    |                 |
|                                                                                                                              | Elavil                 |                    | S                  | Unknown         |                                      |                      |                    | Not Reported    |                 |
|                                                                                                                              | Ritalin                |                    | S                  | Unknown         |                                      |                      |                    | Not Reported    |                 |
|                                                                                                                              | Ritalin                |                    | S                  | Unknown         | The Patient Was Weaned Off The Drug. |                      |                    | Not Reported    |                 |
|                                                                                                                              | Abilify                |                    | S                  | Unknown         |                                      | 135 DAY              |                    | Not Reported    |                 |
|                                                                                                                              | Geodon                 |                    | S                  | Oral            |                                      | 32 DAY               |                    | Not Reported    |                 |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>  |
| 11-Aug-2005                                                                                                                  | 5861007                | DIRECT             | N                  |                 |                                      |                      | 27 YR              | Female          | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
| Alopecia                                                                                                                     | Lexapro                |                    |                    | S               | Oral                                 | 1 Day Oral           |                    |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>  |
| 12-Aug-2005                                                                                                                  | 5829175                | EXPEDITED (15-DAY) | Y                  | OT              | 13148                                |                      | 26 YR              | Female          | USA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
| Tachycardia                                                                                                                  | Wellbutrin             |                    |                    | S               |                                      |                      | 150mg Per Day      | 30 DAY          | Glaxosmithkline |
|                                                                                                                              | Lexapro                |                    |                    | S               |                                      |                      | 10mg Per Day       | 134 DAY         | Not Reported    |
|                                                                                                                              | Unspecified Ingredient |                    |                    | C               |                                      |                      |                    |                 | Not Reported    |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>  |
| 12-Aug-2005                                                                                                                  | 5863889                | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-02780-01                     |                      | 59 YR              | Male            | FRA             |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>         |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
| Abnormal Behaviour;<br>Agitation; Confusional<br>State; Diet Refusal;<br>Disorientation; Negativism;<br>Persecutory Delusion | Escitalopram Oxalate   |                    |                    | S               | Oral                                 | 1 Tablet Qd Po       |                    |                 | Not Reported    |
|                                                                                                                              | Lexomil (Bromazepam)   |                    |                    | C               |                                      |                      |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Aug-2005              | 5863892                     | EXPEDITED (15-DAY) | Y                  | DE              | S05-UKI-02764-01     |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death             | Cipralext                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Flupentixol Dihydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Zopiclone                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Quinine Bisulfate           |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Aug-2005                                                                                                     | 5844333                      | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-03429-01     |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Cough; Dizziness; Drug Interaction; Heart Rate Increased; Heart Rate Irregular; Laryngitis | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd, Po         |                 | Not Reported |                |
|                                                                                                                 | Dextromethorphan\Guaifenesin |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Aspirin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Aug-2005                   | 5864704              | EXPEDITED (15-DAY) | Y                  | OT              | 05-08-1390           |                      | 60 YR           | Male         | ITA            |
| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Rectal Haemorrhage | Mirtazapine          |                    |                    | S               |                      | 15-7.5mg Qd          |                 | Not Reported |                |
|                               | Venlafaxine          |                    |                    | S               |                      | 150-37.5mg Qd        |                 | Not Reported |                |
|                               | Escitalopram Oxalate |                    |                    | S               |                      | 20-5mg               |                 | Not Reported |                |
|                               | Omeprazole           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                               | Irbesartan           |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Aug-2005              | 5864779        | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 83 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |            |   |      |                |       |              |
|----------------------------------------------|------------|---|------|----------------|-------|--------------|
| Asthenia; Hyponatraemia;<br>Medication Error | Lexapro    | S | Oral | 10 Mg Po Daily | 6 DAY | Not Reported |
|                                              | Lisinopril | C |      |                |       | Not Reported |
|                                              | Calcium +D | C |      |                |       | Not Reported |
|                                              | Aspirin    | C |      |                |       | Not Reported |
|                                              | Vitamin    | C |      |                |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2005              | 5866540       | EXPEDITED (15-DAY) | N                  | HO, LT          | S04-USA-07194-02     |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Immature Respiratory<br>System; Infantile Colic;<br>Maternal Exposure During<br>Pregnancy; Premature<br>Baby | Celexa                               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                    | Lexapro                              |              |            | S           | Oral         | 50 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                    | Lexapro                              |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                    | Lexapro                              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                    | Claritin                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Natelle (Prenatal Vitamins)          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Rocephin                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Zofran                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Terbutaline Sulfate                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Magnesium Sulfate                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Procardia                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                    | Spinal Analgesia/Anesthesia<br>(Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2005              | 5866541       | EXPEDITED (15-DAY) | N                  | HO              | S04-USA-06296-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Dizziness; Drug<br>Ineffective; Maternal<br>Exposure During<br>Pregnancy; Nausea; Pain;<br>Pregnancy; Premature<br>Labour; Procedural Pain;<br>Vomiting | Lexapro        |              |            | S           | Oral         | 50 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                               | Claritin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                               | Natelle        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2005                                                    | 5866521        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03889-01     |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gestational Diabetes;<br>Maternal Exposure During<br>Pregnancy | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Lexapro        |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Zofran         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Benadryl       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Aug-2005                                                                         | 5864819                | EXPEDITED (15-DAY) | N                  | OT              | US-ROCHE-414054      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Colitis; Gastric Ulcer;<br>Gastroesophageal Reflux<br>Disease; Oesophageal<br>Ulcer | Cellcept               |                    |                    | S               | Oral                 | 600mg Weekly.        |                 | Roche        |                |
|                                                                                     | Fosamax                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Prednisone             |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Lexapro                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Gemfibrozil            |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Morphine               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Temazepam              |                    |                    | S               | Oral                 |                      |                 | Roche        |                |
|                                                                                     | Unspecified Ingredient |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Calcium Gluconate      |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Multi-Vitamin          |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                     | Ibuprofen              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                     | Acetaminophen          |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Aug-2005              | 5867638        | EXPEDITED (15-DAY) | N                  | DE              | S05_USA_03912-01     |                      |                 | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |         |   |              |
|------------------------------------------------|---------|---|--------------|
| Completed Suicide; Gun Shot Wound; Head Injury | Lexapro | S | Not Reported |
|------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2005              | 5868149       | DIRECT           | N                  | DE              |                      |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Burning Sensation; Completed Suicide; Gun Shot Wound; Insomnia; Restlessness; Thinking Abnormal | Lexapro        |              |            | S           | Oral         | 10 Mg 1 X Daily Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2005              | 5798492       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-02235-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Tardive Dyskinesia | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                               | Citalopram     |              |            | C           |              |                    |                 | Not Reported |
|                               | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |
|                               | Temazepam      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2005              | 5869414       | EXPEDITED (15-DAY) | Y                  | HO              | DSA_26863_2005       |                      | 50 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation; Coma Scale Abnormal; Depressed Level Of Consciousness; Hypercapnia; Miosis; Overdose; Sopor; Suicide Attempt | Lorazepam               |              |            | S           | Oral         | Df Once Po         |                 | Not Reported |
|                                                                                                                                     | Ciprallex               |              |            | S           | Oral         | 1 Df Once Po       |                 | Not Reported |
|                                                                                                                                     | Zopiclone               |              |            | S           | Oral         | Df Once Po         |                 | Not Reported |
|                                                                                                                                     | Clorazepate Dipotassium |              |            | S           | Oral         | Df Once Po         |                 | Not Reported |
|                                                                                                                                     | Trazodone               |              |            | S           | Oral         | Df Once Po         |                 | Not Reported |
|                                                                                                                                     | Chlorprothixene         |              |            | S           | Oral         | Df Once Po         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 23-Aug-2005                                                                                                                                                          | 5870914               | EXPEDITED (15-DAY) | Y                  | OT              | SO5-USA-03682-01     |                         | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Porphyria; Rash                                                                                                                                                      | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd, Po            |                 | Not Reported |                |
|                                                                                                                                                                      | Procrit               |                    |                    | S               |                      | 30000 Units Qmon        |                 | Not Reported |                |
|                                                                                                                                                                      | Coumadin              |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Ivig (Immunoglobulin) |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Tarka                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Coreg                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Bovina (Irbandronate) |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Orpn (Iron)           |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2005                                                                                                                                                          | 5855183               | EXPEDITED (15-DAY) | Y                  | CA              | S05-SWI-02528-02     |                         | < 1 DAY         | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia Foetal;<br>Caesarean Section;<br>Congenital Anomaly;<br>Foetal Growth Restriction;<br>Maternal Exposure During<br>Pregnancy                              | Ciprallex             |                    |                    | S               | Transplacental       | 15 Mg Qd Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2005                                                                                                                                                          | 5766153               | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01213-02     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Decreased<br>Activity; Maternal<br>Exposure During Breast<br>Feeding; Maternal<br>Exposure During<br>Pregnancy; Neonatal<br>Disorder; Selective Eating | Lexapro               |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                      | Lexapro               |                    |                    | S               |                      | 20 Mg Qd Bf             |                 | Not Reported |                |
|                                                                                                                                                                      | Tylenol Pm            |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Stadol                |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                      | Darvocet              |                    |                    | C               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Small For Dates  
Baby; Somnolence  
Neonatal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2005              | 4076963       | NON-EXPEDITED    | Y                  | DE              | USA-2003-0006530     |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose;<br>Overdose | Oxycontin                     |              |            | S           |              | 20 Mg, Q12h        |                 | Not Reported |
|                                  | Reglan                        |              |            | S           |              | 10 Mg, Qid Prn     |                 | Not Reported |
|                                  | Lexapro                       |              |            | S           |              | 10, Daily          |                 | Not Reported |
|                                  | Percocet                      |              |            | S           |              | 5 Mg, Q4h Prn      |                 | Not Reported |
|                                  | Zantac                        |              |            | S           |              | 300 Mg, Bid Prn    |                 | Not Reported |
|                                  | Zanaflex                      |              |            | S           |              |                    |                 | Not Reported |
|                                  | Flagyl                        |              |            | S           |              | 500 Mg, Bid        |                 | Not Reported |
|                                  | Cyclobenzaprine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                  | Amoxicillin                   |              |            | C           |              |                    |                 | Not Reported |
|                                  | Warfarin Sodium               |              |            | C           |              |                    |                 | Not Reported |
|                                  | Methadone Hydrochloride       |              |            | C           |              |                    |                 | Not Reported |
|                                  | Amitriptyline                 |              |            | C           |              |                    |                 | Not Reported |
|                                  | Celebrex                      |              |            | C           |              |                    |                 | Not Reported |
|                                  | Zoloft                        |              |            | C           |              |                    |                 | Not Reported |
|                                  | Concerta                      |              |            | C           |              |                    |                 | Not Reported |
|                                  | Mavik                         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2005              | 5796570       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-02225-01     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Phlebitis; Treatment<br>Noncompliance | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                       | Seroquel       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2005              | 5871878       | DIRECT           | Y                  | HO              |                      |                      | 7 DAY      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|-------------------------------------------|------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Drug Withdrawal Syndrome; Hyperreflexia; Maternal Exposure During Pregnancy; Neonatal Seizure; Subarachnoid Haemorrhage; Subdural Haemorrhage | Lexapro<br>Prednisone<br>Augmentin<br>Ranitidine Hydrochloride<br>Advair Diskus<br>Flonase<br>Penicillin<br>Clacium<br>Zyrtec |                  |                    | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C |                                          |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 30-Aug-2005                                                                                                                                   | 5803024                                                                                                                       | NON-EXPEDITED    | N                  | HO, LT                                    | US-BRISTOL-MYERS SQUIBB COMPANY-12965893 |                      | 30 YR           | Female                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Depression; Drug Ineffective; Intentional Product Misuse; Mania; Suicide Attempt; Weight Increased                                            | Abilify<br>Trazodone Hydrochloride<br>Lexapro<br>Lithium<br>Lamictal<br>Seroquel                                              |                  |                    | S<br>S<br>S<br>S<br>S<br>S                | Oral                                     |                      |                 | Not Reported<br>Apothecon<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                                    |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 30-Aug-2005                                                                                                                                   | 5868944                                                                                                                       | NON-EXPEDITED    | N                  |                                           | US-BRISTOL-MYERS SQUIBB COMPANY-12960563 |                      |                 | Female                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Anger; Drug Interaction; Irritability; Mood Swings                                                                                            | Abilify<br>Cytomel<br>Lexapro                                                                                                 |                  |                    | S<br>S<br>S                               |                                          |                      |                 | Not Reported<br>Not Reported<br>Not Reported                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                                                                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 30-Aug-2005                                                                                                                                   | 5868967                                                                                                                       | NON-EXPEDITED    | N                  |                                           | US-BRISTOL-MYERS SQUIBB COMPANY-12971420 |                      | 43 YR           | Female                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                                                                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                        |         |   |      |  |                          |  |  |              |
|------------------------|---------|---|------|--|--------------------------|--|--|--------------|
| Abdominal Distension;  | Abilify | S |      |  |                          |  |  | Not Reported |
| Amenorrhoea; Blister;  | Lexapro | S | Oral |  | Increased To 20 Mg/Day   |  |  | Not Reported |
| Constipation; Face     |         |   |      |  | After 1 Week Of Therapy. |  |  |              |
| Oedema;                | Lexapro | S | Oral |  | Increased To 20 Mg/Day   |  |  | Not Reported |
| Hypomenorrhoea;        |         |   |      |  | After 1 Week Of Therapy. |  |  |              |
| Increased Tendency To  | Topamax | C |      |  |                          |  |  | Not Reported |
| Bruise; Menorrhagia;   | Ambien  | C |      |  |                          |  |  | Not Reported |
| Polymenorrhoea; Vision | Ativan  | C |      |  |                          |  |  | Not Reported |
| Blurred                |         |   |      |  |                          |  |  |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2005              | 5869013       | NON-EXPEDITED    | Y                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12984332 |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Drug Interaction;    | Abilify        |              |            | S           |              |                    |                 | Not Reported |
| Intentional Product         | Cytomel        |              |            | S           |              |                    |                 | Not Reported |
| Misuse; Irritability;       | Klonopin       |              |            | S           |              |                    |                 | Not Reported |
| Lethargy; Suicidal Ideation | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                             | Strattera      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2005              | 5869153       | NON-EXPEDITED    | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13043013 |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------|-----------------|--------------|
| Parkinsonism          | Abilify        |              |            | S           | Oral         |                                                                                           |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | Dosage: Increased To<br>20mg Daily On 03-Jan-<br>2005                                     |                 | Not Reported |
|                       | Prozac         |              |            | S           | Oral         | Dosage: 20mg Daily 07-<br>Feb-2005 To Unknown,<br>40mg Daily 24-Apr-2005<br>To Continuing |                 | Not Reported |
|                       | Depakote       |              |            | C           |              |                                                                                           |                 | Not Reported |
|                       | Lisinopril     |              |            | C           |              |                                                                                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |   |              |
|----------------------------------------------------------------|---|--------------|
| Diovan                                                         | C | Not Reported |
| Coreg                                                          | C | Not Reported |
| Wellbutrin                                                     | C | Not Reported |
| Dosage: Decreased To 200mg Daily On 11-Apr-2005 And Continuing |   |              |
| Acetaminophen\Hydrocodone Bitartrate                           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 30-Aug-2005              | 5869533        | NON-EXPEDITED    | N                  |                 | US-GLAXOSMITHKLINE-A0558167A |                      | 42 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Insomnia      | Wellbutrin XI  |                  |                    | S               | Oral                         | 150mg Per Day        | 8 WEEK          | Glaxosmithkline |                |
|                          | Effexor Xr     |                  |                    | S               | Oral                         | 37.5mg Per Day       | 4 YR            | Not Reported    |                |
|                          | Lexapro        |                  |                    | S               | Oral                         |                      |                 | Not Reported    |                |
|                          | Celebrex       |                  |                    | C               |                              |                      |                 | Not Reported    |                |
|                          | Neurontin      |                  |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Aug-2005              | 5869575        | NON-EXPEDITED    | Y                  |                 | US-GLAXOSMITHKLINE-A0559560A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hyperhidrosis            | Wellbutrin XI  |                  |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Aug-2005              | 5869690        | NON-EXPEDITED    | N                  |                 | US-GLAXOSMITHKLINE-A0562623A |                      | 55 YR           | Male            | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness; Myalgia       | Wellbutrin     |                  |                    | S               | Oral                         | 150mg Per Day        | 6 DAY           | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                          | Prevacid       |                  |                    | C               |                              |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Aug-2005                                                                                                     | 5870084        | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2005UW12747          |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Cardio-Respiratory Arrest;<br>Liver Disorder; Multiple<br>Organ Dysfunction<br>Syndrome | Seroquel       |                    |                    | S               | Oral                 |                      |                 | Zeneca       |                |
|                                                                                                                 | Lithium        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Vistaril       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2005                                                                                                     | 5871968        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04051-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                         | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2005                                                                                                     | 5871969        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04045-01     |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Weight<br>Increased                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                 | Antibiotics    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2005                                                                                                     | 5871970        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04027-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal<br>Haemorrhage; Platelet<br>Disorder                                                           | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                 | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 31-Aug-2005                                                                                                                                                 | 5874213          | EXPEDITED (15-DAY) | Y                  | CA              | S05-UKI-03089-02     |                         |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Palate;<br>Dysmorphism; Finger<br>Deformity; Maternal<br>Exposure During<br>Pregnancy                                                                 | Cipralext        |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                             | Prochlorperazine |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2005                                                                                                                                                 | 5874236          | EXPEDITED (15-DAY) | Y                  | DE              | S05-UKI-03087-01     |                         | 54 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Head<br>Injury; Multiple Injuries                                                                                                        | Cipralext        |                    |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2005                                                                                                                                                 | 5874657          | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-03967-01     |                         | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Completed<br>Suicide; Condition<br>Aggravated; Drug<br>Ineffective; Drug<br>Withdrawal Syndrome;<br>Insomnia; Nervousness;<br>Restlessness; Tremor | Lexapro          |                    |                    | S               | Unknown              | Unk                     |                 | Not Reported |                |
|                                                                                                                                                             | Effexor          |                    |                    | S               | Unknown              | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2005                                                                                                                                                 | 5874663          | EXPEDITED (15-DAY) | Y                  | HO, RI          | S05-USA-06025-01     |                         | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorectal Disorder;                                                                                                                                         | Lexapro          |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                              |                              |        |      |             |                              |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------|------|-------------|------------------------------|
| Asthma; Forceps Delivery;<br>Maternal Exposure During<br>Pregnancy; Muscle Strain;<br>Pregnancy; Premature<br>Labour; Vaginal<br>Haemorrhage | Lexapro<br>Prenatal Vitamins | S<br>C | Oral | 20 Mg Qd Po | Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------|------|-------------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2005              | 5859869       | EXPEDITED (15-DAY) | Y                  | HO              | S05-PRT-02685-01     |                      | 58 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                      | <u>Product</u>                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Abdominal Pain;<br>Depression; Diarrhoea;<br>Faeces Pale;<br>Hyperhidrosis | Ciprallex<br>Warfarin Sodium<br>Digoxin<br>Amiloride Hcl W/<br>Hydrochlorothiazide |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2005              | 5874892       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04059-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Homicide              | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2005              | 5874922       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04061-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Homicidal Ideation;<br>Physical Assault | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2005              | 5875407       | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2005IT01511      |                      | 60 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                           |   |                         |              |
|------------------------|---------------------------|---|-------------------------|--------------|
| Drug Interaction;      | Mirtazapine               | S | 15 Mg, Qd; 7.5, Qd      | Not Reported |
| Epistaxis; Platelet    | Venlafaxine Hydrochloride | S | 150 Mg, Qd; 100 Mg, Qd; | Not Reported |
| Aggregation Increased; |                           |   | 37.5 Mg, Qd             |              |
| Rectal Haemorrhage     | Escitalopram Oxalate      | S | 20 Mg, Qd; 15 Mg, Qd; 5 | Not Reported |
|                        | Omeprazole                | C | Mg, Qd                  | Not Reported |
|                        | Irbesartan                | C |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2005              | 5849936       | EXPEDITED (15-DAY) | Y                  | OT              | 2005PK01362          |                      | 39 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Incomplete;<br>Abortion Missed; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Seroquel       |              |            | S           |              | 50 Mg Up To 400 Mg |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              | 50 Mg Up To 400 Mg |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    | 7 DAY           | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    | 7 DAY           | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Seroquel       |              |            | S           |              |                    |                 | Zeneca       |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    | 5 DAY           | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    | 5 DAY           | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                              | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 06-Sep-2005                                                                                                                                                                                                                                                                                                          | 5872246        | EXPEDITED (15-DAY) | N                  | HO, OT          | 2005116861           |                             | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthropod Bite; Drug Ineffective; Dry Mouth; Foot Fracture; Hip Arthroplasty; Hyperhidrosis; Incorrect Dose Administered; Insomnia; Migraine                                                                                                                                                                         | Detrol La      |                    |                    | S               | Oral                 | 4 Mg (4 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Soma           |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Lexapro        |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Celebrex       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Plaquenil      |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Neurontin      |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2005                                                                                                                                                                                                                                                                                                          | 5876716        | DIRECT             | N                  | CA, DS, LT, RI  |                      |                             | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Balance Disorder; Brain Injury; Bruxism; Chills; Disturbance In Attention; Dysstasia; Fall; Headache; Heart Rate Increased; Hyperacusis; Hypersensitivity; Hypertension; Panic Reaction; Paraesthesia; Photophobia; Premature Ejaculation; Sexual Dysfunction; Sleep Disorder; Vertigo; Weight Increased | Lexapro        |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Zoloft         |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Provigil       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Trileptal      |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Seroquel       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Buspar         |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Ultramadol     |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Flexeril       |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Sep-2005                                                                                                                                                                                                                                                                                                          | 5877001        | EXPEDITED (15-DAY) | Y                  | HO              | T05-USA-03086-01     |                             | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                               |                                                                                        |                            |          |                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------|----------|----------------------------------------------------------------------------------------------|
| Anhedonia; Antibody Test Positive; Caesarean Section; Depressed Mood; Feeling Guilty; Gestational Diabetes; Initial Insomnia; Libido Decreased; Maternal Exposure During Pregnancy; Metrorrhagia; Mitral Valve Prolapse; Pneumonia; Pre-Eclampsia; Pregnancy; Premature Baby; Stress; Tachycardia; Upper Respiratory Tract Infection; Urinary Tract Infection | Escitalopram Oxalate<br>Claritin<br>Zoloft<br>Prenatal Vitamins<br>Rhogam<br>Albuterol | S<br>C<br>C<br>C<br>C<br>C | 10 Mg Qd | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------|----------|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2005              | 5877003       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04134-01     |                      | 93 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|---------------------------------------|-----------------------------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Febrile Neutropenia; Hepatototoxicity | Lexapro (Escitalopram)<br>Zelnorm<br>Nexium (Esomeprazole)<br>Hydrochlorothiazide |              |            | S<br>C<br>C<br>C | Oral         | 20 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2005              | 5877262       | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-03165-01     |                      | 34 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Weight Increased      | Ciprallex<br>Fluoxetine<br>Arthrotec |              |            | S<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2005              | 5880276       | EXPEDITED (15-DAY) | Y                  | HO              | S05-UKI-03169-01     |                      | 48 YR      | Female     | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Chest Pain; Sinus Arrhythmia                                                                                                    | Ciprallex                      |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2005                                                                                                                     | 5864509                        | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-USA-01042-01              |                               | 53 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dehydration; Dizziness; Dry Mouth; Escherichia Infection; Nausea; Therapeutic Response Unexpected; Urinary Retention; Urosepsis | Lexapro                        |                           |                             | S                        | Oral                          | 20 Mg Bid Po                  |                          | Not Reported        |                         |
|                                                                                                                                 | Lexapro                        |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                 | Lexapro                        |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                 | Trileptal                      |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Crestor                        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Hydrochlorothiazide            |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Sep-2005                                                                                                                     | 5863883                        | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | S05-AUS-02778-01              |                               | 53 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia; Seizure                                                                                                          | Lexapro                        |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                 | Lexapro                        |                           |                             | S                        | Oral                          | 15 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                 | Ramipril                       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Metoprolol                     |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Norvasc                        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Aspirin (Acetylsalicylic Acid) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Clopidogrel                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Allopurinol                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                 | Lipitor                        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Sep-2005                                                                                                                     | 5872623                        | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-USA-03979-01              |                               | 53 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                          |                                      |   |      |             |              |
|------------------------------------------------------------------------------------------|--------------------------------------|---|------|-------------|--------------|
| Abdominal Pain; Dry Mouth; Insomnia; Postmenopausal Haemorrhage; Urinary Tract Infection | Lexapro                              | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                          | Progesterone                         | S |      |             | Not Reported |
|                                                                                          | Estrogens                            | S |      |             | Not Reported |
|                                                                                          | Wellbutrin (Bupropion Hydrochloride) | C |      |             | Not Reported |
|                                                                                          | Lisinopril                           | C |      |             | Not Reported |
|                                                                                          | Singulair                            | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2005              | 4215792       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S04-USA-06025-01     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthma; Forceps Delivery; Labour Complication; Labour Induction; Maternal Exposure During Pregnancy; Muscle Strain; Premature Labour; Vaginal Haemorrhage | Lexapro           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                           | Lexapro           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                           | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2005              | 5880535       | DIRECT           | N                  | OT              |                      |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acne; Alopecia; Androgenetic Alopecia | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Forest       |
|                                       | Bactrim        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2005              | 5880592       | DIRECT           | N                  | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia              | Lexapro          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Forest       |
|                       | Ortho Tri Cyclen |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2005                                                                                                               | 5880808        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04116-01     |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Confusional State;<br>Constipation; Dementia<br>Alzheimer'S Type; Gait<br>Disturbance; Treatment<br>Noncompliance | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                           | Namenda        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                           | Namenda        |                    |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                                                                           | Namenda        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                           | Namenda        |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                           | Reminyl        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2005                                                                                                               | 5881328        | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-UKI-03255-01     |                      | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematemesis; Melaena                                                                                                     | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                                                                               | 5795242        | NON-EXPEDITED      | Y                  | HO, OT          | S05-USA-00617-01     |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Depression;<br>Suicidal Ideation                                                       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                           | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                           | Saizen         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                           | Metadate Cd    |                    |                    | S               | Oral                 | 20 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                           | Synthroid      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                                                                               | 5804657        | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-01759-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |                           |   |      |               |         |                 |
|-------------------------------------------------------------------------------|---------------------------|---|------|---------------|---------|-----------------|
| Diplopia; Drug Interaction;<br>Facial Paralysis; Nausea;<br>Vertigo; Vomiting | Wellbutrin                | S | Oral | 150mg Per Day |         | Glaxosmithkline |
|                                                                               | Lexapro                   | S | Oral | 40mg Per Day  | 357 DAY | Forest          |
|                                                                               | No Concurrent Medications | C |      |               |         | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5822551       | NON-EXPEDITED    | Y                  | HO              | S05-USA-01861-01     |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastric Haemorrhage   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Aspirin        |              |            | S           |              |                    |                 | Not Reported |
|                       | Alcohol        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5822589       | NON-EXPEDITED    | Y                  | HO              | S05-USA-01146-01     |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nephrolithiasis       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Trivora        |              |            | C           |              |                    |                 | Not Reported |
|                       | Dynacin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5822739       | NON-EXPEDITED    | Y                  | HO              | S05-USA-02568-01     |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Blood Pressure<br>Decreased; Drug<br>Interaction; Heart Rate<br>Increased; Intentional<br>Product Misuse; Irritability;<br>Lethargy; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                               | Lexapro        |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                                         | Cytomel            |                    | S               |                       |                      |                 |              | Not Reported   |
|------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
|                                                                  |                                         | Abilify            |                    | S               |                       |                      |                 |              | Not Reported   |
|                                                                  |                                         | Klonopin           |                    | S               |                       |                      |                 |              | Not Reported   |
|                                                                  |                                         | Strattera          |                    | C               |                       |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                      | 5827206                                 | EXPEDITED (15-DAY) | Y                  | HO              | S05-NOR-02118-01      |                      |                 | Female       | NOR            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Diarrhoea; Dysphonia;<br>Tremor        | Ciprallex                               |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                      | 5844939                                 | EXPEDITED (15-DAY) | Y                  | LT, OT          | S05-UKI-02358-01      |                      | 59 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intracranial Aneurysm;<br>Subarachnoid<br>Haemorrhage            | Ciprallex                               |                    |                    | S               | Oral                  | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                  | Clopidogrel                             |                    |                    | S               | Oral                  | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Aspirin (Acetylsalicylic Acid)          |                    |                    | S               | Oral                  | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Salmeterol                              |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                  | Terbutaline Sulfate                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                  | Lekovit Ca                              |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                  | Tiotropium Bromide (Tiotropium Bromide) |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                  | Atorvastatin                            |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                  | Pantoprazole Sodium                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                      | 5877657                                 | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20050901973 |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Failure<br>Congestive; Cerebral<br>Infarction; Completed | Acetaminophen And Codeine Phosphate     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Acetaminophen\Hydrocodone               |                    |                    | S               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                           |   |   |  |  |  |  |  |              |
|--------------------------|---------------------------|---|---|--|--|--|--|--|--------------|
| Suicide; Intentional     | Acetaminophen\Hydrocodone |   | S |  |  |  |  |  | Not Reported |
| Product Misuse; Liver    | Escitalopram Oxalate      |   | S |  |  |  |  |  | Not Reported |
| Function Test Abnormal;  | Ibuprofen                 |   | S |  |  |  |  |  | Not Reported |
| Pneumonia; Renal Failure | Celecoxib                 |   | S |  |  |  |  |  | Not Reported |
|                          | Zolpidem                  |   | S |  |  |  |  |  | Not Reported |
|                          | Metronidazole             |   | S |  |  |  |  |  | Not Reported |
|                          | Diazepam                  |   | S |  |  |  |  |  | Not Reported |
|                          | Metaxalone                |   | S |  |  |  |  |  | Not Reported |
|                          | Amitriptyline             |   | S |  |  |  |  |  | Not Reported |
|                          | Citalopram                |   | S |  |  |  |  |  | Not Reported |
|                          | Metformin                 |   | S |  |  |  |  |  | Not Reported |
|                          | Aspirin                   |   | S |  |  |  |  |  | Not Reported |
|                          | Bupropion                 |   | S |  |  |  |  |  | Not Reported |
|                          | Codeine                   |   | S |  |  |  |  |  | Not Reported |
|                          | Promethazine              |   | S |  |  |  |  |  | Not Reported |
|                          | Nabumetone                |   | S |  |  |  |  |  | Not Reported |
|                          | Ibuprofen                 | Y | S |  |  |  |  |  | Not Reported |
|                          | Asa                       | Y | S |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5881347       | DIRECT           | Y                  | OT              |                      |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alopecia              | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5881891       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-04205-01     |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun<br>Shot Wound; Partner<br>Stress; Treatment<br>Noncompliance | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5882911       | DIRECT           | N                  | DE              |                      |                      | 37 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Confusional State;<br>Intentional Product Misuse | Zoloft          |                    |                    | S               | Oral                 | 1 Day Po             |                 | Not Reported |                |
|                                                                        | Lexapro         |                    |                    | S               |                      | 1 Day                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                            | 5883009         | EXPEDITED (15-DAY) | Y                  | DS, HO          | S05-UKI-03314-01     |                      | 33 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Magnesium<br>Decreased; Generalised<br>Tonic-Clonic Seizure      | Cipralext       |                    |                    | S               | Oral                 | 20 Mg Po             |                 | Not Reported |                |
|                                                                        | Granisetron     |                    |                    | S               | Subcutaneous         | 2 Mg Daily Sc        |                 | Not Reported |                |
|                                                                        | Feldene         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Oxybutynin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Gabapentin      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Lorazepam       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Loperamide      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Levomepromazine |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Metronidazole   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                            | 5883403         | EXPEDITED (15-DAY) | Y                  | LT, OT          | S05-UKI-03317-01     |                      | 41 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Gastrointestinal<br>Haemorrhage               | Cipralext       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Zumeston        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Lormetazepam    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Diazepam        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                            | 5883408         | EXPEDITED (15-DAY) | Y                  | OT              | S05-CAN-03318-01     |                      | 80 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Product Quality Issue;                       | Cipralext       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Lexapro         |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

#### Seizure

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2005                      | 5883412        | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-03313-01     |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure | Cipralex       |                    |                    | S               |                      | 10 Mg Po             |                 | Not Reported |                |
|                                  | Zolpidem       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                  | Dothiepin      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2005              | 5884729        | NON-EXPEDITED    | Y                  | HO              | S05-USA-03909-01     |                      | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2005              | 5884732        | NON-EXPEDITED    | N                  | DS              | S05-USA-03754-01     |                      | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Diplopia     | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Digoxin        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Coumadin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Altace         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Pravachol      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Allopurinol    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Synthroid      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Lasix          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Singulair      |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2005              | 5884734       | NON-EXPEDITED    | N                  | HO              | S05-USA-03625-01     |                      | 56 YR      | Male       | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Mania; Suicidal Ideation                                                                                             | Lexapro             |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Zyprexa             |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                      | Aricept             |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                      | Lisinopril          |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                      | Ambien              |                  |                    | C               |                      |                      | Not Reported    |              |                |
|                                                                                                                      | Hydrochlorothiazide |                  |                    | C               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                                                                          | 5884737             | NON-EXPEDITED    | N                  | HO, LT          | S05-USA-03610-01     |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Fatigue;<br>Irritability; Suicide Attempt                                          | Lexapro             |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                                                                          | 5884739             | NON-EXPEDITED    | N                  | HO              | S05-USA-03603-01     |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Malaise; Suicide Attempt                                                                                    | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Lexapro             |                  |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Tenex               |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005                                                                                                          | 5884740             | NON-EXPEDITED    | N                  | HO              | S05-USA-03515-01     |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dry Mouth;<br>Dysuria; Genital Burning<br>Sensation; Rib Fracture;<br>Suicidal Ideation; Suicide Attempt | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Lexapro             |                  |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Lexapro             |                  |                    | S               |                      | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                      | Lexapro             |                  |                    | S               |                      | 20 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                           |                    |                    |                 |                       |                      |                 |              |                |
|--------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Clonazepam               |                           |                    | C                  |                 |                       | Not Reported         |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2005              | 6299532                   | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20050902024 |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatinine         | Haldol                    |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Increased; Hepatic       | Ziprasidone Hydrochloride |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Enzyme Increased;        | Benzotropine              |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Hyperpyrexia;            | Escitalopram Oxalate      |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Hypotension; Muscle      | Clonazepam                |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Rigidity; Ventricular    | Simvastatin               |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Tachycardia              | Bupropion                 |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2005              | 5879232                   | EXPEDITED (15-DAY) | Y                  | DE              | CH-JNJFOC-20050901541 |                      |                 | Male         | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Haldol                    |                    |                    | S               | Oral                  | Reported As 3-4mg    |                 | Not Reported |                |
|                          | Haldol                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Haldol                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Haldol                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Haldol                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Remeron                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Remeron                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Remeron                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Lorazepam                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |                                          |
|----------------------|---|------|------------------------------------------|
| Cipralex             | S | Oral | Not Reported                             |
| Cipralex             | S | Oral | Not Reported                             |
| Agar\Phenolphthalein | S | Oral | Not Reported                             |
| Agar\Phenolphthalein | S | Oral | Not Reported                             |
| Agar\Phenolphthalein | S | Oral | Not Reported                             |
| Cosaar Plus          | S | Oral | Not Reported                             |
| Cosaar Plus          | S | Oral | Had Been Taken For Years<br>Not Reported |
| Sortis               | S | Oral | Had Been Taken For Years<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2005              | 5879627       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20050902016 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bundle Branch Block;<br>Cardiac Arrest; Completed<br>Suicide; Intentional<br>Product Misuse; Loss Of<br>Consciousness;<br>Overdose; Serotonin<br>Syndrome | Topamax              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                           | Bupropion            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                           | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                           | Oxcarbazepine        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2005              | 5879631       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20050901926 |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Oxycodone And Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Oxycodone                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Diazepam                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                         |                       | Quetiapine         |                    | S               | Oral                  |                                      |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                         |                       | Gabapentin         |                    | S               | Oral                  |                                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2005                                                                                                                                                                                             | 6747156               | NON-EXPEDITED      | N                  | OT              | US-JNJFOC-20040806645 |                                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mouth Ulceration                                                                                                                                                                                        | Topamax               |                    |                    | S               | Oral                  | 25 Mg, In 1 Day, Oral                |                 | Not Reported |                |
|                                                                                                                                                                                                         | Escitalopram Oxalate  |                    |                    | S               | Oral                  | 25 Mg, In 1 Day , Oral;<br>See Image |                 | Not Reported |                |
|                                                                                                                                                                                                         |                       |                    |                    |                 | Oral                  | 25 Mg, In 1 Day , Oral;<br>See Image |                 |              |                |
|                                                                                                                                                                                                         | Zoloft                |                    |                    | S               | Oral                  | 150 Mg, In 1 Day, Oral               |                 | Not Reported |                |
|                                                                                                                                                                                                         | Vioxx                 |                    |                    | S               |                       | 25 Mg, In 1 Day                      |                 | Not Reported |                |
|                                                                                                                                                                                                         | Zocor                 |                    |                    | C               |                       |                                      |                 | Not Reported |                |
|                                                                                                                                                                                                         | Nexium (Esomeprazole) |                    |                    | C               |                       |                                      |                 | Not Reported |                |
|                                                                                                                                                                                                         | Mirapex               |                    |                    | C               |                       |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2005                                                                                                                                                                                             | 5837867               | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03294-01      |                                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Basal Ganglion Degeneration; Dry Mouth; Dysarthria; Nervous System Disorder; Nervousness; Nuclear Magnetic Resonance Imaging Brain Abnormal; Restlessness; Speech Disorder; Tardive Dyskinesia | Lexapro               |                    |                    | S               | Oral                  | 10 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                                                                                                                                         | Namenda               |                    |                    | S               | Oral                  | 10 Mg Bid Po                         |                 | Not Reported |                |
|                                                                                                                                                                                                         | Namenda               |                    |                    | S               | Oral                  | 5 Mg Qd Po                           |                 | Not Reported |                |
|                                                                                                                                                                                                         | Namenda               |                    |                    | S               | Oral                  | 5 Mg Bid Po                          |                 | Not Reported |                |
|                                                                                                                                                                                                         | Namenda               |                    |                    | S               | Oral                  | 15 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                                                                                                                                         | Aricept               |                    |                    | S               |                       | 10 Mg Qd                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2005                                                                                                                                                                                             | 5842005               | EXPEDITED (15-DAY) | Y                  | DE              | S05-UKI-02357-01      |                                      |                 | Male         | GBR            |

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| <a href="#">Preferred Term</a>                                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Completed Suicide                                                                                                                                                          | Ciprallex               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Sep-2005                                                                                                                                                                | 5866528                 | EXPEDITED (15-DAY)        | N                           | OT                       | S05-USA-03905-01              |                               | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated;<br>Petit Mal Epilepsy                                                                                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qhs Po                  |                          | Not Reported        |                         |
|                                                                                                                                                                            | Zonegran                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                                            | Phenobarbital           |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Sep-2005                                                                                                                                                                | 5885544                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-ITA-03334-01              |                               | 45 YR                    | Female              | ITA                     |
| <a href="#">Preferred Term</a>                                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Angioedema; Urticaria                                                                                                                                                      | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2005                                                                                                                                                                | 5836038                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-USA-03276-01              |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Disorder; Feeling<br>Abnormal; Heart Rate<br>Irregular; Loss Of<br>Consciousness; Sinus<br>Bradycardia; Sinus<br>Tachycardia;<br>Supraventricular<br>Extrasystoles | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                            | Vioxx                   |                           |                             | S                        | Oral                          | 25 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                            | Fosamax                 |                           |                             | S                        | Oral                          | 70 Mg Qw Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2005                                                                                                                                                                | 5845150                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S05-USA-03457-01              |                               | 31 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                                                                                                        |                      |                    |                    |                 |                      |                      |                 |            |                |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| Completed Suicide; Gun Shot Wound                                                                      |                      | Lexapro            | S                  | Oral            | 10 Mg Qd Po          |                      | Not Reported    |            |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2005                                                                                            | 5885323              | DIRECT             | N                  | DE              |                      |                      | 61 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide                                                                                      | Lexapro              |                    |                    | S               |                      |                      | 30 DAY          | Forest     |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Sep-2005                                                                                            | 5835587              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S05-PAN-02194-01     |                      | 16 YR           | Female     | PAN            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Interaction;<br>Intentional Product Misuse; Overdose; Suicide Attempt; Toxicity To Various Agents | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                        | Zolpidem             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                        | Zolpidem             |                    |                    | S               | Oral                 | 400 Mg Once Po       |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Sep-2005                                                                                            | 5886500              | EXPEDITED (15-DAY) | Y                  | OT              | S05-PRT-03392-01     |                      | 28 YR           | Female     | PRT            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition Aggravated; Drug Ineffective; Psychomotor Hyperactivity                             | Ciprallex            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                        | Bromazepam           |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Sep-2005                                                                                            | 5886748              | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-04155-01     |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Toxicity To Various Agents                                                                             | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 |            | Not Reported   |

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|  |          |   |      |              |              |
|--|----------|---|------|--------------|--------------|
|  | Lexapro  | S | Oral | 20 Mg Bid Po | Not Reported |
|  | Percocet | C |      |              | Not Reported |
|  | Klonopin | C |      |              | Not Reported |
|  | Seroquel | C |      |              | Not Reported |
|  | Fioricet | C |      |              | Not Reported |
|  | Caltrate | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Sep-2005              | 5883634              | EXPEDITED (15-DAY) | Y                  | DE              | 2005AC01406          |                      | 40 YR           | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Quetiapine           |                    |                    | S               |                      | Route: Aspiration    |                 | Zeneca       |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Clonazepam           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Sep-2005              | 5885462              | EXPEDITED (15-DAY) | Y                  | DE              | 2005AC01471          |                      | 25 YR           | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Amitriptyline        |                    |                    | S               | Oral                 |                      |                 | Zeneca       |                |
|                          | Alprazolam           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Sep-2005              | 5890407              | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-03473-01     |                      | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Prazepam             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Equanil              |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2005              | 5891112       | EXPEDITED (15-DAY) | Y                  | DE              | 2005129275           |                      | 25 YR      | Unknown    | USA            |

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| <u>Preferred Term</u>                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cardio-Respiratory Arrest;<br>Intentional Product<br>Misuse; Overdose                       | Alprazolam (Alprazolam)     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Amitriptyline Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Unspecified Ingredient      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2005                                                                                 | 5891475                     | EXPEDITED (15-DAY) | Y                  | DE              | 2005129277           |                      | 50 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose                                                              | Doxepin Hydrochloride       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Metoprolol Tartrate         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Unspecified Ingredient      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                 | 5854479                     | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-02532-01     |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hypertension;<br>Hypokalaemia                                                      | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                 | 5874651                     | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-04006-01     |                      | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Suicidal Ideation; Thinking<br>Abnormal; Toxicologic<br>Test Abnormal | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Tramadol                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Minocycline\Minocycline     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Hydrochloride               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                 | 5874894                     | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04044-01     |                      | 45 YR           | Female       | USA            |



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| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Bulimia Nervosa;<br>Depression; Restlessness;<br>Weight Increased                                                                               | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Abilify        |                    |                    | S               |                      | 20 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                 | Klonopin       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                                                                     | 5892694        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04330-01     |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased;<br>Drug Interaction                                                                                                    | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                                                                     | 5892695        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04289-01     |                      | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Calcinosis; Herpes Zoster;<br>Hyperthyroidism; Thyroid<br>Neoplasm                                                     | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Flomax         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Proscar        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2005                                                                                                                                     | 5892703        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04381-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Decreased<br>Appetite; Drug Interaction;<br>Feeling Abnormal | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                 | Lipitor        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Lipitor        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 29-Sep-2005                                                                 | 5888143        | EXPEDITED (15-DAY) | N                  | LT              | US-JNJFOC-20050905751 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                                       | Tylenol        |                    | Y                  | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Tylenol        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Klonopin       |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2005                                                                 | 5712077        | EXPEDITED (15-DAY) | Y                  | DE              | S04-UKI-08243-01      |                      | 17 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Completed Suicide; Depression; Victim Of Homicide              | Ciprallex      |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2005                                                                 | 5889229        | EXPEDITED (15-DAY) | N                  | LT              | US-JNJFOC-20050905735 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                                       | Motrin         |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Lexapro        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Klonopin       |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2005                                                                 | 5892030        | DIRECT             | Y                  | HO              |                       |                      | 95 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Generalised Exanthematous Pustulosis; Pyrexia; White Blood Cell Count | Lexapro        |                    |                    | S               |                       |                      | 3 WEEK          | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2005              | 4032971       | EXPEDITED (15-DAY) | N                  | DS, HO, OT      | 2003114592           |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Abnormal Behaviour;        | Geodon         |              |            | S           | Oral         | 80 Mg (Daily), Oral            |                 | Not Reported |
| Bradyphrenia;              | Xanax          |              |            | S           |              |                                |                 | Not Reported |
| Cholelithiasis;            | Lexapro        |              |            | S           |              |                                |                 | Not Reported |
| Coordination Abnormal;     | Topamax        |              |            | S           |              | 100 Mg                         |                 | Not Reported |
| Depression; Diplegia;      | Prozac         |              |            | S           |              | 40 Mg (Qd Interval: Every Day) |                 | Not Reported |
| Disorientation; Dizziness; |                |              |            |             |              |                                |                 |              |
| Drug Dependence; Drug      |                |              |            |             |              |                                |                 |              |
| Interaction; Drug          | Cymbalta       |              |            | S           |              |                                |                 | Not Reported |
| Withdrawal Syndrome; Dry   | Climara        |              |            | C           |              |                                |                 | Not Reported |
| Mouth; Dysarthria; Feeling | Adderall       |              |            | C           |              |                                |                 | Not Reported |
| Abnormal; Feeling Cold;    |                |              |            |             |              |                                |                 |              |
| Gait Disturbance; Gait     |                |              |            |             |              |                                |                 |              |
| Inability; Glossodynia;    |                |              |            |             |              |                                |                 |              |
| Hallucination; Headache;   |                |              |            |             |              |                                |                 |              |
| Hot Flush; Hyperhidrosis;  |                |              |            |             |              |                                |                 |              |
| Impaired Work Ability;     |                |              |            |             |              |                                |                 |              |
| Major Depression; Mental   |                |              |            |             |              |                                |                 |              |
| Disorder; Mood Swings;     |                |              |            |             |              |                                |                 |              |
| Oral Pain; Panic Attack;   |                |              |            |             |              |                                |                 |              |
| Paranoia; Photophobia;     |                |              |            |             |              |                                |                 |              |
| Photopsia; Psychotic       |                |              |            |             |              |                                |                 |              |
| Disorder; Schizoaffective  |                |              |            |             |              |                                |                 |              |
| Disorder; Sjogren'S        |                |              |            |             |              |                                |                 |              |
| Syndrome; Stupor;          |                |              |            |             |              |                                |                 |              |
| Suicidal Ideation          |                |              |            |             |              |                                |                 |              |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>                      | <u>Sex</u>      | <u>Country</u>   |
|----------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|---------------------------------|-----------------|------------------|
| 03-Oct-2005                                        | 5892185        | DIRECT           | N                  | LT              |                      |                      | 21 YR                           | Male            | USA              |
| <u>Preferred Term</u>                              | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>       |
| Aggression; Personality Change; Suicidal Ideation; | Strattera      |                  |                    |                 | S                    | Oral                 | One Pill Per Day One Per Day Po |                 | Eli Lilly And Co |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |         |   |      |                            |              |
|----------------------------------------------------------|---------|---|------|----------------------------|--------------|
| Suicide Attempt; Thinking Abnormal; Threat Of Redundancy | Lexapro | S | Oral | One Per Day One Per Day Po | Not Reported |
|----------------------------------------------------------|---------|---|------|----------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2005              | 5896027       | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-04408-01     |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;                                                                                                                                                                                                                                      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Aggression; Agitation;                                                                                                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 20 Mg Po           |                 | Not Reported |
| Anger; Anxiety; Completed Suicide; Condition Aggravated; Depressed Mood; Depression; Drug Ineffective; Drug Ineffective For Unapproved Indication; Educational Problem; Hostility; Intentional Self-Injury; Overdose; Suicidal Ideation; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 10 Mg Po           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2005              | 5896030       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-04399-01     |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure Increased; Diplopia;                                   | Lexapro        |              |            | S           | Oral         | 40 Mg Qhs Po       |                 | Not Reported |
| Feeling Jittery; Heart Rate Increased; Intentional Self-Injury; Muscle Spasms; | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Mydriasis; Thinking Abnormal; Tremor                                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                | Adderall       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2005              | 5896686       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_27145_2005       |                      | 58 YR      | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Intentional Product<br>Misuse; Overdose | Lorazepam            |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
|                                                               | Valproic Acid        |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
|                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Oct-2005                                                   | 5803797              | EXPEDITED (15-DAY) | Y                  | DE              | S05-IRL-01738-01     |                      | 24 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Oct-2005                                                   | 5897973              | EXPEDITED (15-DAY) | Y                  | DE              | DSA_70813_2005       |                      | 42 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose                                                      | Methadone            |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                               | Tramadol             |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2005                                                   | 5898957              | EXPEDITED (15-DAY) | Y                  | DE              | PAR_0269_2005        |                      | 50 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose                                | Doxepin              |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
|                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
|                                                               | Metoprolol           |                    |                    | S               | Oral                 | Df Unk Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2005                                                   | 5900575              | EXPEDITED (15-DAY) | Y                  | DE              | AND_0038_2005        |                      | 55 YR           | Unknown      | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Overdose                                                                                                                                             | Acetaminophen And Codeine |                    |                    | S               | Unknown              | Df Unk Unk           |                 | Not Reported |                |
|                                                                                                                                                                            | Acetaminophen\Hydrocodone |                    |                    | S               | Unknown              | Df Unk Unk           |                 | Not Reported |                |
|                                                                                                                                                                            | Escitalopram Oxalate      |                    |                    | S               | Unknown              | Df Unk Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2005                                                                                                                                                                | 5901942                   | EXPEDITED (15-DAY) | Y                  | DE              | PAR_0326_2005        |                      | 58 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose                                                                                                                                             | Valproic Acid             |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                                                                                                                                            | Escitalopram Oxalate      |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                                                                                                                                            | Lorazepam                 |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2005                                                                                                                                                                | 5903182                   | DIRECT             | Y                  | HO, LT, RI      |                      |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen Positive;<br>Electrocardiogram<br>Abnormal;<br>Electrocardiogram Qt<br>Prolonged; Heart Rate<br>Irregular; Intentional<br>Product Misuse;<br>Overdose; Syncope | Escitalopram Oxalate      |                    |                    | S               | Oral                 | Po Tid               |                 | Not Reported |                |
|                                                                                                                                                                            | Bupropion                 |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                                                                                                                            | Folic Acid                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Thiamine                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                            | M.V.I. Adult              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Pancrelipase              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                            | Oxazepam                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2005                                                                                                                                                                | 5903358                   | DIRECT             | Y                  | DE              |                      |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide                                                                                                                                             | Geodon                    |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                                                                                                                            | Lexapro                   |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                            | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Oct-2005                                                                         | 5903480           | DIRECT           | Y                  | CA              |                      |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypermetropia; Maternal Exposure During Pregnancy; Small For Dates Baby; Strabismus | Lexapro           |                  |                    | S               | Oral                 | 20mg Daily Po        | 2 YR            | Not Reported |                |
|                                                                                     | Prenatal Vitamins |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                     | Phenergan         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                     | Antivert          |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Oct-2005                                                         | 5904313        | DIRECT           | Y                  | HO              |                      |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Intentional Product Misuse; Intentional Self-Injury; Overdose | Oxycodone      |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Seroquel       |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Ativan         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Topamax        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Tylenol        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Oct-2005                                                             | 5806087           | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-02559-02     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cyanosis Neonatal; Maternal Exposure During Pregnancy; Neonatal Hypoxia | Lexapro           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Prenatal Vitamins |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Oct-2005              | 5809412        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-02558-02     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                   |   |              |
|-----------------------------|-------------------|---|--------------|
| Pregnancy; Neonatal Hypoxia | Prenatal Vitamins | C | Not Reported |
|-----------------------------|-------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2005              | 5899542       | DIRECT           | Y                  | HO              |                      |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2005              | 5905382       | EXPEDITED (15-DAY) | Y                  | DS              | S05-NOR-03580-01     |                      | 85 YR      | Female     | NOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;    | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Decreased Appetite;   | Ciprallex      |              |            | S           | Oral         | 5 Mg Qod Po        |                 | Not Reported |
| Insomnia; Nausea;     | Clonazepam     |              |            | C           |              |                    |                 | Not Reported |
| Restlessness          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2005              | 5905387       | EXPEDITED (15-DAY) | Y                  | DE              | S05-NLD-03579-01     |                      | 79 YR      | Female     | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Disorder;     | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Haemorrhage           | Atenolol       |              |            | C           |              |                    |                 | Not Reported |
|                       | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |
|                       | Dextran        |              |            | C           |              |                    |                 | Not Reported |
|                       | Amaryl         |              |            | C           |              |                    |                 | Not Reported |
|                       | Metformin      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2005              | 5904068       | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-03644-01     |                      | 60 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glaucoma

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2005              | 5904073       | EXPEDITED (15-DAY) | Y                  | HO              | A044-002-005755      |                      | 85 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Depression; Drug Interaction; Faeces Discoloured; Gastritis Erosive; Gastrointestinal Haemorrhage; Melaena; Rectal Haemorrhage; Upper Gastrointestinal Haemorrhage | Aricept                                   |              |            | S           | Oral         | 10 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                                                                                                                                    | Escitalopram Oxalate                      |              |            | S           | Oral         | See Image             |                 | Not Reported |
|                                                                                                                                                                    |                                           |              |            |             | Oral         | See Image             |                 |              |
|                                                                                                                                                                    | Bendroflumethiazide (Bendroflumethiazide) |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                    | Latanoprost                               |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                    | Timolol Maleate                           |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2005              | 5904230       | EXPEDITED (15-DAY) | Y                  | DE              | 2005-BP-12458RO      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Ammonia Increased; Blood Bilirubin Increased; Mental Status Changes | Methadone Hydrochloride |              |            | S           | Oral         | 5 Mg Bid (5 Mg), Po 1 To 2 Weeks |                 | Not Reported |
|                                                                     | Seroquel                |              |            | S           | Oral         | 125 Mg Qhs Po 1 To 2 Weeks       |                 | Not Reported |
|                                                                     | Lexapro                 |              |            | S           | Oral         | 10 Mg/Day Po 1 To 2 Weeks        |                 | Not Reported |
|                                                                     | Xeloda                  |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2005              | 5905472       | DIRECT           | Y                  | OT              |                      |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Blood Sodium Decreased | Lexapro        |              |            | S           |              | 20ml Via J-Tube Daily |                 | Not Reported |
|                        | Protonix       |              |            | C           |              |                       |                 | Not Reported |
|                        | Synthroid      |              |            | C           |              |                       |                 | Not Reported |
|                        | Imipenim       |              |            | C           |              |                       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |              |
|--------------------------|---|--------------|
| Insulin Nos              | C | Not Reported |
| Procrit                  | C | Not Reported |
| Dilaudid                 | C | Not Reported |
| Zofran                   | C | Not Reported |
| Acetaminophen            | C | Not Reported |
| Vancomycin Hydrochloride | C | Not Reported |
| Ativan                   | C | Not Reported |
| Lasix                    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2005              | 5906704       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_0922_2005        |                      | 30 YR      | Unknown    | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose | Bupropion            |              |            | S           | Oral         | Df, Po             |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           |              | Df,                |                 | Not Reported |
|                                | Oxcarbazepine        |              |            | S           |              | Df,                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2005              | 5907141       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_0943_2005        |                      | 39 YR      | Unknown    | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose | Bupropion            |              |            | S           | Oral         | Df Po              |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           |              | Df                 |                 | Not Reported |
|                                | Topiramate           |              |            | S           |              | Df                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2005              | 5907144       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_0942_2005        |                      | 52 YR      | Unknown    | USA            |

| <u>Preferred Term</u>          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose | Bupropion                |              |            | S           | Oral         | Df Po              |                 | Not Reported |
|                                | Escitalopram Oxalate     |              |            | S           |              | Df                 |                 | Not Reported |
|                                | Paroxetine Hydrochloride |              |            | S           |              | Df                 |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2005                                                                                                          | 5853109        | NON-EXPEDITED      | Y                  | HO              | 2005SP000329                             |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cellulitis; Erythema Multiforme                                                                                      | Lunesta        |                    |                    | S               | Oral                                     | 2 Mg; Hs; Oral       |                 | Not Reported |                |
|                                                                                                                      | Lexapro        |                    |                    | S               | Oral                                     | 10 Mg; Qd; Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2005                                                                                                          | 5905842        | DIRECT             | N                  | RI              |                                          |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Drug Withdrawal Syndrome; Fatigue; Headache; Influenza Like Illness; Insomnia; Pain; Urinary Tract Disorder | Lexapro        |                    |                    | S               | Oral                                     | 1 10mg Pill Daily Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2005                                                                                                          | 5906070        | DIRECT             | N                  | HO              |                                          |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Dizziness; Hallucination, Auditory; Hallucination, Visual; Nausea; Nervous System Disorder; Vomiting    | Lexapro        |                    |                    | S               | Oral                                     | 10mg Once Daily Po   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2005                                                                                                          | 5902276        | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-13083746 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bulimia Nervosa; Depression; Increased                                                                               | Abilify        |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |          |   |      |                                                                |              |
|------------------------|----------|---|------|----------------------------------------------------------------|--------------|
| Appetite; Restlessness | Lexapro  | S | Oral | Dosage: Increased To 20 Mg Dially On 06-Aug-2005 To Continuing | Not Reported |
|                        | Klonopin | C |      |                                                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2005              | 5908207       | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-03775-01     |                      | 39 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Missed; Foetal Death; Maternal Exposure During Pregnancy | Cipralext      |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                   | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                   | Cipralext      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                   | Seroquel       |              |            | S           |              | 50 Mg Qd           |                 | Not Reported |
|                                                                   | Seroquel       |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |
|                                                                   | Seroquel       |              |            | S           |              | 250 Mg Qd          |                 | Not Reported |
|                                                                   | Seroquel       |              |            | S           |              | 400 Mg Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5878894       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04148-01     |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Disease Recurrence; Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                      | Zonegran       |              |            | C           |              |                    |                 | Not Reported |
|                                      | Seroquel       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5907978       | DIRECT           | Y                  | HO              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Pressure Increased; Dyspnoea; Feeling Abnormal; Flushing; Heart Rate Increased; Rash | Lexapro        |              |            | S           | Oral         | 10mg Qd Po         |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Macular; Sensation Of  
Foreign Body; Skin  
Burning Sensation

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5909888       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04588-01     |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Paraesthesia; Self-<br>Injurious Ideation; Suicidal<br>Ideation; Vertigo; Weight<br>Decreased | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                      | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5909892       | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-04561-01     |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Completed<br>Suicide; Gun Shot Wound;<br>Homicidal Ideation;<br>Physical Assault | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5909911       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-04578-01     |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Bilirubin Increased;<br>Blood Sodium Decreased;<br>Drug Interaction | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                           | Seroquel       |              |            | S           |              | 25 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2005              | 5909965       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04587-01     |                      | 45 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Withdrawal Syndrome                                                                                          | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2005                                                                                                       | 5885194                     | EXPEDITED (15-DAY) | Y                  | DE              | T05-SWI-03337-01     |                      | 72 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asphyxia; Completed Suicide; Depressive Symptom; Mutism; Restlessness; Sleep Disorder; Thinking Abnormal | Ciprallex                   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Ciprallex                   |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Remeron                     |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Remeron                     |                    |                    | S               | Oral                 | 60 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Haldol                      |                    |                    | S               | Oral                 | 3.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                   | Haldol                      |                    |                    | S               | Oral                 | 2 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Haldol                      |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Haldol                      |                    |                    | S               | Oral                 | 2 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Haldol                      |                    |                    | S               | Oral                 | 4 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 3 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 2 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 1.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 0.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                   | Lorazepam                   |                    |                    | S               | Oral                 | 1.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                   | Atorvastatin                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                   | Paragar                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Cosaar (Losartan Potassium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Fluoxetine                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                   | Diazepam                    |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 20-Oct-2005                                                                                            | 5842006                              | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-02360-01             |                      | 34 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Malaise;<br>Muscle Tightness;<br>Paraesthesia;<br>Tachycardia; Tremor;<br>Trismus; Vertigo | Escitalopram Oxalate                 |                    |                    | S               | Oral                         | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                        | Atarax                               |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                        | Stresam (Etifoxine)                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2005                                                                                            | 5905561                              | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-05P-163-0313856-00 |                      | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                        | Acetaminophen\Hydrocodone Bitartrate |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
|                                                                                                        | Escitalopram Oxalate                 |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
|                                                                                                        | Clonazepam                           |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2005                                                                                            | 5905596                              | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-05P-163-0314050-00 |                      | 58 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Product Misuse; Overdose                                             | Valproic Acid                        |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
|                                                                                                        | Escitalopram Oxalate                 |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
|                                                                                                        | Lorazepam                            |                    |                    | S               |                              | Not Reported         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2005                                                                                            | 5914395                              | EXPEDITED (15-DAY) | Y                  | OT              | S05-CAN-03792-01             |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |                       |   |      |             |              |
|---------------------|-----------------------|---|------|-------------|--------------|
| Pruritus; Urticaria | Cipralex              | S | Oral | 10 Mg Qd Po | Not Reported |
|                     | Ibuprofen             | C |      |             | Not Reported |
|                     | Tylenol (Paracetamol) | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2005              | 5914401       | EXPEDITED (15-DAY) | Y                  | HO              | S05-UKI-03788-01     |                      | 84 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Polyuria              | Cipralex       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                       | Cipralex       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
|                       | Amlodipine     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 20-Oct-2005              | 6475976       | EXPEDITED (15-DAY) | Y                  | OT              | US-KINGPHARMUSA00001-K200501325 |                      | 51 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Coma Scale Abnormal; Dizziness; Loss Of Consciousness; Muscle Twitching; Myoclonus | Kemadrin       |              |            | S           | Oral                                  | 15 Mg, Qd          |                 | King         |
|                                                                                    | Kemadrin       |              |            | S           |                                       | 5 Mg, Qd           |                 | King         |
|                                                                                    | Zyprexa        |              |            | S           | Oral                                  | 5 Mg, Qd           |                 | Not Reported |
|                                                                                    | Cipralex       |              |            | S           | Oral                                  | 10 Mg, Qd          |                 | Not Reported |
|                                                                                    | Cipralex       |              |            | S           | Oral                                  | 30 Mg, Qd          |                 | Not Reported |
|                                                                                    | Midazolam      |              |            | S           | Oral                                  | 15 Mg, Qd          |                 | Not Reported |
|                                                                                    | Midazolam      |              |            | S           |                                       | 30 Mg, Qd          |                 | Not Reported |
|                                                                                    | Valium         |              |            | S           | Intravenous (not otherwise specified) | 10 Mg, Unk         | 1440 MIN        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2005              | 5906307       | EXPEDITED (15-DAY) |                    | OT              | CA-ABBOTT-05P-028-0313974-00 |                      | 54 YR      | Female     | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |             |   |      |  |  |  |  |  |  |              |
|---------------------|-------------|---|------|--|--|--|--|--|--|--------------|
| Pruritus; Urticaria | Ciprallex   | S | Oral |  |  |  |  |  |  | Not Reported |
|                     | Ibuprofen   | C |      |  |  |  |  |  |  | Not Reported |
|                     | Paracetamol | C |      |  |  |  |  |  |  | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 21-Oct-2005                       | 7385661                | EXPEDITED (15-DAY)        |                             | OT                       | US-ABBOTT-05P-163-0313540-00  |                               | 38 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Breast Cancer In Situ          | Lexapro                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Multivitamins           |                       |                     | C                    | Topical               |                             |                          | Not Reported        |
|                                | Minoxidil               |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-Oct-2005                       | 5903103                | EXPEDITED (15-DAY)        | Y                           | DE                       | AND_0141_2005                 |                               | 38 YR               | Unknown             | USA                     |

| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a>     | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------|-----------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cardiac Arrest; Completed Suicide; Overdose; Respiratory Arrest | Acetaminophen W/Hydrocodone |                       |                     | S                    | Oral                  | Df, Po                      |                          | Not Reported        |
|                                                                 | Escitalopram Oxalate        |                       |                     | S                    | Oral                  | Df, Po                      |                          | Not Reported        |
|                                                                 | Clonazepam                  |                       |                     | S                    |                       | Df                          |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-Oct-2005                       | 5917404                | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-USA-04628-02              |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Breath Holding; Heart Rate Decreased; Oxygen Saturation Decreased | Lexapro                 |                       |                     | S                    | Transplacental        | 10 Mg Qd Transplacental     |                          | Not Reported        |
|                                                                   | Lexapro                 |                       |                     | S                    |                       | 10 Mg Qd Bf                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Oct-2005                       | 5910774                | DIRECT                    | N                           | HO, LT                   |                               |                               | 22 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                 |                               |                           |                             |                          |                               |                               |                          |                                              |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------------------|-------------------------|
| Emotional Disorder;<br>Intentional Self-Injury;<br>Suicide Attempt                                                                                              |                               | Lexapro                   |                             | S                        |                               | 1 Tablet Daily                |                          | Forest                                       |                         |
| <a href="#">FDA Received Date</a>                                                                                                                               | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 25-Oct-2005                                                                                                                                                     | 5918117                       | EXPEDITED (15-DAY)        | N                           | OT                       | S05-USA-04683-01              |                               | 28 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                  | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Confusional State;<br>Euphoric Mood;<br>Headache; Loss Of<br>Consciousness; Refusal<br>Of Treatment By Patient;<br>Seizure; Tinnitus; Tonic<br>Clonic Movements | Lexapro<br>Protonix<br>Zofran |                           |                             | S<br>C<br>C              |                               |                               |                          | Not Reported<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                                                               | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 25-Oct-2005                                                                                                                                                     | 5918170                       | EXPEDITED (15-DAY)        | Y                           | HO                       | S05-UKI-03864-01              |                               | 28 YR                    | Female                                       | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                  | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Blister; Malaise; Rash<br>Pruritic; Vomiting                                                                                                                    | Ciprallex                     |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                                               | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 26-Oct-2005                                                                                                                                                     | 5910756                       | DIRECT                    | Y                           | OT                       |                               |                               | 63 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                  | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Agitation                                                                                                                                                       | Escitalopram Oxalate          |                           |                             | S                        | Oral                          | 5 Mg Tid Po                   |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                                               | <a href="#">Case #</a>        | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 27-Oct-2005                                                                                                                                                     | 5884736                       | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | S05-USA-03614-01              |                               | 53 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                  | <a href="#">Product</a>       | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Intestinal Obstruction;                                                                                                                                         | Lexapro                       |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported                                 |                         |

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|                                   |                         |   |      |          |              |
|-----------------------------------|-------------------------|---|------|----------|--------------|
| Pancreatitis Acute;<br>Pseudocyst | Maxzide                 | S | Oral | 75 Mg Po | Not Reported |
|                                   | Mavik                   | S | Oral | 8 Mg Po  | Not Reported |
|                                   | Trazodone Hydrochloride | C |      |          | Not Reported |
|                                   | Indocin                 | C |      |          | Not Reported |
|                                   | Reglan                  | C |      |          | Not Reported |
|                                   | Erythromycin            | C |      |          | Not Reported |
|                                   | Premarin                | C |      |          | Not Reported |
|                                   | Zyrtec                  | C |      |          | Not Reported |
|                                   | Singulair               | C |      |          | Not Reported |
|                                   | Provigil                | C |      |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2005              | 5904889       | EXPEDITED (15-DAY) | Y                  | HO              | S05-AUT-03578-01     |                      | 30 YR      | Male       | AUS            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Circulatory Collapse;<br>Generalised Non-<br>Convulsive Epilepsy; Loss<br>Of Consciousness;<br>Malaise; Shock | Ciprallex          |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                                               | Dietary Supplement |              |            | S           |              | 30 Drops Prn       |                 | Not Reported |
|                                                                                                               | Aspirin            |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
|                                                                                                               | Lisinopril         |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                               | Pravacol           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2005              | 5915109       | EXPEDITED (15-DAY) | Y                  | LT              | S05-GER-03738-01     |                      | 69 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Circulatory<br>Collapse; Hyperkalaemia;<br>Mydriasis | Ciprallex                                  |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                      | Lyrica                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Valoron N                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Voltaren                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Nexium (Esomeprazole)                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Kalinor (Potassium Chloride)               |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Metoclopramide                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Fragmin (Heparin-Fraction,<br>Sodium Slat) |              |            | C           |              |                    |                 | Not Reported |
|                                                                      |                                            |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Oct-2005                                                                                   | 5895847        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04382-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cluster Headache; Feeling Abnormal; Loss Of Personal Independence In Daily Activities; Nausea | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                               | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|--------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Oct-2005                                     | 5906309            | EXPEDITED (15-DAY) |                    | LT              | DE-ABBOTT-05P-062-0313996-00 |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Circulatory Collapse; Mydriasis | Cipralext          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                 | Lyrica             |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                 | Lyrica             |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                 | Valoron N          |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                 | Voltaren           |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                 | Esomeprazole       |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                 | Potassium Chloride |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                 | Metoclopramide     |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                 | Enoxaparin Sodium  |                    |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Nov-2005                     | 5920625        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04273-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Stem Infarction; Dystonia | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2005              | 5886077       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04272-01     |                      | 39 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                      |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|--------------------|----------------------|----------------------|-----------------|-----------------|----------------------|
| Anaemia; International Normalised Ratio Increased; Thrombosis                                                                     | Lexapro                                             |                    |                    | S                  | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                      |
|                                                                                                                                   | Ativan                                              |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>       |
| 02-Nov-2005                                                                                                                       | 5904090                                             | EXPEDITED (15-DAY) | N                  | OT                 | S05-USA-04514-01     |                      | 47 YR           | Male            | USA                  |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                      |
| Abdominal Pain Upper; Anxiety; Blood Pressure Fluctuation; Diarrhoea; Dyspnoea; Heart Rate Abnormal; Mydriasis; Visual Impairment | Lexapro                                             |                    |                    | S                  | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                      |
|                                                                                                                                   | Klonopin                                            |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Depakote                                            |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   |                                                     |                    |                    |                    |                      |                      |                 |                 |                      |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u>       |
| 02-Nov-2005                                                                                                                       | 5921604                                             | EXPEDITED (15-DAY) | Y                  | HO                 | S05-FRA-03996-01     |                      | 70 YR           | Female          | FRA                  |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                      |
| Agranulocytosis; Pyrexia; Self-Medication; White Blood Cell Count Decreased                                                       | Escitalopram Oxalate                                |                    |                    | S                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Tetrazepam                                          |                    |                    | S                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Aceprometazine\Meprobamate                          |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Amaryl                                              |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Visceralgine Forte                                  |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Aspirin Lysine                                      |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Mopral (Omeprazole)                                 |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Vastarel                                            |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Calcium W/Colecalciferol (Calcium W/Colecalciferol) |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Sectral                                             |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Victan (Ethyl Loflazepate)                          |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | Atorvastatin Calcium                                |                    |                    | C                  |                      |                      |                 | Not Reported    |                      |
|                                                                                                                                   | <u>FDA Received Date</u>                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> |                      |                      |                 | <u>Outcomes</u> | <u>Mfr Control #</u> |
| 02-Nov-2005                                                                                                                       | 6685340                                             | EXPEDITED (15-DAY) | Y                  | OT                 | S05-SWI-03647-01     |                      | 52 YR           | Female          | CHE                  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Loss Of Consciousness;<br>Myoclonus                                                                                                     | Cipralext            |                    |                    | S               | Oral                                     | 10 Mg Tid Po         |                 | Not Reported |                |
|                                                                                                                                         | Cipralext            |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                         | Zyprexa              |                    |                    | S               | Oral                                     | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                         | Dormicum (Midazolam) |                    |                    | S               | Oral                                     | 15 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                                         | Dormicum (Midazolam) |                    |                    | S               | Oral                                     | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                         | Kemadrin             |                    |                    | S               | Oral                                     | 5 Mg Po              |                 | Not Reported |                |
|                                                                                                                                         | Valium               |                    |                    | S               | Intravenous (not<br>otherwise specified) | 10 Daily Iv          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2005                                                                                                                             | 5916815              | EXPEDITED (15-DAY) |                    | HO              | 2005UW16044                              |                      | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bilirubin Increased;<br>Blood Sodium Decreased;<br>Drug Interaction                                                               | Seroquel             |                    |                    | S               | Oral                                     |                      |                 | Zeneca       |                |
|                                                                                                                                         | Lexapro              |                    |                    | S               | Oral                                     |                      | 7 DAY           | Not Reported |                |
|                                                                                                                                         | Lexapro              |                    |                    | S               | Oral                                     |                      | 7 DAY           | Not Reported |                |
|                                                                                                                                         | Lexapro              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                                                         | Lexapro              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2005                                                                                                                             | 5921270              | DIRECT             | Y                  |                 |                                          |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Withdrawal<br>Syndrome; Headache;<br>Medication Error; Pain;<br>Product Dispensing Error;<br>Wrong Product<br>Administered | Lexapro              |                    |                    | S               |                                          | Tablet               |                 | Forest       |                |
|                                                                                                                                         | Lipitor              |                    |                    | S               |                                          | Tablet               |                 | Pfizer       |                |
|                                                                                                                                         | Crestor              |                    |                    | S               |                                          | Tablet               |                 | Astrazeneca  |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2005                                                                                                                                                                                                                                                                                                                        | 5923271                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-04156-01     |                      | 42 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcohol Use;<br>Dissociative Amnesia;<br>Treatment Noncompliance                                                                                                                                                                                                                                                        | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Cipralext                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Alcohol                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2005                                                                                                                                                                                                                                                                                                                        | 5923273                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-04005-01     |                      | 25 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrested Labour;<br>Caesarean Section;<br>Maternal Exposure During<br>Pregnancy                                                                                                                                                                                                                                                    | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Cipralext                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Clotrimazole             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2005                                                                                                                                                                                                                                                                                                                        | 5880868                  | EXPEDITED (15-DAY) | N                  | DS, HO, LT, OT  | 2005-09-0270         |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Aphasia; Blood<br>Pressure Diastolic<br>Decreased; Blood<br>Pressure Systolic<br>Increased;<br>Cerebrovascular Accident;<br>Gait Inability;<br>Hypersensitivity; Liver<br>Tenderness; Loss Of<br>Consciousness; Memory<br>Impairment; Mental<br>Disorder; Myocardial<br>Infarction; Neoplasm<br>Malignant; Renal Failure; | Pegintron                |                    |                    | S               | Subcutaneous         | 50 Mcg Subcutaneous  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Rebetol                  |                    |                    | S               | Oral                 | 600 Mg Oral          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Lexapro                  |                    |                    | S               | Oral                 | 20 Mg Oral           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Clonidine Hydrochloride  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Morphine Sulfate Tablets |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Nexium (Esomeprazole     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Magnesium)               |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                    | Xanax                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    | Klonopin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                    |                          |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Seizure; Skin  
Discolouration; Skin  
Exfoliation; Spinal  
Compression Fracture;  
Wheelchair User

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Nov-2005                                                                              | 5892698                          | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04393-01     |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoglycaemia;<br>Metrorrhagia                                                           | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Humalog                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Femhrt                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Lipitor                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Ditropan                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2005                                                                              | 5907971                          | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-03152-01     |                      | 32 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus<br>Inadequate Control;<br>Hypertriglyceridaemia;<br>Pancreatitis Acute | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Insulin Nos                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Risperdal                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Zolpidem Tartrate                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Mianserin Hydrochloride          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Lorazepam                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Theraline (Alimemazine Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Dipiperon (Pipamperone)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          |                                  |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2005                                                                              | 5925054                          | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-03846-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Depression;<br>Inappropriate Schedule Of<br>Product Administration;            | Lexapro                          |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                          | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                      |   |      |              |              |
|----------------------------|--------------------------------------|---|------|--------------|--------------|
| Mental Disorder; Paranoia; | Lexapro                              | S | Oral | 20 Mg Qd Po  | Not Reported |
| Psychotic Disorder;        | Lexapro                              | S | Oral | 20 Mg Qd Po  | Not Reported |
| Somnolence                 | Wellbutrin (Bupropion Hydrochloride) | S |      |              | Not Reported |
|                            | Risperdal                            | S | Oral | 3 Mg Qd Po   | Not Reported |
|                            | Risperdal                            | S |      |              | Not Reported |
|                            | Risperdal                            | S | Oral | 0.5 Mg Qd Po | Not Reported |
|                            | Multi-Vitamin                        | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Nov-2005              | 5921657       | DIRECT           | Y                  | OT              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased | Lexapro        |              |            | S           | Oral         | 10 Mg, Decreased To 5 Mg Qd Po | 532 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Nov-2005              | 5922289       | DIRECT           | N                  | OT              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Crying; Drug Hypersensitivity; Drug Withdrawal Syndrome; Dyskinesia; Feeling Drunk; Heart Rate Increased; Muscle Spasms; Psychiatric Symptom; Somnolence; Tremor | Zoloft         |              |            | S           | Oral         | 1 Per Day Po       |                 | Not Reported |
|                                                                                                                                                                                      | Lexapro        |              |            | S           | Oral         | 1 Per Day Po       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2005                                                                                                           | 5877011                           | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04139-01     |                      | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Hypertensive Crisis; Hypoaesthesia; Loss Of Consciousness; Renal Failure; Urosepsis | Lexapro                           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Metoprolol                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Antiretrovirals (Nos)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Dapsone                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Prevacid                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Diovan                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Hydrochlorothiazide               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Cephalexin                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Zithromax                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2005                                                                                                           | 5892685                           | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-03472-01     |                      | 37 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety; Homicidal Ideation; Suicidal Ideation                                                            | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                       | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                       | Paroxetine Hydrochloride          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2005                                                                                                           | 5888191                           | EXPEDITED (15-DAY) | Y                  | HO              | S05-NOR-03396-01     |                      | 25 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                               | Cipralax                          |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                       | Cipralax                          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Sobril (Oxazepam)                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Vallergran (Alimemazine Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Imovane (Zopiclone)               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Furosemide                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Docosate Sodium                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       |                                   |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                             |   |              |
|-------------------------------------------------------------|---|--------------|
| Sennosides (Sennoside A+B Calcium)                          | C | Not Reported |
| Metoprolol                                                  | C | Not Reported |
| Potassium Chloride                                          | C | Not Reported |
| Ipratropium/Salbutamol 20/120 Mg (Salbutamol W/Ipratropium) | C | Not Reported |
| Acetaminophen (Paracetamol) (Acetaminophen)                 | C | Not Reported |
| Sodium Phosphate (Sodium Phosphate (32 P))                  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2005              | 5926685       | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-04850-01     |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5874896       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04099-01     |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Pain; Confusional State; Dizziness; Hypertension; Mania; Palpitations | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                             | Lotensin              |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Seroquel              |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Paxil                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Entex Pse             |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Hydrochlorothiazide   |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Lipitor               |              |            | C           |              |                    |                 | Not Reported |
|                                                                             | Albuterol             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5877002       | EXPEDITED (15-DAY) | N                  | HO, LT          | S05-USA-04098-01     |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                       |   |              |             |              |
|------------------------------|-----------------------|---|--------------|-------------|--------------|
| Anaemia; Ascites;            | Lexapro               | S | Oral         | 20 Mg Qd Po | Not Reported |
| Cerebrovascular Accident;    | Lexapro               | S | Oral         | 10 Mg Qd Po | Not Reported |
| Drug Hypersensitivity; Fall; | Pegintron             | S | Subcutaneous | 50 Mcg Sc   | Not Reported |
| Foot Fracture; Hepatitis;    | Rebetol               | S | Oral         | 600 Mg Po   | Not Reported |
| Mental Disorder;             | Morphine Sulfate      | C |              |             | Not Reported |
| Myocardial Infarction;       | Clonidine             | C |              |             | Not Reported |
| Neoplasm Malignant;          | Xanax                 | C |              |             | Not Reported |
| Nightmare; Oedema            | Nexium (Esomeprazole) | C |              |             | Not Reported |
| Peripheral; Refusal Of       | Cannabis (Cannabis)   | C |              |             | Not Reported |
| Treatment By Patient;        | Klonopin              | C |              |             | Not Reported |
| Renal Disorder; Renal        | Fentanyl              | C |              |             | Not Reported |
| Failure; Seizure;            |                       |   |              |             |              |
| Somnambulism; Spinal         |                       |   |              |             |              |
| Compression Fracture;        |                       |   |              |             |              |
| Weight Increased             |                       |   |              |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5899802       | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-03563-01     |                      | 20 YR      | Male       | DEU            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased | Ciprallex      |              |            | S           | Oral         | 5 Mg Po            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5914398       | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-03799-01     |                      | 19 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Brain Scan Abnormal;    | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Cerebral Disorder;      | Sulfamethoxazole     |              |            | C           |              |                    |                 | Not Reported |
| Dysarthria; Dyskinesia; | Norvir               |              |            | C           |              |                    |                 | Not Reported |
| Headache; Inflammation; | Epivir               |              |            | C           |              |                    |                 | Not Reported |
| Nystagmus               | Viread               |              |            | C           |              |                    |                 | Not Reported |
|                         | Fosamprenavir        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5922072       | EXPEDITED (15-DAY) |                    | OT              | PHEH2005US12219      |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Arrhythmia; Palpitations                                                    | Lamisil                     |                    |                    | S               | Oral                 |                      |                 | Novartis     |                |
|                                                                             | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                 | 5927870                     | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL003957         |                      | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest | Clonazepam                  |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                             | Escitalopram Oxalate        |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                             | Acetaminophen W/Hydrocodone |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                 | 5928943                     | EXPEDITED (15-DAY) | Y                  | HO              | S05-BEL-04796-01     |                      | 35 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Dyskinesia; Tremor                                                 | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                             | Trazodone Hydrochloride     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                 | 5928945                     | EXPEDITED (15-DAY) | Y                  | DE              | S05-FRA-04479-01     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                           | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                 | 5929199                     | EXPEDITED (15-DAY) | Y                  | HO              | 2005-11-0034         |                      | 85 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                               | Clarinx                     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |   |      |                |              |
|--|--------------------------|---|------|----------------|--------------|
|  | Domperidone              | S | Oral | 3 Qd Oral      | Not Reported |
|  | Furosemide               | S | Oral | 20 Mg Qd Oral  | Not Reported |
|  | Omeprazole               | S | Oral | 20 Mg Qd Oral  | Not Reported |
|  | Cipraxel                 | S | Oral | 10 Mg Qd Oral  | Not Reported |
|  | Tamsulosin Hydrochloride | S | Oral | 0.4 Mg Qd Oral | Not Reported |
|  | Perindopril Erbumine     | C |      |                | Not Reported |
|  | Zopiclone                | C |      |                | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5929943       | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-04478-01     |                      |            | Male       | DEU            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract              | Cipraxel       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5931138       | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL004172         |                      | 40 YR      | Unknown    | USA            |

  

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aspiration; Cardiac Arrest; Overdose; Respiratory Arrest; Unevaluable Event | Clonazepam           |              |            | S           |              |                    |                 | Purepac      |
|                                                                             | Quetiapine           |              |            | S           |              |                    |                 | Not Reported |
|                                                                             | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2005              | 5932888       | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL004031         |                      | 24 YR      | Unknown    | USA            |

  

| <u>Preferred Term</u>       | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Overdose | Chlorpromazine Hydrochloride |              |            | S           | Unknown      | Unknown            |                 | Alphapharm   |
|                             | Amitriptyline                |              |            | S           | Unknown      | Unknown            |                 | Not Reported |
|                             | Escitalopram Oxalate         |              |            | S           | Unknown      | Unknown            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Nov-2005                                                                   | 5932968                 | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL004018         |                      | 58 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                    | Lorazepam               |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
|                                                                               | Valproic Acid           |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                   | 5932976                 | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL004024         |                      | 25 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Overdose;<br>Respiratory Arrest;<br>Unevaluable Event         | Alprazolam              |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
|                                                                               | Amitriptyline           |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Unknown; Unk; Po     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                   | 5933315                 | EXPEDITED (15-DAY) | N                  | DE, HO          | S05-USA-04849-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Self-Injury;<br>Multiple Injuries; Overdose | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                               | Acetaminophen           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                               | Acetaminophen           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2005                                                                   | 5933436                 | EXPEDITED (15-DAY) | Y                  | DE              | 2005AL004226         |                      | 42 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Event; Overdose                                                       | Tramadol Hydrochloride  |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                               | Methadone Hydrochloride |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                  |                |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                                             |                |                    | S                  | Oral            | Po                   | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                                                      | 5904908        | EXPEDITED (15-DAY) | Y                  | OT              | S05-NOR-03632-01     |                      | 33 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoeic Attack; Dizziness<br>Postural; Fall;<br>Hypertension; Orthostatic<br>Hypotension; Tremor | Cipralext      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                                                      | 5927586        | DIRECT             | N                  | OT              |                      |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                                                      | 5927638        | DIRECT             | N                  |                 |                      |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Depression; Diarrhoea;<br>Drug Withdrawal<br>Syndrome; Nervousness        | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Once Daily Po  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                                                      | 5928802        | EXPEDITED (15-DAY) | Y                  | RI, OT          | S05-USA-04589-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intestinal Infarction;<br>Intestinal Ischaemia                                                   | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Nov-2005                                                       | 5929039                     | EXPEDITED (15-DAY) | Y                  | DE              | S05-UKI-04974-01     |                      | 67 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide; Intentional Self-Injury              | Cipralext                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                   | Flupentixol Dihydrochloride |                    |                    | S               | Oral                 | 1 Tablet Qd Po       |                 | Not Reported |                |
|                                                                   | Zopiclone                   |                    |                    | S               |                      | 7.5 Mg Qd            |                 | Not Reported |                |
|                                                                   | Quinine Bisulfate           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                       | 5929043                     | EXPEDITED (15-DAY) | Y                  | DS              | S05-FRA-04968-01     |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Oedema                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                   | Lexomil (Bromazepam)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                   | Nexium                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                       | 5929154                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-UKI-04967-01     |                      | 48 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention; Urinary Tract Infection                        | Cipralext                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                   | Cipralext                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2005                                                       | 5929538                     | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2005S1010719         |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intestinal Obstruction; Pancreatic Pseudocyst; Pancreatitis Acute | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg;Qd;Oral        |                 | Not Reported |                |
|                                                                   | Maxzide                     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

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|                              |   |      |         |              |
|------------------------------|---|------|---------|--------------|
| Mavik                        | S | Oral | 8 Mg;Po | Not Reported |
| Trazodone Hydrochloride      | C |      |         | Not Reported |
| Indomethacin                 | C |      |         | Not Reported |
| Erythromycin                 | C |      |         | Not Reported |
| Metoclopramide Hydrochloride | C |      |         | Not Reported |
| Estrogens Conjugated         | C |      |         | Not Reported |
| Cetirizine Hydrochloride     | C |      |         | Not Reported |
| Montelukast Sodium           | C |      |         | Not Reported |
| Modafinil                    | C |      |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2005              | 5929433       | DIRECT           | Y                  | HO              |                      |                      | 85 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional State; Hyponatraemia; Hypophagia; Lethargy | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |
|                                                                  | Maxzide              |              |            | S           | Oral         | 25 Mg Daily Po     | 2 MTH           | Not Reported |
|                                                                  | Aspirin              |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Celebrex             |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Folic Acid           |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Xalatan              |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Levoxyl              |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Reglan               |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Lescol XI            |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Multivitamins        |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Toprol XI            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2005              | 5931662       | DIRECT           | N                  | RI              |                      |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Bilirubin Increased; Erythema; Hot Flush; Skin Disorder; Skin Tightness | Lexapro        |              |            | S           | Oral         | 10mg Once Daily Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Nov-2005              | 5933485       | EXPEDITED (15-DAY) | Y                  | DE              | 2005-BP-19471RO      |                      | 42 YR      | Unknown    | USA            |

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| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Death                                                                                        | Methadone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                              | Tramadol Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                              | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2005                                                                                  | 5934608                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-USA-04906-01     |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination;<br>Inappropriate Schedule Of<br>Product Administration;<br>Psychotic Disorder | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                              | Intron A                |                    |                    | S               | Subcutaneous         | 19 Mu Tiw Sc         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2005                                                                                  | 5934662                 | EXPEDITED (15-DAY) | Y                  | DE              | 2005-BP-19502RO      |                      | 25 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Overdose;<br>Respiratory Arrest                                              | Alprazolam              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                              | Amitriptyline           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                              | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2005                                                                                  | 5931471                 | DIRECT             | Y                  | LT              |                      |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Homicidal<br>Ideation; Nausea; Suicidal<br>Ideation                               | Lexapro                 |                    |                    | S               | Oral                 | Half Tablet Daily Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2005                                                                                  | 5933131                 | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04923-01     |                      | 13 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                   |         |   |      |                |              |
|-------------------------------------------------------------------|---------|---|------|----------------|--------------|
| Attention-Seeking Behaviour; Intentional Overdose; Partner Stress | Lexapro | S | Oral | 220 Mg Once Po | Not Reported |
|                                                                   | Lexapro | S | Oral | 10 Mg Qd Po    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2005              | 5933208       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-04940-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Chest Pain;               | Insulin Nos    |              |            | C           |              |                    |                 | Not Reported |
| Hypoaesthesia;            | Lisinopril     |              |            | C           |              |                    |                 | Not Reported |
| Paraesthesia              |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2005              | 5933544       | EXPEDITED (15-DAY) | Y                  | OT              | S05-NLD-05158-01     |                      | 79 YR      | Female     | NLD            |

| <u>Preferred Term</u>                   | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colour Blindness; Visual Acuity Reduced | Ciprallex                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                         | Alprazolam                       |              |            | C           |              |                    |                 | Not Reported |
|                                         | Ascal (Acetylsalicylate Calcium) |              |            | C           |              |                    |                 | Not Reported |
|                                         | Lormetazepam                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2005              | 5805051       | EXPEDITED (15-DAY) | Y                  | DS, OT          | S05-UKI-01727-01     |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Gait Disturbance; Movement Disorder; Muscle Rigidity; Tremor | Ciprallex                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                | Abilify                   |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                | Abilify                   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                | Amisulpride (Amisulpride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Unspecified Ingredient    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2005              | 5811872       | EXPEDITED (15-DAY) | Y                  | OT              | T05-SWI-01891-01     |                      | 51 YR      | Male       | CHE            |

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| <u>Preferred Term</u>                                                                                               | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dizziness; Drug Dependence; Epilepsy; Loss Of Consciousness; Myoclonus; Overdose; Somatic Symptom Disorder | Cipralext                  |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                     | Cipralext                  |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                     | Zyprexa                    |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                     | Kemadrin                   |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                     | Procyclidine Hydrochloride |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                     | Dormicum (Nitrazepam)      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2005              | 5874655       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-04037-01     |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuser; Ecchymosis; Lividity; Overdose | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                             | Heroin                  |              |            | S           |              |                    |                 | Not Reported |
|                                             | Flexeril                |              |            | C           |              |                    |                 | Not Reported |
|                                             | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                             | Allegra                 |              |            | C           |              |                    |                 | Not Reported |
|                                             | Unspecified Ingredient  |              |            | C           |              |                    |                 | Not Reported |
|                                             | Atarax                  |              |            | C           |              |                    |                 | Not Reported |
|                                             | Orphenadrine            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2005              | 5927061       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-12754743 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Interaction; Suicidal Ideation | Pravachol      |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                                     | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2005              | 5929942       | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-04644-01     |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

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### Detailed Report

|                                                                                              |                        |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Victim Of Sexual Abuse                                                                       | Escitalopram Oxalate   | S                  | Oral               | 10 Mg Daily Po  | Not Reported         |                      |                 |              |                |
|                                                                                              | Lormetazepam           | S                  |                    |                 | Not Reported         |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2005                                                                                  | 5932278                | DIRECT             | Y                  | HO              |                      |                      | 86 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Malnutrition | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                              | Coumadin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Spironolactone         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Altace                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Digoxin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Coreg                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Furosemide             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Lupron                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Temazepam              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2005                                                                                  | 5936017                | EXPEDITED (15-DAY) | Y                  | DS              | S05-UKI-05160-01     |                      | 77 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation                                                                            | Ciprallex              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                              | Etoricoxib             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Temazepam              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Co-Amilofruse          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Digoxin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2005                                                                                  | 5952061                | NON-EXPEDITED      | Y                  | OT              | 2005019371           |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Back Pain;<br>Depression;<br>Haemorrhoids; Hepatitis                                | Lipitor                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                              | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg,Oral           |                 | Not Reported |                |
|                                                                                              | Tramadol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                              | Clonazepam             |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| Lorazepam                                                                                                                                                                                                                                                     |                       |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                                                                                                      | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2005                                                                                                                                                                                                                                                   | 4028712               | EXPEDITED (15-DAY) | Y                  |                 | S03-SWI-04412-01     |                      | 73 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Anxiety;<br>Dermatitis Allergic;<br>Disturbance In Attention;<br>Drug Eruption; Fall;<br>Gamma-<br>Glutamyltransferase<br>Increased; Insomnia;<br>Monocyte Count<br>Increased; Neutrophil<br>Count Increased;<br>Parkinsonism; Reading<br>Disorder | Cipralext             |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Cipralext             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Vioxx                 |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Zyprexa               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Temesta (Lorazepam)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Duphalac                                                                                                                                                                                                                                                      |                       |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| Paragol                                                                                                                                                                                                                                                       |                       |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| Fig Syrup                                                                                                                                                                                                                                                     |                       |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| Zyprexa                                                                                                                                                                                                                                                       |                       |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                      | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2005                                                                                                                                                                                                                                                   | 5858691               | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03682-01     |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Porphyria; Rash; Skin<br>Ulcer                                                                                                                                                                                                                                | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Procrit               |                    |                    | S               |                      | 30000 Units Qmon     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Coumadin              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Ivig (Immunoglobulin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Tarka                 |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                           | Coreg                |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|---------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                           | Bovina (Ibandronate) |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                           | Iron                 |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2005               | 5885611              | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04237-01     |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;     | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Libido Decreased; Painful | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Erection; Penile          | Lexapro              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
| Curvature; Spontaneous    | Lexapro              |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| Penile Erection           | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                           | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                           | Klonopin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2005               | 5923504              | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04814-01     |                      | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Head Injury;        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Hyponatraemia             | Ativan               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Pravachol            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2005               | 5937410              | EXPEDITED (15-DAY) | Y                  | DE              | 2005-BP-19668RO      |                      | 58 YR           | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;        | Lorazepam            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Overdose                  | Valproic Acid        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2005                                                                                               | 5722533                    | EXPEDITED (15-DAY) | Y                  | DE              | PHBS2005SE01249              |                      | 36 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriosclerosis Coronary Artery; Bronchitis; Cardiomegaly; Cardiopulmonary Failure; Myocardial Ischaemia | Leponex                    |                    |                    | S               | Oral                         | 600 Mg/D             |                 | Novartis     |                |
|                                                                                                           | Clopentixol Hydrochloride  |                    |                    | S               | Oral                         | 5 Mg/D               |                 | Not Reported |                |
|                                                                                                           | Cipralelex                 |                    |                    | S               | Oral                         | 20 Mg/D              |                 | Not Reported |                |
|                                                                                                           | Atarax                     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                           | Akineton                   |                    |                    | C               | Oral                         | 2 Mg/D               |                 | Not Reported |                |
|                                                                                                           | Diazepam                   |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2005                                                                                               | 5919689                    | EXPEDITED (15-DAY) | Y                  | HO              | S05-SWI-03869-01             |                      | 55 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Amylase Increased; Gamma-Glutamyltransferase Increased; Lipase Increased            | Cipralelex                 |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Nexium (Esomeprazole)      |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                           | Zoloft                     |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                           | Seroquel                   |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2005                                                                                               | 5806971                    | EXPEDITED (15-DAY) |                    | OT              | CH-ABBOTT-05P-151-0301153-00 |                      | 52 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Epilepsy; Overdose                                                                             | Cipralelex                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                           | Cipralelex                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                           | Olanzapine                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                           | Procyclidine Hydrochloride |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                           | Procyclidine Hydrochloride |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |              |
|-----------|---|------|--------------|
| Midazolam | C | Oral | Not Reported |
| Midazolam | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2005              | 5915194       | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | US016178             |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Depressed Level Of Consciousness; Feeling Abnormal; Intentional Overdose; Myocardial Infarction; Pulmonary Oedema; Sepsis; Tachycardia | Gabitril                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Acetaminophen\Hydrocodone     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Amitriptyline                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Cyclobenzaprine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Pioglitazone Hydrochloride    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                           | Lovastatin                    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2005              | 5928942       | EXPEDITED (15-DAY) | Y                  | HO              | S05-ESP-04485-01     |                      | 78 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Dyspnoea; Generalised Tonic-Clonic Seizure; Hyponatraemia; Respiratory Tract Infection | Cipralex                         |              |            | S           | Oral         | 5 Mg Po            |                 | Not Reported |
|                                                                                              | Chlorthalidone                   |              |            | S           | Oral         | 50 Mg Po           |                 | Not Reported |
|                                                                                              | Levothroid                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Neosidantoina (Phenytoin Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Tavanic                          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2005              | 5930127       | EXPEDITED (15-DAY) | Y                  | HO              | S05-ESP-05141-01     |                      | 40 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Cipralex                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Aspirin                        |              |            | C           |              |                    |                 | Not Reported |
|                       | Nolotil (Metamizole Magnesium) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                             |                          |                    |                    |                 |                                                 |                      |                 |                 |                |
|-------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| Omeprazole                                                                                                  |                          |                    | C                  |                 |                                                 |                      |                 |                 | Not Reported   |
| Lorazepam                                                                                                   |                          |                    | C                  |                 |                                                 |                      |                 |                 | Not Reported   |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Nov-2005                                                                                                 | 5932057                  | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13112339 |                      | 62 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Restlessness; Weight Increased                                                                              | Abilify                  |                    |                    | S               | Oral                                            |                      |                 | Not Reported    |                |
|                                                                                                             | Lexapro                  |                    |                    | S               | Oral                                            |                      |                 | Not Reported    |                |
|                                                                                                             | Oxybutynin               |                    |                    | C               |                                                 |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Nov-2005                                                                                                 | 5932761                  | NON-EXPEDITED      | N                  |                 | S05-USA-04395-01                                |                      | 58 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Breath Odour; Cough; Dizziness; Dysgeusia; Eructation; Headache; Hot Flush; Hyperhidrosis; Nausea | Wellbutrin XI            |                    |                    | S               | Oral                                            | 150mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                             | Lexapro                  |                    |                    | S               | Oral                                            |                      |                 | Forest          |                |
|                                                                                                             | Strattera                |                    |                    | C               | Unknown                                         |                      |                 | Not Reported    |                |
|                                                                                                             | Vicodin                  |                    |                    | C               | Unknown                                         |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Nov-2005                                                                                                 | 5938770                  | EXPEDITED (15-DAY) | Y                  | HO              | 2005S1011109                                    |                      | 85 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hyponatraemia                                                                                               | Desloratadine            |                    |                    | S               | Oral                                            | Oral                 |                 | Not Reported    |                |
|                                                                                                             | Domperidone              |                    |                    | S               | Oral                                            | Qd; Oral             |                 | Not Reported    |                |
|                                                                                                             | Furosemide               |                    |                    | S               | Oral                                            | 20 Mg; Qd; Oral      |                 | Not Reported    |                |
|                                                                                                             | Omeprazole               |                    |                    | S               | Oral                                            | 20 Mg; Qd; Oral      |                 | Not Reported    |                |
|                                                                                                             | Cipralext                |                    |                    | S               | Oral                                            | 10 Mg; Qd; Oral      |                 | Not Reported    |                |
|                                                                                                             | Tamsulosin Hydrochloride |                    |                    | S               | Oral                                            | 0.4 Mg; Qd; Oral     |                 | Not Reported    |                |
|                                                                                                             | Perindopril              |                    |                    | C               |                                                 |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                                |                    |                    |                 |                              |                      |                 |              |                |
|----------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Zopiclone                                                                  |                                |                    | C                  |                 |                              | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2005                                                                | 5956694                        | NON-EXPEDITED      | N                  | HO              | 200510661BWH                 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia; Panic Attack                                                | Ciprofloxacin Extended-Release |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                            | Lexapro                        |                    |                    | S               | Oral                         | 30 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                            | Flagyl                         |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2005                                                                | 5868602                        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-03963-01             |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Syncope                                                           | Lexapro                        |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                            | Lexapro                        |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                            | Lorazepam                      |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2005                                                                | 5933839                        | EXPEDITED (15-DAY) |                    | HO              | ES-ABBOTT-05P-144-0317753-00 |                      | 89 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Atrophy;<br>Cerebral Ischaemia;<br>Hypokalaemia;<br>Hyponatraemia | Ciprallex                      |                    |                    | S               | Oral                         |                      | 10 DAY          | Not Reported |                |
|                                                                            | Indapamide                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                            | Lormetazepam                   |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                            | Gabapentin                     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                            | Timolol Maleate                |                    |                    | C               | Topical                      |                      |                 | Not Reported |                |
|                                                                            | Gliclazide                     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2005                                                                | 5852727                        | EXPEDITED (15-DAY) | Y                  | HO              | S04-USA-06025-02             |                      | < 1 DAY         | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Foetal Growth Restriction;<br>Foetal Hypokinesia;<br>Forceps Delivery; Labour<br>Complication; Maternal<br>Exposure During Breast<br>Feeding; Maternal<br>Exposure During<br>Pregnancy; Pilonidal Cyst<br>Congenital; Premature<br>Baby; Small For Dates<br>Baby; Umbilical Cord<br>Around Neck; Umbilical<br>Hernia | Lexapro                    |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Prenatal Vitamins          |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Albuterol                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Pitocin                    |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Fentanyl Epidural          |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2005                                                                                                                                                                                                                                                                                                          | 5881906                    | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04179-01     |                         | 51 YR           | Female       | USA            |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness Unilateral; Optic<br>Neuritis                                                                                                                                                                                                                                                                              | Lexapro                    |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Vitamins                   |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2005                                                                                                                                                                                                                                                                                                          | 5936380                    | EXPEDITED (15-DAY) | Y                  | HO              | S05-ESP-05322-01     |                         | 89 YR           | Female       | ESP            |
|                                                                                                                                                                                                                                                                                                                      |                            |                    |                    |                 |                      |                         |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Atrophy;<br>Cerebral Ischaemia;<br>Hypokalaemia;<br>Hyponatraemia                                                                                                                                                                                                                                           | Ciprallex                  |                    |                    | S               | Oral                 | 5 Mg Po                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Indapamide                 |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Noctamid (Lormetazepam)    |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Gabapentin                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Timoptil (Timolol Maleate) |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Gliclazide                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2005                                                                                                                                                                                                                                                                                                          | 5938398                    | DIRECT             | N                  |                 |                      |                         | 43 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|-----------------|----------------|
| Malaise; Nausea                                                                                 | Lexapro                |                    |                    | S               | Oral                     | 1 10mg Tablet Once A Day Po |                 | Forest          |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Dec-2005                                                                                     | 5940002                | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05004-01         |                             | 29 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams;<br>Asthma; Drug Interaction;<br>Panic Reaction;<br>Respiratory Tract Infection | Advair Diskus          |                    |                    | S               | Respiratory (inhalation) |                             |                 | Glaxosmithkline |                |
|                                                                                                 | Albuterol              |                    |                    | S               | Respiratory (inhalation) |                             |                 | Glaxosmithkline |                |
|                                                                                                 | Ipratropium            |                    |                    | S               | Respiratory (inhalation) |                             |                 | Glaxosmithkline |                |
|                                                                                                 | Lexapro                |                    |                    | S               |                          | 10mg Per Day                |                 | Not Reported    |                |
|                                                                                                 | Singulair              |                    |                    | S               |                          |                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 05-Dec-2005                                                                                     | 5865035                | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-USA-03744-01         |                             | 76 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |                |
| Hyponatraemia                                                                                   | Lexapro                |                    |                    | S               | Oral                     | 10 Mg Qd Po                 |                 | Not Reported    |                |
|                                                                                                 | Unspecified Ingredient |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Advair Diskus          |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Atrovent               |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Diovan                 |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Aciphex                |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Lipitor                |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Niaspan                |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Aspirin                |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Mycobutin              |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Biaxin                 |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Ethambutol             |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Ambien                 |                    |                    | C               |                          |                             |                 | Not Reported    |                |
|                                                                                                 | Xanax                  |                    |                    | C               |                          |                             |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2005                                                                                                                                                                                                                                                                                                                                                      | 5884733        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-03626-01                                |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Chest Pain;<br>Contusion; Dizziness;<br>Electrocardiogram<br>Abnormal;<br>Hypercholesterolaemia;<br>Hypokalaemia; Injury;<br>Ligament Sprain; Loss Of<br>Consciousness; Migraine;<br>Mitral Valve<br>Incompetence;<br>Musculoskeletal Pain;<br>Nervous System Disorder;<br>Periorbital Haematoma;<br>Road Traffic Accident;<br>Skin Laceration; Syncope | Lexapro        |                    |                    | S               | Oral                                            | 20 Mg Qhs Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2005                                                                                                                                                                                                                                                                                                                                                      | 5935620        | EXPEDITED (15-DAY) | N                  | OT              | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13196712 |                      | 51 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Drug Interaction                                                                                                                                                                                                                                                                                                                                      | Abilify        |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                  | Ergenyl        |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                  | Sortis         |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                  | Beloc-Zok      |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                  | Euglucon N     |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                  | Ciprallex      |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2005                                                                                                                                                                                                                                                                                                                                                      | 5938498        | DIRECT             | N                  | OT              |                                                 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                           |         |   |      |                      |        |
|---------------------------------------------------------------------------|---------|---|------|----------------------|--------|
| Alopecia; Hypotrichosis;<br>Maternal Exposure During<br>Pregnancy; Stress | Lexapro | S | Oral | 20 Mg Once A 'Day Po | Forest |
|---------------------------------------------------------------------------|---------|---|------|----------------------|--------|

| <u>FDA Received Date</u>                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2005                                         | 5909914             | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04573-01     |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Fatigue; Hyperhidrosis | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Toprol XL           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Pravachol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Hydrochlorothiazide |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                     | Lisinopril          |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2005                            | 5936007        | EXPEDITED (15-DAY) | N                  | DE, HO          | US-JNJFOC-20051200227 |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Injury;<br>Overdose | Tylenol        |                    | Y                  | S               |                       |                      |                 | Not Reported |                |
|                                        | Tylenol        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                        | Excedrin       |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                        | Excedrin       |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                        | Excedrin       |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                        | Excedrin       |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                        | Lexapro        |                    |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Dec-2005                                             | 5947209        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05091-01     |                      | 12 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Focal Dyscognitive<br>Seizures | Lexapro        |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 07-Dec-2005                                                                                                                                                                          | 5971598                                     | NON-EXPEDITED      | Y                  | OT              | 2005108481           |                                     | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Erectile Dysfunction; Erection Increased; Headache; Nervousness; Vision Blurred                                                                                    | Viagra                                      |                    |                    | S               | Oral                 | 100 Mg (100 Mg, As Necessary), Oral |                 | Not Reported |                |
|                                                                                                                                                                                      | Lexapro                                     |                    |                    | S               | Oral                 | Oral                                |                 | Not Reported |                |
|                                                                                                                                                                                      | Lorazepam                                   |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Atenolol (Atenolol)                         |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Insulin Nos                                 |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Nexium (Esomeprazole)                       |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Acetylsalicylic Acid (Acetylsalicylic Acid) |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2005                                                                                                                                                                          | 5905615                                     | EXPEDITED (15-DAY) | Y                  | DE, HO          | T05-USA-02375-01     |                                     | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Agitation; Dehydration; Depressed Level Of Consciousness; Failure To Thrive; Hypophagia; Respiratory Rate Increased; Serotonin Syndrome; Urinary Tract Infection | Lexapro                                     |                    |                    | S               | Oral                 | 10 Mg Qd Po                         |                 | Not Reported |                |
|                                                                                                                                                                                      | Aricept                                     |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Acetylsalicylic Acid                        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Multivitamins                               |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Ativan                                      |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                      | Warfarin Sodium                             |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2005                                                                                                                                                                          | 5926345                                     | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-03951-01     |                                     | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Feeling Abnormal; Gait Disturbance; Heat Stroke;                                                                                                                         | Lexapro                                     |                    |                    | S               | Oral                 | 10 Mg Qd Po                         |                 | Not Reported |                |
|                                                                                                                                                                                      | Levoxyl                                     |                    |                    | C               |                      |                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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Impaired Work Ability;  
Judgement Impaired;  
Malaise; Somnolence;  
Vertigo; Weight Increased

| <u>FDA Received Date</u>        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Dec-2005                     | 5939893                | EXPEDITED (15-DAY) | Y                  | HO              | S05-SWI-05313-01     |                      | 69 YR           | Male         | CHE            |
| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paralysis                       | Ciprallex              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2005                     | 5941878                | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-05522-01     |                      |                 | Male         | GBR            |
| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Sexual Abuse | Ciprallex              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                     | 5948138                | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05102-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Seizure   | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Bid Po         |                 | Not Reported |                |
|                                 | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Bid Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                     | 5948732                | EXPEDITED (15-DAY) | Y                  | HO              | S05-UKI-05537-01     |                      | 41 YR           | Female       | GBR            |
| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Somnolence             | Ciprallex              |                    |                    | S               | Oral                 | 20 Mg Qd; Po         |                 | Not Reported |                |
|                                 | Tramadol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Montelukast            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Terbutaline Sulfate    |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| Symbicort                                                                                     |                               |                    | C                  |                 |                              | Not Reported         |                 |              |                |
|-----------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                                                                                   | 5948733                       | EXPEDITED (15-DAY) | Y                  | DE              | S05-UKI-05536-01             |                      | 43 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Impulsive Behaviour;<br>Mental Disorder                                 | Ciprallex                     |                    |                    | S               | Oral                         | 5 Mg Qd; Po          |                 | Not Reported |                |
|                                                                                               | Zolpidem                      |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                                                                                   | 5948804                       | EXPEDITED (15-DAY) | Y                  | HO              | S05-FIN-05535-01             |                      | 57 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Movement Disorder                                                                             | Ciprallex                     |                    |                    | S               | Oral                         | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                               | Hydantin (Phenytoin)          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                               | Acetaminophen                 |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                               | Trineurin                     |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                               | Levolac (Lactulose)           |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                               | Keppra                        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                               | Emgesan (Magnesium Hydroxide) |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                                                                                   | 5948807                       | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-05625-01             |                      | 69 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Cognitive Disorder; Generalised Tonic-Clonic Seizure; Hemiparesis; Muscle Spasticity | Ciprallex                     |                    |                    | S               | Oral                         | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                               | Metoclopramide                |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2005                                                                                   | 7385665                       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-05P-163-0318303-00 |                      | 35 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Intentional Overdose                                               | Lexapro                   |                    |                    | S               | Oral                                            |                              |                 | Not Reported |                |
|                                                                                          | Lexapro                   |                    |                    | S               | Oral                                            |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2005                                                                              | 5939576                   | EXPEDITED (15-DAY) | Y                  | OT              | IE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13202320 |                              | 82 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokinesia; Hypotension;<br>Pupil Fixed; Salivary<br>Hypersecretion; Seizure;<br>Tremor | Abilify                   |                    |                    | S               | Oral                                            |                              |                 | Not Reported |                |
|                                                                                          | Lexapro                   |                    |                    | S               | Oral                                            |                              |                 | Not Reported |                |
|                                                                                          | Amlodipine Besylate       |                    |                    | C               |                                                 |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2005                                                                              | 5948380                   | DIRECT             | N                  | HO, RI          |                                                 |                              | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Medication Error                                                    | Lexapro                   |                    |                    | S               | Oral                                            | 1 Tab 1 Time Per Day Po      |                 | Forest       |                |
|                                                                                          | Ultracet                  |                    |                    | S               | Oral                                            | 2 Tabs 3 Times Per Day<br>Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2005                                                                              | 5949494                   | EXPEDITED (15-DAY) | Y                  | DE              | MK200512-0053-1                                 |                              | 55 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                               | Acetaminophen And Codeine |                    |                    | S               |                                                 |                              |                 | Not Reported |                |
|                                                                                          | Escitalopram Oxalate      |                    |                    | S               |                                                 |                              |                 | Not Reported |                |
|                                                                                          | Acetaminophen\Hydrocodone |                    |                    | C               |                                                 |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2005                                                                              | 5934949                   | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2005FR17166                                 |                              | 33 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Coma; Coma Scale Abnormal;<br>Electrocardiogram Qrs Complex Abnormal;<br>Endotracheal Intubation;<br>Intentional Product Misuse; Overdose;<br>Sinoatrial Block | Tegretol                    |                    |                    | S               | Oral                 |                      | 1440 MIN        | Novartis     |                |
|                                                                                                                                                                | Anafranil                   |                    |                    | S               | Oral                 |                      | 1440 MIN        | Not Reported |                |
|                                                                                                                                                                | Tranxene T-Tab              |                    |                    | S               | Oral                 |                      | 1440 MIN        | Not Reported |                |
|                                                                                                                                                                | Zopiclone                   |                    |                    | S               | Oral                 |                      | 1440 MIN        | Not Reported |                |
|                                                                                                                                                                | Effexor                     |                    |                    | S               | Oral                 |                      | 1440 MIN        | Not Reported |                |
|                                                                                                                                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                 |                      | 1440 MIN        | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2005                                                                                                                                                    | 5951150                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-01574-01     |                      | 20 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Seizure                                                                                               | Cipralex                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                | Mirtazapine                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2005                                                                                                                                                    | 5951233                     | EXPEDITED (15-DAY) | Y                  | HO              | 2005162372           |                      | 30 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence; Toxicity To Various Agents                                                                                                                         | Atarax                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                | Flupentixol Dihydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                | Zolpidem Tartrate           |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                | Olanzapine (Olanzapine)     |                    |                    | S               |                      | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                | Mianserin Hydrochloride     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2005                                                                                                                                                    | 5963823                     | NON-EXPEDITED      | Y                  | HO              | 2004095999           |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                                                |   |      |                                  |              |
|------------------------------------------------------------------------|------------------------------------------------|---|------|----------------------------------|--------------|
| Depression Suicidal;<br>Intentional Overdose; Loss<br>Of Consciousness | Xanax                                          | S | Oral | Oral                             | Not Reported |
|                                                                        | Clopidogrel Bisulfate                          | S | Oral | 75 Mg (75 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                        | Zolpidem Tartrate                              | S | Oral | 130 Mg (130 Mg, Once),<br>Oral   | Not Reported |
|                                                                        | Semisodium Valproate                           | S | Oral | 4 Gram (4 Gram, Once),<br>Oral   | Not Reported |
|                                                                        | Clonazepam                                     | S |      |                                  | Not Reported |
|                                                                        | Escitalopram Oxalate                           | S |      |                                  | Not Reported |
|                                                                        | Acetylsalicylic Acid<br>(Acetylsalicylic Acid) | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2005              | 5963827       | NON-EXPEDITED    | Y                  | HO              | 2004112623           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Depression; Suicide<br>Attempt | Xanax                |              |            | S           | Oral         | 16 Tablets (Once), Oral          |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (20 Mg, 1 In 2 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2005              | 5895421       | EXPEDITED (15-DAY) | Y                  | HO              | S05-GER-03552-01     |                      | 68 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis Toxic       | Ciprallex                                           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Edronax                                             |              |            | C           |              |                    |                 | Not Reported |
|                       | Novodigal (Digoxin)                                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Glucophage (Metformin<br>Hydrochloride) (Metformin) |              |            | C           |              |                    |                 | Not Reported |
|                       | Doxepin                                             |              |            | C           |              |                    |                 | Not Reported |
|                       | Aprovel (Irbesartan)                                |              |            | C           |              |                    |                 | Not Reported |
|                       | Aquaphor Tablet (Xipamide)                          |              |            | C           |              |                    |                 | Not Reported |
|                       | Asa (Acetylsalicylic Acid)                          |              |            | C           |              |                    |                 | Not Reported |
|                       | Clorazepate Dipotassium                             |              |            | C           |              |                    |                 | Not Reported |
|                       |                                                     |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 14-Dec-2005                                                                                                                                                                                                                         | 5934471             | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-0511USA04559        |                      | 29 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams;<br>Asthma; Drug Interaction;<br>Panic Reaction;<br>Respiratory Tract Infection                                                                                                                                     | Singular            |                    |                    | S               | Oral                         |                      |                 | Merck           |                |
|                                                                                                                                                                                                                                     | Advair Diskus       |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Ipratropium Bromide |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Albuterol           |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Lexapro             |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Dec-2005                                                                                                                                                                                                                         | 5941076             | EXPEDITED (15-DAY) | N                  | CA, HO          | US-GLAXOSMITHKLINE-A0585524A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Aortic Valve Disease;<br>Atrial Septal Defect;<br>Bicuspid Aortic Valve;<br>Coarctation Of The Aorta;<br>Maternal Exposure During<br>Pregnancy; Mitral Valve<br>Disease; Mitral Valve<br>Incompetence; Ventricular<br>Septal Defect | Paxil               |                    |                    | S               | Oral                         | 12.5mg Per Day       | 15 MTH          | Glaxosmithkline |                |
|                                                                                                                                                                                                                                     | Lexapro             |                    |                    | S               | Oral                         | 10mg Unknown         |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Prenatabs Fa        |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Calcium Gluconate   |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Iron Supplement     |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Dec-2005                                                                                                                                                                                                                         | 5951334             | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-05646-01             |                      | 75 YR           | Female          | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Hypersensitivity;<br>Pyrexia; Rash;                                                                                                                                                                                            | Ciprallex           |                    |                    | S               | Oral                         | 15 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                                                                     | Amlodipine          |                    |                    | C               |                              |                      |                 | Not Reported    |                |

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|             |                               |   |              |
|-------------|-------------------------------|---|--------------|
| Tachycardia | Trandolapril                  | C | Not Reported |
|             | Galfer (Ferrous Fumarate)     | C | Not Reported |
|             | Lansoprazole                  | C | Not Reported |
|             | Actonel                       | C | Not Reported |
|             | Calcichew (Calcium Carbonate) | C | Not Reported |
|             | Atorvastatin                  | C | Not Reported |
|             | Acetylsalicylic Acid          | C | Not Reported |
|             | Multivitamins                 | C | Not Reported |
|             | Fortisip                      | C | Not Reported |
|             | Calogen (Calcitonin, Salmon)  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2005              | 5929730       | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2005US12505      |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaphylactic Reaction; | Zelnorm        |              |            | S           |              | 6 Mg, Bid          | 1440 MIN        | Novartis     |
| Dysphagia; Dyspnoea;   | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd          | 1440 MIN        | Not Reported |
| Hypertension;          |                |              |            |             |              |                    |                 |              |
| Hypoaesthesia;         |                |              |            |             |              |                    |                 |              |
| Pharyngeal Oedema      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2005              | 5950889       | DIRECT           | Y                  | LT              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Tenderness;     | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Forest     |
| Condition Aggravated;     |                |              |            |             |              |                    |                 |            |
| Dysgeusia; Fatigue;       |                |              |            |             |              |                    |                 |            |
| Flatulence; Hepatic       |                |              |            |             |              |                    |                 |            |
| Enzyme Increased;         |                |              |            |             |              |                    |                 |            |
| Hepatotoxicity; Impaired  |                |              |            |             |              |                    |                 |            |
| Work Ability; Increased   |                |              |            |             |              |                    |                 |            |
| Tendency To Bruise;       |                |              |            |             |              |                    |                 |            |
| Infectious Mononucleosis; |                |              |            |             |              |                    |                 |            |
| Nausea; Pruritus          |                |              |            |             |              |                    |                 |            |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Dec-2005               | 5951554                       | EXPEDITED (15-DAY) | N                  | HO              | S05-USA-05129-01             |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;       | Lexapro                       |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported |                |
| Aggression; Intentional   | Lexapro                       |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
| Self-Injury; Muscle       | Allegra                       |                    |                    | C               |                              |                      |                 | Not Reported |                |
| Twitching; Overdose;      | Albuterol                     |                    |                    | C               |                              |                      |                 | Not Reported |                |
| Panic Attack; Screaming;  | Singulair                     |                    |                    | C               |                              |                      |                 | Not Reported |                |
| Skin Laceration; Suicidal |                               |                    |                    |                 |                              |                      |                 |              |                |
| Ideation; Tremor          |                               |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2005               | 5903751                       | EXPEDITED (15-DAY) |                    | DE, HO, LT      | US-ABBOTT-05P-163-0313859-00 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;  | Acetaminophen\Hydrocodone     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Cardiac Arrest; Completed | Bitartrate                    |                    |                    |                 |                              |                      |                 |              |                |
| Suicide; Intentional      | Tiagabine Hydrochloride       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Overdose; Mental Status   | Escitalopram Oxalate          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Changes; Myocardial       | Amitriptyline                 |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Infarction; Pulmonary     | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Oedema; Sepsis;           | Pioglitazone Hydrochloride    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Tachycardia;              | Lovastatin                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Unresponsive To Stimuli   |                               |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2005               | 5942707                       | EXPEDITED (15-DAY) | Y                  | HO              | 2005CG02059                  |                      | 38 YR           | Male         | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arterial Thrombosis;      | Inexium                       |                    |                    | S               | Oral                         |                      |                 | Astrazeneca  |                |
| Depression;               | Cyamemazine                   |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Dyslipidaemia;            | Vastarel                      |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| Musculoskeletal Pain;     |                               |                    |                    |                 |                              |                      |                 |              |                |

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|                                                  |                      |   |      |  |  |  |  |              |
|--------------------------------------------------|----------------------|---|------|--|--|--|--|--------------|
| Peripheral Artery Thrombosis; Pulmonary Embolism | Stilnox              | S | Oral |  |  |  |  | Not Reported |
|                                                  | Zyprexa              | S | Oral |  |  |  |  | Not Reported |
|                                                  | Escitalopram Oxalate | S | Oral |  |  |  |  | Not Reported |
|                                                  | Victan               | C |      |  |  |  |  | Not Reported |
|                                                  | Xanax                | C |      |  |  |  |  | Not Reported |
|                                                  | Cortancyl            | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2005                                           | 5952035        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05174-01     |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness; Diarrhoea; Impaired Driving Ability; Tremor | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Dec-2005                                    | 5952092        | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2005GB01850      |                      | 39 YR           | Female       | GBR            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impulsive Behaviour; Overdose; Suicide Attempt | Diazepam       |                    |                    | S               |                      | 60-70 Mg             |                 | Not Reported |                |
|                                                | Cipralext      |                    |                    | S               | Oral                 | 5-20 Mg, Oral        |                 | Not Reported |                |
|                                                | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Dec-2005              | 5952238                              | EXPEDITED (15-DAY) | Y                  | LT              | S05-USA-04566-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis     | Lexapro                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Strattera                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Dec-2005                                                                                                                                                                   | 5953239                   | DIRECT             | Y                  | HO, LT, RI      |                                   |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Neuroleptic Malignant Syndrome                                                                                                                                       | Ziprasidone Hydrochloride |                    |                    | S               | Oral                              | 60 Mg Twice Daily Po |                 | Not Reported |                |
|                                                                                                                                                                               | Lexapro                   |                    |                    | S               | Oral                              | 10 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2005                                                                                                                                                                   | 5896020                   | EXPEDITED (15-DAY) | Y                  | HO              | T05-USA-03407-01                  |                      | 87 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Creatinine Increased; Blood Glucose Increased; Blood Urea Increased; Dehydration; Eosinophil Count Increased; Fluid Intake Reduced; Hypernatraemia; Sedation | Lexapro                   |                    |                    | S               | Oral                              | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                               | Tylenol (Paracetamol)     |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Vicodin                   |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Ativan                    |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Donepezil Hydrochloride   |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Ranitidine                |                    |                    | C               |                                   |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Torsemide                 |                    |                    | C               |                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2005                                                                                                                                                                   | 5933203                   | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-04937-01                  |                      | 9 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Heart Rate Increased; Loss Of Consciousness; Tremor                                                                                                                | Lexapro                   |                    |                    | S               | Oral                              | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                               | Lexapro                   |                    |                    | S               |                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2005                                                                                                                                                                   | 5948592                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-SYNTHELABO-A02200503241 |                      | 38 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                    |                             |   |         |       |              |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------|---|---------|-------|--------------|
| Arterial Thrombosis; Blood Cholesterol Increased; Blood Triglycerides Increased; Dyslipidaemia; Pulmonary Embolism | Stilnox                     | S | Oral    | 10 Mg | Not Reported |
|                                                                                                                    | Cyamemazine                 | S | Oral    | 50 Mg | Not Reported |
|                                                                                                                    | Vastarel                    | S | Oral    | 35 Mg | Not Reported |
|                                                                                                                    | Zyprexa                     | S | Oral    | Unk   | Not Reported |
|                                                                                                                    | Inexium                     | S | Oral    | 20 Mg | Not Reported |
|                                                                                                                    | Escitalopram Oxalate        | S | Oral    | Unk   | Not Reported |
|                                                                                                                    | Xanax                       | C | Oral    | Unk   | Not Reported |
|                                                                                                                    | Cortancyl                   | C | Oral    | Unk   | Not Reported |
|                                                                                                                    | Victan                      | C | Oral    | Unk   | Not Reported |
|                                                                                                                    | Tramadol Hydrochloride      | C | Unknown | Unk   | Not Reported |
|                                                                                                                    | Amitriptyline Hydrochloride | C | Unknown | Unk   | Not Reported |
|                                                                                                                    | Anetholtrithion             | C | Oral    | Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2005              | 5954053       | EXPEDITED (15-DAY) | Y                  | DS              | S05-UKI-05669-01     |                      | 55 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psychiatric Symptom; Self-Injurious Ideation; Suicidal Ideation | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                 | Amitriptyline  |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Temazepam      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2005              | 5954470       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03830-01     |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Depression; Insomnia; Mania | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                         | Adderall (Amphetamines) |              |            | C           |              |                    |                 | Not Reported |
|                                         | Depakote                |              |            | C           |              |                    |                 | Not Reported |
|                                         | Lamictal                |              |            | C           |              |                    |                 | Not Reported |
|                                         | Sonata                  |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2005                                                               | 5955133              | EXPEDITED (15-DAY) | Y                  | OT              | S05-UKI-05681-01     |                      | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Gait Disturbance                                                | Ciprallex            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Atenolol             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Bendrofluazide       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Livial               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Eprosartan           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Lansoprazole         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Doxazosin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2005                                                               | 5834764              | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03200-01     |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Function Abnormal                                                 | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Birth Control Pills  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2005                                                               | 5953754              | EXPEDITED (15-DAY) | Y                  | DS              | S05-NLD-05699-01     |                      | 22 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accommodation Disorder; Mydriasis                                         | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Oxazepam             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2005                                                               | 5926631              | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-04643-01     |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cholestasis; Hepatic Failure; Hepatitis; Prothrombin Time Ratio | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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|                   |                            |   |              |
|-------------------|----------------------------|---|--------------|
| Decreased; Weight | Bromazepam                 | C | Not Reported |
| Decreased         | Aceprometazine\Meprobamate | C | Not Reported |
|                   | Hept-A-Myl (Hepataminol    | C | Not Reported |
|                   | Hydrochloride)             |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 27-Dec-2005              | 5951370       | EXPEDITED (15-DAY) | Y                  | HO, OT          | GB-SANOFI-SYNTHELABO-A01200508847 |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|--------------|
| Intracranial Aneurysm; Ruptured Cerebral Aneurysm; Subarachnoid Haemorrhage | Clopidogrel         |              |            | S           | Oral                     |                    | 3 DAY           | Not Reported |
|                                                                             | Cipraxel            |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                             | Aspirin             |              |            | S           | Oral                     |                    |                 | Not Reported |
|                                                                             | Salmeterol          |              |            | C           | Respiratory (inhalation) | 2 Puffs Bid Unk    |                 | Not Reported |
|                                                                             | Terbutaline Sulfate |              |            | C           | Respiratory (inhalation) | 2 Puffs Bid Unk    |                 | Not Reported |
|                                                                             | Adcal-D3            |              |            | C           | Oral                     | Unk                |                 | Not Reported |
|                                                                             | Spiriva             |              |            | C           | Respiratory (inhalation) | Unk                |                 | Not Reported |
|                                                                             | Atorvastatin        |              |            | C           | Oral                     |                    |                 | Not Reported |
|                                                                             | Pantoprazole Sodium |              |            | C           | Unknown                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2005              | 6747136       | EXPEDITED (15-DAY) | Y                  | DE              | MK200512-0423-1      |                      | 38 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest | Acetaminophen\Hydrocodone Bitartrate |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                             | Escitalopram Oxalate                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                             | Clonazepam                           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2005              | 5957648       | EXPEDITED (15-DAY) | Y                  | DE              | MK200512-0494-1      |                      | 42 YR      | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Overdose                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Methadose              |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Tramadol Hydrochloride |                    |                    | S               |                      |                      | Not Reported    |              |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Escitalopram Oxalate   |                    |                    | S               |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2005                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5958578                | EXPEDITED (15-DAY) | Y                  | DE              | S05-GER-05719-01     |                      | 19 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Sudden Death                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Ciprallex              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2005                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5926281                | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04746-01     |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Agitation; Anaemia;<br>Azotaemia; Blood<br>Bicarbonate Increased;<br>Blood Chloride<br>Decreased; Blood Glucose<br>Increased; Chronic Kidney<br>Disease; Condition<br>Aggravated; Depression;<br>Hypophagia;<br>Hypovolaemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Mental Disorder; Metabolic<br>Alkalosis;<br>Nephrosclerosis;<br>Paranoia; Skin Turgor<br>Decreased; Specific<br>Gravity Urine Increased;<br>Weight Decreased | Lexapro                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Demadex                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Ziac                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Norvasc                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Seroquel               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Aspirin                |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Dec-2005                                      | 5951279        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05098-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ageusia                                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2005                                      | 5956147        | DIRECT             | Y                  | OT              |                      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Abdominal Pain;         | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Not Reported |                |
| Eruclatation; Flatulence;<br>Nausea              | Wellbutrin XI  |                    |                    | C               | Oral                 | 20 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2006                                      | 5960040        | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-05285-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nephrolithiasis; Sepsis;<br>Ureteric Obstruction | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                  | Toprol XI      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Aspirin        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Crestor        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Vitamins       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                  | Prempro        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2006                                      | 5960042        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05286-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased                         | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Adderall       |                    |                    | S               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 03-Jan-2006                                 | 6035464                | EXPEDITED (15-DAY) | Y                  | HO, LT          | AT-JNJFOC-20051205044                           |                                   | 21 YR           | Male         | AUT            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Respiratory Depression | Durogesic              |                    |                    | S               | Transdermal                                     |                                   |                 | Not Reported |                |
|                                             | Ciprallex              |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Morphine Hydrochloride |                    |                    | S               | Other                                           |                                   |                 | Not Reported |                |
|                                             | Oxycontin              |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Alprazolam             |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Flunitrazepam          |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Gewadal                |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Gewadal                |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
|                                             | Caffeine               |                    |                    | S               | Unknown                                         | 1 Ampoule                         |                 | Not Reported |                |
|                                             | Voltaren               |                    |                    | S               | Unknown                                         |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2006                                 | 5953953                | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12840021 |                                   | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                   | Desyrel                |                    |                    | S               | Oral                                            | Duration Of Therapy: "A<br>While" |                 | Apothecon    |                |
|                                             | Desyrel                |                    |                    | S               | Oral                                            | Duration Of Therapy: "A<br>While" |                 | Apothecon    |                |
|                                             | Lexapro                |                    |                    | S               |                                                 |                                   |                 | Not Reported |                |
|                                             | Toprol XL              |                    |                    | C               |                                                 |                                   |                 | Not Reported |                |
|                                             | Lipitor                |                    |                    | C               |                                                 |                                   |                 | Not Reported |                |
|                                             | Lopid                  |                    |                    | C               |                                                 |                                   |                 | Not Reported |                |
|                                             | Fioricet               |                    |                    | C               |                                                 |                                   |                 | Not Reported |                |
|                                             | Lortab                 |                    |                    | C               |                                                 |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 04-Jan-2006                                                                         | 5954782                  | EXPEDITED (15-DAY) | N                  | HO              | US-GLAXOSMITHKLINE-A0569235A |                      | 87 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Depression; Disorientation; Drug Ineffective; Nausea; Panic Attack; Stress | Paxil Cr                 |                    |                    | S               | Oral                         | 12.5mg Per Day       | 6 WEEK          | Glaxosmithkline |                |
|                                                                                     | Paxil                    |                    |                    | S               | Oral                         | 10mg Per Day         | 2 YR            | Glaxosmithkline |                |
|                                                                                     | Lexapro                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                     | Paroxetine Hydrochloride |                    |                    | S               | Oral                         | 10mg Per Day         | 1 MTH           | Glaxosmithkline |                |
|                                                                                     | Atenolol                 |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2006                                                                         | 5956617                  | DIRECT             | Y                  | LT              |                              |                      | 40 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Intentional Overdose; Substance Abuse; Suicidal Ideation                            | Lexapro                  |                    |                    | S               |                              | X1                   |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2006                                                                         | 5961915                  | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-05748-01             |                      |                 | Female          | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dyskinesia; Salivary Gland Calculus                                                 | Escitalopram Oxalate     |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                     | Flecainide Acetate       |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 04-Jan-2006                                                                         | 5961917                  | EXPEDITED (15-DAY) | Y                  | HO              | S05-FRA-05749-01             |                      | 38 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arterial Thrombosis; Blood Cholesterol Increased; Blood Triglycerides               | Escitalopram Oxalate     |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                                     | Cyamemazine              |                    |                    | S               | Oral                         | 50 Mg Qd Po          |                 | Not Reported    |                |

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|                          |                            |   |      |             |              |
|--------------------------|----------------------------|---|------|-------------|--------------|
| Increased; Chest X-Ray   | Vastarel                   | S | Oral | 35 Mg Qd Po | Not Reported |
| Abnormal; Dyslipidaemia; | Zolpidem Tartrate          | S | Oral | 10 Mg Qd Po | Not Reported |
| Musculoskeletal Pain;    | Zyprexa                    | S |      |             | Not Reported |
| Peripheral Artery        | Inexium                    | S | Oral | 25 Mg Qd Po | Not Reported |
| Thrombosis; Pulmonary    | Xanax                      | C |      |             | Not Reported |
| Embolism                 | Victan (Ethyl Loflazepate) | C |      |             | Not Reported |
|                          | Unspecified Ingredient     | C |      |             | Not Reported |

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------|----------------------|----------------|
| 05-Jan-2006                               | 5720021        | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12762043 |                                                                                                 | 40 YR           | Female               | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Confusional<br>State; Insomnia | Serzone        |                  |                    | S               | Oral                                            |                                                                                                 |                 | Bristol Myers Squibb |                |
|                                           | Lexapro        |                  |                    | S               | Oral                                            | 11-Oct-04 To 12-Oct-04<br>10mg/D; Oct-04 - Oct-04 5<br>Mg/D; 2.5 Mg/D Oct-04 To<br>26-Oct-2004. |                 | Not Reported         |                |
|                                           | Wellbutrin     |                  |                    | C               |                                                 |                                                                                                 |                 | Not Reported         |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 05-Jan-2006                     | 5959056        | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05264-01     |                      |                 | Male            | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction;<br>Dyskinesia | Lamictal       |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                 | Lexapro        |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2006                                                | 5961120        | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-05297-02     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound; Suicidal<br>Ideation | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 05-Jan-2006                                                                                                                                                                                                                               | 5961123                           | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-05298-01     |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide                                                                                                                                                                                                                         | Lexapro                           |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jan-2006                                                                                                                                                                                                                               | 5961163                           | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-05298-02     |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide; Gun Shot Wound                                                                                                                                                                                                         | Lexapro                           |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jan-2006                                                                                                                                                                                                                               | 5961258                           | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-05298-03     |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide                                                                                                                                                                                                                         | Lexapro                           |                    |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jan-2006                                                                                                                                                                                                                               | 5921752                           | EXPEDITED (15-DAY) | Y                  | DS              | S05-PRT-03940-01     |                      | 49 YR           | Male       | PRT            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Glucose Increased; Drug Withdrawal Syndrome; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Headache; | Ciprallex                         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Ciprallex                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Selegiline Hydrochloride          |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Piridexil                         |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Sinemet                           |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Ticlopidine                       |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Risidon (Metformin Hydrochloride) |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Insulin Nos                       |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Insulin Nos                       |                    |                    | C               |                      |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |                                  |        |                              |
|--------------------------------------------------------------|----------------------------------|--------|------------------------------|
| Hyperaemia;<br>Hyperhidrosis;<br>Hypertension;<br>Somnolence | Pergolide<br>Mixtard Human 70/30 | C<br>C | Not Reported<br>Not Reported |
|--------------------------------------------------------------|----------------------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2006              | 5960054       | DIRECT           | Y                  | OT              |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Abdominal Pain;         | Lexapro        |              |            | S           | Oral         | 20 Mg Daily Po     |                 | Not Reported |
| Eructation; Flatulence;<br>Muscle Spasms; Nausea | Wellbutrin XL  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jan-2006              | 5962913       | EXPEDITED (15-DAY) | Y                  | HO              | KII-2005-0020491     |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lethargy; Overdose;                         | Oxycontin            |              |            | S           | Oral         | See Text, Oral     |                 | Not Reported |
| Oxygen Saturation<br>Decreased; Respiratory | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Rate Decreased;<br>Tachycardia              | Alcohol              |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2006              | 5887829       | EXPEDITED (15-DAY) | Y                  | DE              | 2005-132313-NL       |                      | 72 YR      | Male       | CHE            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Anxiety; Asphyxia; Autism<br>Spectrum Disorder; | Mirtazapine    |              |            | S           | Oral         | 30 Mg/60 Mg Oral      | 8 WEEK          | Not Reported |
| Completed Suicide;                              |                |              |            |             | Oral         | 30 Mg/60 Mg Oral      | 6 DAY           |              |
| Depressive Symptom;                             | Haloperidol    |              |            | S           | Oral         | 3 Mg/2 Mg/1 Mg/2 Mg/4 | 11 DAY          | Not Reported |
| Morbid Thoughts;                                |                |              |            |             | Oral         | Mg Oral               |                 |              |
| Restlessness; Sleep<br>Disorder                 |                |              |            |             | Oral         | 3 Mg/2 Mg/1 Mg/2 Mg/4 | 16 DAY          |              |
|                                                 |                |              |            |             | Oral         | Mg Oral               |                 |              |
|                                                 |                |              |            |             | Oral         | 3 Mg/2 Mg/1 Mg/2 Mg/4 | 1 WEEK          |              |
|                                                 |                |              |            |             |              | Mg Oral               |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |             |      |                                          |        |                                              |
|---------------------------------------------------------------|-------------|------|------------------------------------------|--------|----------------------------------------------|
| Escitalopram Oxalate                                          | S           | Oral | 3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral            | 5 DAY  | Not Reported                                 |
|                                                               |             | Oral | 3 Mg/2 Mg/1 Mg/2 Mg/4 Mg Oral            | 17 DAY |                                              |
|                                                               |             | Oral | 5 Mg/10 Mg/15 Mg Oral                    | 23 DAY |                                              |
| Lorazepam                                                     | S           | Oral | 5 Mg/10 Mg/15 Mg Oral                    | 18 DAY | Not Reported                                 |
|                                                               |             | Oral | 5 Mg/10 Mg/15 Mg Oral                    | 1 WEEK |                                              |
|                                                               |             | Oral | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral | 5 DAY  |                                              |
|                                                               |             | Oral | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral |        |                                              |
|                                                               |             | Oral | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral | 2 WEEK |                                              |
|                                                               |             | Oral | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral | 8 DAY  |                                              |
|                                                               |             | Oral | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral | 4 DAY  |                                              |
| Mineral Oil\Phenolphthalein<br>Cosaar<br>Atorvastatin Calcium | S<br>C<br>C |      | 1 Mg/3 Mg/2 Mg/1.5 Mg/0.5 Mg/1.5 Mg Oral | 1 WEEK | Not Reported<br>Not Reported<br>Not Reported |
|                                                               |             |      |                                          |        |                                              |
|                                                               |             |      |                                          |        |                                              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2006              | 5895823       | EXPEDITED (15-DAY) | Y                  | DE              | S05-ISR-03498-01     |                      | 66 YR      | Male       | ISR            |

| <u>Preferred Term</u>             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound | Ciprallex              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                   | Citalopram             |              |            | C           |              |                    |                 | Not Reported |
|                                   | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
|                                   | Oxazepam               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2006              | 5961913       | EXPEDITED (15-DAY) | Y                  | OT              | S05-CAN-05751-01     |                      | 35 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |          |   |      |             |              |
|-----------------------------|----------|---|------|-------------|--------------|
| Confusional State; Drug     | Cipralex | S | Oral | 10 Mg Qd Po | Not Reported |
| Hypersensitivity; Drug      | Ativan   | C |      |             | Not Reported |
| Screen Positive; Drug       | Cogentin | C |      |             | Not Reported |
| Withdrawal Syndrome;        | Benadryl | C |      |             | Not Reported |
| Hallucination; Laboratory   |          |   |      |             |              |
| Test Interference; Seizure; |          |   |      |             |              |
| Serotonin Syndrome;         |          |   |      |             |              |
| Suicidal Ideation           |          |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2006              | 5929974       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-04897-01     |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Intentional Overdose;<br>Toxicity To Various Agents | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2006              | 5963467       | DIRECT           | Y                  |                 |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cough                 | Lexapro        |              |            | S           | Ophthalmic   | 10 Mg Daily Po     |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2006              | 5959667       | EXPEDITED (15-DAY) | Y                  | OT              | GB-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13237417 |                      | 69 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Hepatic Steatosis; Liver<br>Function Test Abnormal | Abilify              |              |            | S           | Oral         | Dosage: Reduced To 10<br>Mg Daily, Then Withdrawn |                 | Not Reported |
|                                                                                | Cipralex             |              |            | S           | Oral         |                                                   |                 | Not Reported |
|                                                                                | Tegretol             |              |            | C           | Oral         |                                                   |                 | Not Reported |
|                                                                                | Levothyroxine Sodium |              |            | C           | Oral         |                                                   |                 | Not Reported |
|                                                                                | Levothyroxine Sodium |              |            | C           |              |                                                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                             |                      |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Theophylline                                                                                                                                                                |                      |                    | C                  |                 | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2006                                                                                                                                                                 | 6014103              | NON-EXPEDITED      | N                  |                 | 2005SP003485         |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Somnolence                                                                                                                                             | Lunesta              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg;Qd;Oral         |                 | Not Reported |                |
|                                                                                                                                                                             | Singulair            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2006                                                                                                                                                                 | 5892691              | EXPEDITED (15-DAY) | N                  | DS              | S05-USA-04333-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Gait<br>Disturbance; Insomnia;<br>Joint Swelling; Loss Of<br>Personal Independence In<br>Daily Activities; Oedema<br>Peripheral; Streptococcus<br>Test Positive | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                             | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2006                                                                                                                                                                 | 5969372              | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-00162-01     |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Respiratory Arrest;<br>Ventricular Tachycardia                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                             | Concerta             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2006                                                                                                                                                                 | 5969864              | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-00033-01     |                      | 32 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |            |   |      |             |              |
|---------------------------|------------|---|------|-------------|--------------|
| Abnormal Dreams;          | Ciprallex  | S | Oral | 20 Mg Qd Po | Not Reported |
| Emotional Distress; Fear; | Ciprallex  | S | Oral | 20 Mg Qd Po | Not Reported |
| Hallucination, Visual     | Bisoprolol | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Jan-2006              | 5962537       | EXPEDITED (15-DAY) | N                  | HO              | US-GLAXOSMITHKLINE-A0589290A |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Depression; Drug Ineffective; Suicidal Ideation; Suicide Attempt | Paxil          |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                  | Lamictal       |              |            | S           | Oral         |                    | 3 YR            | Glaxosmithkline |
|                                                                  | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                  | Effexor        |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2006              | 5947626       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05093-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Disorder; Intentional Overdose | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2006              | 5963715       | EXPEDITED (15-DAY) | Y                  | OT              | US-MERCK-0511USA00567 |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Headache; Hepatic Steatosis; Hepatotoxicity; Hypertensive Crisis; Hypoaesthesia; Oedema | Vytorin        |              |            | S           | Ophthalmic   |                    | 40 DAY          | Merck        |
|                                                                                                                                                                                                         | Lopid          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                         | Tylenol        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                         | Vytorin        |              |            | S           | Ophthalmic   |                    | 40 DAY          | Merck        |
|                                                                                                                                                                                                         | Seroquel       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                         | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |            |   |         |              |
|------------|------------|---|---------|--------------|
| Peripheral | Coreg      | C | Unknown | Not Reported |
|            | Ecotrin    | C | Unknown | Not Reported |
|            | Toprol XL  | C | Unknown | Not Reported |
|            | Furosemide | C | Unknown | Not Reported |
|            | K-Dur      | C | Unknown | Not Reported |
|            | Clonidine  | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2006                                                                       | 5973108        | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00178-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood                                                                   | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Po             |                 | Not Reported |                |
| Magnesium Decreased;<br>Bronchitis; Feeling<br>Abnormal; Hyponatraemia;<br>Tremor | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Jan-2006                                                                                                                                                                    | 5788450        | EXPEDITED (15-DAY) | Y                  | HO, LT, RI      | S05-USA-01992-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;                                                                                                                                                            | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
| Agitation; Chemical<br>Poisoning; Condition                                                                                                                                    | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd; Po          |                 | Not Reported |                |
| Aggravated; Dehydration;<br>Drug Ineffective;<br>Dysphagia; Intentional<br>Overdose; Intestinal<br>Infarction; Loss Of<br>Consciousness;<br>Oesophagectomy; Suicide<br>Attempt | Remeron        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jan-2006              | 5971575       | DIRECT           | N                  | HO, LT, OT      |                      |                      | 38 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|------------------------------------|--------------------------|---------------------|-------------------------|
| Abnormal Behaviour;<br>Alcoholism; Divorced;<br>Gastric Haemorrhage;<br>Hallucination; Legal<br>Problem; Obsessive-<br>Compulsive Disorder | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Once Daily Po                |                          | Not Reported        |                         |
|                                                                                                                                            | Alcohol                 |                           |                             | C                        |                               |                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jan-2006                                                                                                                                | 5971634                 | DIRECT                    | N                           | HO                       |                               |                                    | 29 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Malaise; Nausea;<br>Vasculitis                                                                                                    | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Once Daily Po                |                          | Not Reported        |                         |
|                                                                                                                                            | Apri -Birth Control-    |                           |                             | C                        |                               |                                    |                          | Not Reported        |                         |
|                                                                                                                                            | Allegra                 |                           |                             | C                        |                               |                                    |                          | Not Reported        |                         |
|                                                                                                                                            | Ativan                  |                           |                             | C                        |                               |                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2006                                                                                                                                | 5895393                 | EXPEDITED (15-DAY)        | Y                           | DS                       | T05-GER-03487-01              |                                    |                          | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Hypersensitivity;<br>Lichen Planus;<br>Photosensitivity Reaction;<br>Scratch; Skin Abrasion;<br>Skin Atrophy                          | Escitalopram Oxalate    |                           |                             | S                        |                               |                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2006                                                                                                                                | 5906892                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | 2005122045                    |                                    | 47 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Back Pain; Blood<br>Cholesterol Increased;<br>Blood Pressure<br>Fluctuation;                                                      | Neurontin               |                           |                             | S                        | Oral                          | 600 Mg (200 Mg, 3 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                                                                                            | Unspecified Ingredient  |                           |                             | S                        | Oral                          | Oral                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                   |   |      |               |             |              |
|---------------------------|-------------------|---|------|---------------|-------------|--------------|
| Cerebrovascular Accident; | Lexapro           | S | Oral | 12.5 Mg, Oral | 60 Mg (1 D) | Not Reported |
| Condition Aggravated;     | Zyprexa           | S |      |               |             | Not Reported |
| Drug Hypersensitivity;    | Cymbalta          | S |      |               |             | Not Reported |
| Neuropathy Peripheral;    | Lithium (Lithium) | S |      |               |             | Not Reported |
| Retching; Throat          | Klonopin          | S |      |               |             | Not Reported |
| Tightness; Tongue         | Depakote          | C |      |               |             | Not Reported |
| Paralysis; Tremor         |                   |   |      |               |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2006              | 5974002       | EXPEDITED (15-DAY) | N                  | HO, OT          | 2006008257           |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Drug        | Zyrtec-D               |              |            | S           |              |                    |                 | Not Reported |
| Hypersensitivity;       | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
| Dyspnoea; Hypertension; | Lorazepam              |              |            | C           |              |                    |                 | Not Reported |
| Lung Disorder           | Zantac                 |              |            | C           |              |                    |                 | Not Reported |
|                         | Singulair              |              |            | C           |              |                    |                 | Not Reported |
|                         | Albuterol (Salbutamol) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2006              | 5974885       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2006-01-0993         |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-------------------|--------------|------------|-------------|------------------------------|--------------------------------------------------|-----------------|--------------|
| Depression; Dry Eye; Eye Irritation; Muscle Spasms | Loratadine        |              |            | S           | Oral<br>Oral<br>Oral<br>Oral | Oral<br>Oral<br>Oral<br>Oral                     |                 | Not Reported |
|                                                    | Lexapro           |              |            | S           |                              | See Image<br>See Image<br>See Image<br>See Image |                 | Not Reported |
|                                                    | Prilosec          |              |            | C           |                              |                                                  |                 | Not Reported |
|                                                    | Niacin            |              |            | C           |                              |                                                  |                 | Not Reported |
|                                                    | Calcium Gluconate |              |            | C           |                              |                                                  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Jan-2006                                    | 6001155                       | NON-EXPEDITED      | Y                  | OT              | PERC20050029         |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Drug Abuser;<br>Emotional Disorder | Percocet                      |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Endo         | Not Reported   |
|                                                | Lexapro                       |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                | Marijuana                     |                    |                    | S               |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2006                                    | 5957079                       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05238-01     |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lupus-Like Syndrome                            | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported | Not Reported   |
|                                                | Ibuprofen                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Pseudoephedrine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2006                                    | 5961698                       | EXPEDITED (15-DAY) | Y                  | HO              | S05-IRL-05766-01     |                      | 61 YR           | Male         | IRL            |
| <u>Preferred Term</u>                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemoglobin Decreased;<br>Melaena              | Lexapro                       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                | Mobic                         |                    |                    | S               | Oral                 | 15 Mg Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2006                                    | 5976232                       | EXPEDITED (15-DAY) | Y                  | RI              | S06-USA-00219-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Discharge; Breast<br>Mass               | Lexapro                       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                | Claritin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Skelaxin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Advair Diskus                 |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2006              | 5976237       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00216-01     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2006              | 5926966       | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-424968      |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;       | Demadex        |              |            | S           | Unknown      |                    |                 | Roche        |
| Agitation; Anaemia; Blood  | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
| Bicarbonate Increased;     | Ziac           |              |            | S           | Unknown      |                    |                 | Not Reported |
| Depression;                | Norvasc        |              |            | C           |              |                    |                 | Not Reported |
| Hypovolaemia;              | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
| Inappropriate Antidiuretic | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
| Hormone Secretion;         |                |              |            |             |              |                    |                 |              |
| Mental Disorder; Metabolic |                |              |            |             |              |                    |                 |              |
| Alkalosis; Paranoia;       |                |              |            |             |              |                    |                 |              |
| Tremor; Weight             |                |              |            |             |              |                    |                 |              |
| Decreased                  |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2006              | 5939155       | EXPEDITED (15-DAY) | Y                  | HO              | HQWYE548414NOV05     |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;       | Ziac                           |              |            | S           |              |                    |                 | Not Reported |
| Anaemia; Blood Glucose     | Demadex                        |              |            | S           |              |                    |                 | Not Reported |
| Increased; Depression;     | Effexor                        |              |            | S           |              |                    |                 | Not Reported |
| Hypertension;              | Lexapro                        |              |            | S           |              |                    |                 | Not Reported |
| Hypovolaemia;              | Norvasc                        |              |            | C           |              |                    |                 | Not Reported |
| Inappropriate Antidiuretic | Seroquel                       |              |            | C           |              |                    |                 | Not Reported |
| Hormone Secretion;         | Aspirin (Acetylsalicylic Acid) |              |            | C           |              |                    |                 | Not Reported |
| Metabolic Alkalosis;       |                                |              |            |             |              |                    |                 |              |
| Nephrosclerosis;           |                                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Paranoia; Tremor; Weight  
Decreased

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2006              | 5962468        | EXPEDITED (15-DAY) | N                  | HO              | 2006002050           |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pain; Rash Generalised   | Lyrica         |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                          | Ciprallex      |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2006              | 5974794        | DIRECT           | N                  | DE              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Wellbutrin XI  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Wellbutrin Sr  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Celexa         |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jan-2006               | 5977867        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00218-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Alcohol Withdrawal        | Lexapro        |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| Syndrome; Alcoholism;     | Lexapro        |                    |                    | S               | Oral                 | 60 Mg Qd Po          |                 | Not Reported |                |
| Condition Aggravated;     | Lexapro        |                    |                    | S               | Oral                 | 80 Mg Qd Po          |                 | Not Reported |                |
| Drug Abuser; Drug         | Lexapro        |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| Withdrawal Syndrome;      | Lexapro        |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| Seizure; Self-Medication; | Xanax          |                    |                    | S               |                      | 2 Mg Qd              |                 | Not Reported |                |
| Thinking Abnormal         | Xanax          |                    |                    | S               |                      | 1 Mg Qid             |                 | Not Reported |                |
|                           | Xanax          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Buspar         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Remeron        |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                      |   |              |
|--|--------------------------------------|---|--------------|
|  | Wellbutrin (Bupropion Hydrochloride) | C | Not Reported |
|  | Effexor                              | C | Not Reported |
|  | Klonopin                             | C | Not Reported |
|  | Paxil                                | C | Not Reported |

| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2006                                         | 5925021                  | EXPEDITED (15-DAY) |                    | HO, LT          | US-ABBOTT-05P-163-0308010-00 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intestinal Obstruction;<br>Pancreatitis; Pseudocyst | Mavik                    |                    |                    | S               | Oral                         |                      | 25 YR           | Not Reported |                |
|                                                     | Lexapro                  |                    |                    | S               | Oral                         |                      | 51 DAY          | Not Reported |                |
|                                                     | Dyazide                  |                    |                    | S               | Oral                         |                      | 25 YR           | Not Reported |                |
|                                                     | Hydrochlorothiazide      |                    |                    | S               |                              |                      | 25 YR           | Not Reported |                |
|                                                     | Trazodone Hydrochloride  |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Indomethacin             |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Metoclopramide           |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Erythromycin             |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Estrogens Conjugated     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Cetirizine Hydrochloride |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Singulair                |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Modafinil                |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 27-Jan-2006                                         | 5970616        | NON-EXPEDITED    | N                  |                 | US-GLAXOSMITHKLINE-A0537084A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Dry Mouth; Insomnia; Paraesthesia | Wellbutrin     |                  |                    | S               | Oral                         | 75mg Per Day         | 13 YR           | Glaxosmithkline |                |
|                                                     | Strattera      |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                     | Ziagen         |                  |                    | S               |                              |                      |                 | Glaxosmithkline |                |
|                                                     | Truvada        |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                     | Prevacid       |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                     | Zoloft         |                  |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                     | Lexapro        |                  |                    | S               |                              |                      |                 | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 27-Jan-2006                | 5970655        | NON-EXPEDITED    | N                  |                 | S05-USA-00081-01     |                      | 30 YR           | Female          | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Breast Tenderness          | Wellbutrin     |                  |                    | S               | Oral                 | 300mg Per Day        |                 | Glaxosmithkline |                |
|                            | Lexapro        |                  |                    | S               | Oral                 | 20mg Per Day         | 2 YR            | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2006                | 5970863        | NON-EXPEDITED    | N                  |                 | SO5-USA-03431-01     |                      | 71 YR           | Male            | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Fatigue; | Wellbutrin     |                  |                    | S               | Oral                 | 150mg Per Day        |                 | Glaxosmithkline |                |
| Headache; Insomnia;        | Lexapro        |                  |                    | S               | Oral                 | 10mg Per Day         | 13 MTH          | Not Reported    |                |
| Mental Impairment;         | Diazepam       |                  |                    | C               |                      |                      |                 | Not Reported    |                |
| Nausea; Tinnitus           | Atenolol       |                  |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2006                | 5970885        | NON-EXPEDITED    | N                  |                 | S05-USA-03669-01     |                      | 32 YR           | Male            | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dizziness; Drug            | Wellbutrin     |                  |                    | S               | Oral                 |                      | 7 DAY           | Glaxosmithkline |                |
| Withdrawal Syndrome;       | Lexapro        |                  |                    | S               | Oral                 | 20mg Per Day         | 3 MTH           | Not Reported    |                |
| Headache; Libido           |                |                  |                    |                 |                      |                      |                 |                 |                |
| Decreased; Nausea; Rash    |                |                  |                    |                 |                      |                      |                 |                 |                |
| Generalised                |                |                  |                    |                 |                      |                      |                 |                 |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2006                | 5970886        | NON-EXPEDITED    | N                  |                 | S05-USA-03678-01     |                      | 45 YR           | Female          | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Dizziness; Feeling  | Wellbutrin     |                  |                    | S               | Oral                 | 450mg Per Day        |                 | Glaxosmithkline |                |
| Hot; Headache; Insomnia;   |                |                  |                    |                 |                      |                      |                 |                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |                                |                    |                    |                 |                      |                          |                 |              |                |
|------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Myalgia; Tremor                          |                                | Lexapro            |                    | S               | Oral                 | 40mg Per Day             |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2006                              | 6016889                        | NON-EXPEDITED      | Y                  | OT              | 2005159086           |                          |                 | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                         | Lyrica                         |                    |                    | S               | Unknown              | Unknown (50 Mg, Unknown) |                 |              | Not Reported   |
|                                          | Lexapro                        |                    |                    | S               | Unknown              | 10 Mg Unknown            |                 |              | Not Reported   |
|                                          | Wellbutrin XL                  |                    |                    | C               |                      |                          |                 |              | Not Reported   |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jan-2006                              | 6026243                        | NON-EXPEDITED      | Y                  | HO              | 05-02-0255           |                          | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Intestinal Obstruction     | Clozapine                      |                    |                    | S               | Oral                 | 575mg Qd, Oral           |                 |              | Not Reported   |
|                                          | Benzotropine                   |                    |                    | S               |                      | 1mg Qam; 2mg Hs          |                 |              | Not Reported   |
|                                          | Clonazepam                     |                    |                    | S               | Oral                 | 1mg Hs Prn, Oral         |                 |              | Not Reported   |
|                                          | Lexapro                        |                    |                    | S               | Oral                 | 10mg Qam, Oral           |                 |              | Not Reported   |
| <u>FDA Received Date</u>                 | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2006                              | 5941584                        | EXPEDITED (15-DAY) | Y                  | HO              | 006062               |                          | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;                     | Ziac                           |                    |                    | S               |                      |                          |                 |              | Not Reported   |
| Agitation; Anaemia;                      | Demadex                        |                    |                    | S               |                      |                          |                 |              | Not Reported   |
| Depression; Hypertension;                | Effexor                        |                    |                    | S               |                      |                          |                 |              | Not Reported   |
| Hypovolaemia;                            | Lexapro                        |                    |                    | S               |                      |                          |                 |              | Not Reported   |
| Inappropriate Antidiuretic               | Norvasc                        |                    |                    | C               |                      |                          |                 |              | Not Reported   |
| Hormone Secretion;                       | Seroquel                       |                    |                    | C               |                      |                          |                 |              | Not Reported   |
| Metabolic Alkalosis;                     | Aspirin (Acetylsalicylic Acid) |                    |                    | C               |                      |                          |                 |              | Not Reported   |
| Paranoia; Skin Turgor Decreased; Tremor; |                                |                    |                    |                 |                      |                          |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weight Decreased

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 30-Jan-2006                                                                                                                                                                                                                                                                                                  | 5975566        | DIRECT             | N                  | OT              |                      |                         | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Drug Withdrawal Syndrome; Nightmare                                                                                                                                                                                                                                                         | Lexapro        |                    |                    | S               |                      | 10 Mg Daily             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jan-2006                                                                                                                                                                                                                                                                                                  | 6024776        | NON-EXPEDITED      | Y                  | OT              | 141582USA            |                         | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury; Jaundice; Liver Function Test Abnormal                                                                                                                                                                                                                                                | Copaxone       |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                              | Lexapro        |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2006                                                                                                                                                                                                                                                                                                  | 5866527        | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-03889-02     |                         | 121 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Disorder; Hilar Lymphadenopathy; Laboratory Test Interference; Lymphadenopathy; Maternal Condition Affecting Foetus; Maternal Exposure During Pregnancy; Neonatal Disorder; Oedema; Pulmonary Congestion; Pulmonary Haemorrhage; Respiratory Disorder Neonatal; Skin Discolouration; Sudden | Lexapro        |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                              | Lexapro        |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                              | Lexapro        |                    |                    | S               |                      | 20 Mg Qd Bf             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                              | Zofran         |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                              | Benadryl       |                    |                    | C               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infant Death Syndrome

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Feb-2006                                     | 5951256              | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05109-01     |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Diabetes Mellitus; Weight Increased | Lexapro              |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Hyzaar               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2006                                     | 5987321              | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-00093-01     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphagia                                       | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2006                                     | 5987604              | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05384-01     |                      | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Prostate Cancer                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Seroquel             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 | Clonazepam           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2006                                     | 5987607              | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00295-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia; Condition Aggravated;      | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Birth Control Pills  |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                  |         |   |  |  |  |  |  |              |
|--------------------------------------------------------------------------------------------------|---------|---|--|--|--|--|--|--------------|
| Depression; Feeling Abnormal; Intentional Overdose; Physical Assault; Pyromania; Suicide Attempt | Ritalin | C |  |  |  |  |  | Not Reported |
|--------------------------------------------------------------------------------------------------|---------|---|--|--|--|--|--|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2006              | 5942506       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05055-01     |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness;    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Headache; Memory Impairment; Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2006              | 5955051       | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05240-01     |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;                    | Lexapro                |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Oral Candidiasis; Red Blood Cells Urine; | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Sjogren'S Syndrome;                      | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
| Urinary Tract Infection                  | Evoxac                 |              |            | C           |              |                    |                 | Not Reported |
|                                          | Klonopin               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2006              | 5959430       | EXPEDITED (15-DAY) | Y                  | DE              | S05-PRT-05744-01     |                      | 31 YR      | Male       | PRT            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuser           | Cipralext              |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
|                       | Methadone              |              |            | C           |              |                    |                 | Not Reported |
|                       | Mirtazapine            |              |            | C           |              |                    |                 | Not Reported |
|                       | Oxazepam               |              |            | C           |              |                    |                 | Not Reported |
|                       | Triazolam              |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------|-----------------|-----------------|----------------|
| 07-Feb-2006                                                                                                                                          | 5983973        | DIRECT             | Y                  | DE              |                              |                                          | 20 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Myocardial Infarction; Cardio-Respiratory Arrest; Dyspnoea; Nausea; Sudden Death                                                               | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Daily Po                           |                 | Not Reported    |                |
|                                                                                                                                                      | Seroquel       |                    |                    | S               | Oral                         | 800 Mg Daily Po                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Feb-2006                                                                                                                                          | 5986008        | EXPEDITED (15-DAY) | Y                  | HO, LT, RI      | 2006-137687-NL               |                                          | 65 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Chemical Burn; Dehydration; Drug Ineffective; Dysphagia; Intentional Self-Injury; Intestinal Infarction; Self-Medication; Suicide Attempt | Remeron        |                    |                    | S               |                              |                                          |                 | Not Reported    |                |
|                                                                                                                                                      | Lexapro        |                    |                    | S               | Oral                         | 5 Mg Daily Oral, Increasing To 10 Mg     |                 | Not Reported    |                |
|                                                                                                                                                      | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Daily Oral, About One Or Two Weeks |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2006                                                                                                                                          | 5978823        | NON-EXPEDITED      | N                  |                 | S05-USA-02987-01             |                                          | 42 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>      |                |
| Decreased Appetite; Diarrhoea; Hyperhidrosis; Nausea; Pain; Panic Attack; Weight Increased                                                           | Paxil          |                    |                    | S               | Oral                         | 30mg Per Day                             |                 | Glaxosmithkline |                |
|                                                                                                                                                      | Lexapro        |                    |                    | S               | Oral                         |                                          | 15 DAY          | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2006                                                                                                                                          | 5979096        | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0569243A |                                          | 33 YR           | Female          | USA            |

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| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|---------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Agitation; Disability;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Hyperhidrosis; Nausea;<br>Nightmare; Urticaria | Paxil          |                  |                    | S               | Oral                                 |                      | 6 MTH           | Glaxosmithkline |                |
|                                                                                                                     | Lexapro        |                  |                    | S               | Unknown                              |                      | 4 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2006                                                                                                         | 5979170        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0570854A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Crying; Drug Ineffective;<br>Feeling Abnormal;<br>Irritability                                                      | Paxil          |                  |                    | S               | Oral                                 | 40mg Per Day         | 4 MTH           | Glaxosmithkline |                |
|                                                                                                                     | Paxil Cr       |                  |                    | S               | Oral                                 | 25mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                     | Lexapro        |                  |                    | S               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                     | Celebrex       |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                     | Ativan         |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2006                                                                                                         | 5979772        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0578760A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Panic Attack; Sexual<br>Dysfunction; Tinnitus                                                                       | Paxil          |                  |                    | S               | Oral                                 | 20mg Per Day         | 7 YR            | Glaxosmithkline |                |
|                                                                                                                     | Lexapro        |                  |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Feb-2006                                                                                                         | 5985270        | DIRECT           | Y                  | DE              |                                      |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Death;<br>Alcoholism; Drowning                                                                           | Lexapro        |                  |                    | S               | Oral                                 | 10 Mg Daily Po       |                 | Not Reported    |                |
|                                                                                                                     | Seroquel       |                  |                    | S               | Oral                                 | 100 Mg Daily Po      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5889050       | EXPEDITED (15-DAY) | N                  | RI, OT          | S05-USA-04309-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;        | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Ageusia; Amnesia; Anal  | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Incontinence; Anosmia;  | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Anxiety; Asthenia;      | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Cerebral Disorder;      | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Cholecystectomy;        | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Confusional State;      | Depo-Provera   |              |            | C           |              |                    |                 | Not Reported |
| Dizziness; Feeling      | Fastin         |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Headache;     | Prevacid       |              |            | C           |              |                    |                 | Not Reported |
| Hepatic Steatosis;      |                |              |            |             |              |                    |                 | Not Reported |
| Hypoaesthesia; Impaired |                |              |            |             |              |                    |                 |              |
| Work Ability; Insomnia; |                |              |            |             |              |                    |                 |              |
| Nausea; Ovarian Cyst;   |                |              |            |             |              |                    |                 |              |
| Pain; Palpitations;     |                |              |            |             |              |                    |                 |              |
| Paraesthesia; Product   |                |              |            |             |              |                    |                 |              |
| Dose Omission; Tension  |                |              |            |             |              |                    |                 |              |
| Headache; Teratoma;     |                |              |            |             |              |                    |                 |              |
| Vision Blurred          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5921728       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L05-USA-03935-41     |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Brain Death; Brain        | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Oedema; Encephalopathy;   | Valproic Acid        |              |            | S           |              |                    |                 | Not Reported |
| Haemodialysis;            | Lorazepam            |              |            | S           |              |                    |                 | Not Reported |
| Hyperammonaemia;          | Metformin            |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Posturing;      |                      |              |            |             |              |                    |                 |              |
| Seizure; Self-Medication; |                      |              |            |             |              |                    |                 |              |
| Suicide Attempt           |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5921732       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L05-USA-03935-46     |                      | 30 YR      | Male       | USA            |



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| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Completed Suicide; Foaming At Mouth; Loss Of Consciousness; Overdose; Pneumonia Aspiration; Pulseless Electrical Activity                                                                                                                  | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Bupropion Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Oxcarbazepine            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Lorazepam                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2006                                                                                                                                                                                                                                                                                                | 5921736                  | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-44     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress Syndrome; Anuria; Brain Herniation; Completed Suicide; Disseminated Intravascular Coagulation; Drug Screen Positive; Haemorrhage Intracranial; Hallucination; Hypotension; Intentional Overdose; Multiple Organ Dysfunction Syndrome; Pupil Fixed; Seizure; Tachycardia; Tremor | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Bupropion                |                    |                    | S               |                      | 75 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Paroxetine Hydrochloride |                    |                    | S               |                      | 30 Mg                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Amphetamine Sulfate      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Unspecified Ingredient   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2006                                                                                                                                                                                                                                                                                                | 5921799                  | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-40     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Blood Pressure Systolic Decreased; Cyanosis; Hypoxic-Ischaemic                                                                                                                                                                                                                                 | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Methadone Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Tramadol Hydrochloride   |                    |                    | S               |                      |                      |                 | Not Reported |                |

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Encephalopathy; Loss Of  
Consciousness

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5921803       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L05-USA-03935-38     |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                            | <u>Product</u>                                                                                                                                                                                                                                                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                                                                       | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-----------------------------------------------------------------------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine Increased; Blood Urea Increased; Cardiac Failure Congestive; Cerebral Infarction; Coma; Completed Suicide; Hypertension; International Normalised Ratio Increased; Loss Of Consciousness; Pneumonia; Posturing; Troponin Increased | Escitalopram Oxalate<br>Citalopram<br>Acetaminophen And Codeine<br>Acetaminophen W/Hydrocodone<br>Bitartrate<br>Ibuprofen<br>Nabumetone<br>Celecoxib<br>Zolpidem<br>Metronidazole<br>Diazepam<br>Metaxalone<br>Amitriptyline<br>Metformin<br>Aspirin (Acetylsalicylic Acid)<br>Bupropion<br>Codeine\Promethazine |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5921807       | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-43     |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Overdose              | Escitalopram Oxalate<br>Amitriptyline<br>Chlorpromazine<br>Mirtazapine<br>Acetaminophen\Aspirin\Butalbital<br>Misoprostol<br>Nabumetone |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                            |                                                                                                                 |                    |                    |                                 |                      |                      |                 |                                                                                                              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------|--------------------|---------------------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------------------------------------------------------|----------------|
| Diclofenac                                                                                                                                                                                                 |                                                                                                                 |                    | S                  |                                 |                      | Not Reported         |                 |                                                                                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 10-Feb-2006                                                                                                                                                                                                | 5921809                                                                                                         | EXPEDITED (15-DAY) | Y                  | DE, HO                          | L05-USA-03935-42     |                      | 25 YR           | Female                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Brain Death; Cardiac Arrest; Electrocardiogram Qrs Complex Prolonged; Loss Of Consciousness; Respiratory Arrest                                                                                            | Lexapro<br>Amitriptyline<br>Xanax<br>Amphetamine<br>Meperidine Hcl                                              |                    |                    | S<br>S<br>S<br>S<br>S           |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 10-Feb-2006                                                                                                                                                                                                | 5922394                                                                                                         | EXPEDITED (15-DAY) | Y                  | DE                              | L05-USA-03935-37     |                      | 47 YR           | Female                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Cardio-Respiratory Arrest; Chest Pain; Drug Abuser; Respiratory Rate Increased; Toxicity To Various Agents                                                                                                 | Lexapro<br>Cardizem<br>Potassium<br>Cocaine<br>Nifedipine<br>Hydrochlorothiazide                                |                    |                    | S<br>S<br>S<br>S<br>S<br>S      |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 10-Feb-2006                                                                                                                                                                                                | 5923180                                                                                                         | EXPEDITED (15-DAY) | Y                  | DE                              | L05-USA-03935-50     |                      | 40 YR           | Female                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspiration; Blood Creatinine Increased; Blood Ph Decreased; Brain Death; Cardiac Arrest; Drug Screen Positive; Hypoxic-Ischaemic | Lexapro<br>Seroquel<br>Clonazepam<br>Metformin<br>Depakote<br>Haldol<br>Unspecified Ingredient<br>Phencyclidine |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Encephalopathy; Loss Of  
Consciousness;  
Respiratory Arrest

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5923188       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L05-USA-03935-49     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Electroencephalogram                  | Ambien               |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Loss Of                     | Atenolol             |              |            | S           |              |                    |                 | Not Reported |
| Consciousness;                        | Klonopin             |              |            | S           |              |                    |                 | Not Reported |
| Respiratory Arrest                    | Neurontin            |              |            | S           |              |                    |                 | Not Reported |
|                                       | Topamax              |              |            | S           |              |                    |                 | Not Reported |
|                                       | Xanax                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5923193       | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-48     |                      | 50 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aortic Arteriosclerosis;                                               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Arteriosclerosis Coronary                                              | Doxepin        |              |            | S           |              |                    |                 | Not Reported |
| Artery; Blood Pressure                                                 | Lopresor       |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Cardiomegaly;                                               | Plavix         |              |            | S           |              |                    |                 | Not Reported |
| Completed Suicide; Heart                                               | Temazepam      |              |            | S           |              |                    |                 | Not Reported |
| Rate Decreased; Loss Of<br>Consciousness;<br>Toxicologic Test Abnormal |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5923200       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L05-USA-03935-47     |                      | 16 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram Oxalate                                                     |              |            | S           |              |                    |                 | Not Reported |
|                       | Dextroamphet Saccharat,<br>Amphet Aspartate,<br>Dextroamphet Sulfate And |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amphet Sulfat

| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 10-Feb-2006                                                                    | 5940251        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05035-01                     |                      | 22 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Ventricular Extrasystoles                                                      | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2006                                                                    | 5957082        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05241-01                     |                      | 19 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alcohol Use; Drug Abuser;<br>Loss Of Consciousness;<br>Treatment Noncompliance | Lexapro        |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                | Lexapro        |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                | Alcohol        |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                | Marijuana      |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                | Effexor        |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2006                                                                    | 5961117        | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-05297-01                     |                      | 18 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide; Gun<br>Shot Wound; Suicidal<br>Ideation                     | Lexapro        |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2006                                                                    | 5982022        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0567941A |                      | 45 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Drug Ineffective;<br>Insomnia; Nervousness;                           | Paxil Cr       |                    |                    | S               | Oral                                 | 12.5mg Per Day       |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |         |   |         |              |        |                 |
|------------|---------|---|---------|--------------|--------|-----------------|
| Somnolence | Paxil   | S | Oral    | 20mg Per Day | 2 WEEK | Glaxosmithkline |
|            | Lexapro | S | Unknown |              |        | Not Reported    |
|            | Biotin  | C |         |              |        | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5985946       | DIRECT           | Y                  | OT              |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Erythema; Rash        | Lexapro        |              |            | S           | Oral         | 10mg Po Q Daily    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5986875       | DIRECT           | N                  | HO, LT          |                      |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alcohol Use; Pancreatic Necrosis; Pancreatitis Acute; Treatment Noncompliance | Lexapro        |              |            | S           | Oral         | Daily Po           | 1 YR            | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5993032       | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-45     |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation; Atrioventricular Block First Degree; Bundle Branch Block; Bundle Branch Block Left; Cardiac Arrest; Completed Suicide; Drug Level Above Therapeutic; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Hypotension; Hypoxia; Loss Of | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Bupropion            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Topiramate           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Oxcarbazepine        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Phenytoin            |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Consciousness; Muscle  
Twitching; Serotonin  
Syndrome; Toxicity To  
Various Agents

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5993250       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00343-01     |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aphasia; Areflexia;         | Celexa              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Cerebral Atrophy;           | Lexapro             |              |            | S           |              |                    |                 | Not Reported |
| Cerebral Ischaemia;         | Lexapro             |              |            | S           |              |                    |                 | Not Reported |
| Cerebral Ventricle          | Haldol              |              |            | S           |              |                    |                 | Not Reported |
| Dilatation; Chronic         | Risperdal           |              |            | S           | Oral         | 0.5 Mg Bid Po      |                 | Not Reported |
| Sinusitis; Confusional      | Aricept             |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |
| State; Diarrhoea;           | Aricept             |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Dysarthria; Dystonia;       | Synthroid           |              |            | C           |              |                    |                 | Not Reported |
| Extrapyramidal Disorder;    | Lopresor            |              |            | C           |              |                    |                 | Not Reported |
| Fall; Gait Disturbance;     | Epogen              |              |            | C           |              |                    |                 | Not Reported |
| Gait Inability;             | Protonix            |              |            | C           |              |                    |                 | Not Reported |
| Hallucination; Joint        | Promod (Proglumide) |              |            | C           |              |                    |                 | Not Reported |
| Stiffness; Muscle Rigidity; | Ferrous Sulfate     |              |            | C           |              |                    |                 | Not Reported |
| Nervous System Disorder;    | Vitamin E           |              |            | C           |              |                    |                 | Not Reported |
| Normal Pressure             | Multivitamin (Nos)  |              |            | C           |              |                    |                 | Not Reported |
| Hydrocephalus; Peroneal     |                     |              |            |             |              |                    |                 |              |
| Nerve Palsy; Sciatica;      |                     |              |            |             |              |                    |                 |              |
| Somnolence; Spinal Cord     |                     |              |            |             |              |                    |                 |              |
| Compression; Spinal         |                     |              |            |             |              |                    |                 |              |
| Stenosis; Tardive           |                     |              |            |             |              |                    |                 |              |
| Dyskinesia; Vomiting;       |                     |              |            |             |              |                    |                 |              |
| Weight Decreased            |                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2006              | 5994005       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-00459-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2006                                                                                           | 5996183                    | EXPEDITED (15-DAY) | Y                  | HO              | S06-ESP-00413-01     |                      | 82 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hyponatraemia;<br>Nervousness                                                                | Ciprallex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Seroquel                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Plantaben (Ispaghula Husk) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Plavix                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2006                                                                                           | 5941201                    | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-05053-01     |                      | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Enterocolitis Infectious;<br>Influenza Like Illness                                                   | Lexapro                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                       | Lexapro                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2006                                                                                           | 5992864                    | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00344-01     |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Immune<br>Thrombocytopenic<br>Purpura                                                                 | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Po             |                 | Not Reported |                |
|                                                                                                       | Atenolol                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Zocor                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Lisinopril                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2006                                                                                           | 5992928                    | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00457-01     |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Condition<br>Aggravated; Depression;<br>Dizziness; Erectile<br>Dysfunction; Suicidal | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Lexapro                    |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Ideation; Treatment  
Noncompliance; Type 2  
Diabetes Mellitus

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Feb-2006                       | 5960041                | EXPEDITED (15-DAY)        | N                           | OT                       | S05-USA-05284-01              |                               | 68 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Blood Pressure Increased;<br>Constipation | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                           | Lisinopril              |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                           | Hydrochlorothiazide     |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                           | Armour Thyroid          |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                           | Nexium (Esomeprazole)   |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                           | Celebrex                |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Feb-2006                       | 5996826                | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-FRA-00439-01              |                               | 53 YR               | Male                | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Agitation; Legal Problem       | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Prozac                  |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Feb-2006                       | 5926636                | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-FRA-04645-01              |                               | 45 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Kleptomania                    | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Feb-2006                       | 5997257                | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-ISR-00602-01              |                               | 44 YR               | Female              | ISR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Mastitis; Purulence            | Ciprallex               |                       |                     | S                    | Oral                  | 10 Mg Daily Po              |                          | Not Reported        |

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| <u>FDA Received Date</u>                                        | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 15-Feb-2006                                                     | 5997268                                | EXPEDITED (15-DAY) | Y                  | DS              | S05-CAN-05735-01     |                                     | 19 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                           | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoacusis; Sudden                                              | Cipralext                              |                    |                    | S               | Oral                 | 5 Mg Qd Po                          |                 | Not Reported |                |
| Hearing Loss                                                    | Cipralext                              |                    |                    | S               | Oral                 | 10 Mg Qd Po                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2006                                                     | 5921802                                | EXPEDITED (15-DAY) | Y                  | DE              | L05-USA-03935-39     |                                     | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed                                       | Escitalopram Oxalate                   |                    |                    | S               |                      |                                     |                 | Not Reported |                |
| Suicide; Respiratory Arrest                                     | Acetaminophen W/Hydrocodone Bitartrate |                    |                    | S               |                      |                                     |                 | Not Reported |                |
|                                                                 | Klonopin                               |                    |                    | S               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2006                                                     | 5991952                                | DIRECT             |                    | RI              |                      |                                     | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Muscle Twitching; Panic Attack; Paraesthesia;         | Paxil                                  |                    |                    | S               | Oral                 | 20 Mg 1 Day Po 10 Years On And Off  | 10 YR           | Not Reported |                |
| Restlessness; Thinking Abnormal                                 | Lexapro                                |                    |                    | S               | Oral                 | 20 Mg 1 Day Po Ten Years On And Off | 10 YR           | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2006                                                     | 5999345                                | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00507-01     |                                     | 30 YR           | Male         | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound; Incorrect Dose Administered; | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd, Po                        |                 | Not Reported |                |
|                                                                 | Klonopin (Bupropion Hydrochloride)     |                    |                    | C               |                      |                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                              |                                      |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Treatment Noncompliance                                                                                      | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                              | Ambien                               |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2006                                                                                                  | 5999445                              | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00548-01     |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature Increased;                                                                                  | Lexapro                              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Glomerulosclerosis                                                                                           | Altace                               |                    |                    | S               |                      | 5 Mg Qd              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2006                                                                                                  | 5952033                              | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-05176-01     |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Therapy Non-Responder                                                                              | Lexapro                              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Albuterol                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Atrovent                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Advair Diskus                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2006                                                                                                  | 5987316                              | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWI-00096-01     |                      | 57 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Epilepsy; Flushing; Inappropriate Antidiuretic Hormone Secretion; Respiration Abnormal; Seizure | Cipraxel                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Zyprexa                              |                    |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                                                              | Enalapril Maleate                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Fluvastatin Sodium                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Temesta (Lorazepam)                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Pantozol (Pantoprazole Sodium)       |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 22-Feb-2006                                                                  | 5988715        | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20060203259 |                      | < 1 DAY         | Unknown      | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Breast Feeding; Sedation; Selective Eating Disorder | Topamax        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                              | Lexapro        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                              | Abilify        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                              | Remeron        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                              | Zyprexa        |                    |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Feb-2006                                         | 6000625        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00553-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Pregnancy; Seizure | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                     | Coumadin       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------------------------------|------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 22-Feb-2006                | 6045286                                     | NON-EXPEDITED    | N                  | OT              | HQWYE594417NOV05     |                          | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Headache | Protonix                                    |                  |                    | S               |                      |                          |                 | Not Reported |                |
|                            | Lecithin (Lecithin)                         |                  |                    | S               |                      |                          |                 | Not Reported |                |
|                            | Lexapro                                     |                  |                    | S               | Oral                 | 10 Mg 1x Per 1 Day, Oral |                 | Not Reported |                |
|                            |                                             |                  |                    |                 | Oral                 | 10 Mg 1x Per 1 Day, Oral |                 |              |                |
|                            | Premarin                                    |                  |                    | C               |                      |                          |                 | Not Reported |                |
|                            | Multivitamins, Plain (Multivitamins, Plain) |                  |                    | C               |                      |                          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 23-Feb-2006              | 4144647        | EXPEDITED (15-DAY) | N                  | DE, HO          | US-GLAXOSMITHKLINE-A0511773A |                      | 90 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                                                                                           |                                                     |                       |      |                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------|------|------------------------------------------------------------------------------------|
| Cardioactive Drug Level Increased; Decreased Appetite; Drug Interaction; Hypertension; Loss Of Consciousness; Renal Failure; Transient Ischaemic Attack; Weight Decreased | Lanoxin<br>Lexapro<br>Inderal<br>Megace<br>Digibind | S<br>S<br>C<br>C<br>C | Oral | Glaxosmithkline<br>Not Reported<br>Not Reported<br>Not Reported<br>Glaxosmithkline |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------|------|------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2006              | 5954527       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05183-01     |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;         | Lexapro               |              |            | S           | Oral         | 20 Mg Qhs Po       |                 | Not Reported |
| Condition Aggravated;    | Lexapro               |              |            | S           | Oral         | 5 Mg Qhs Po        |                 | Not Reported |
| Dysarthria; Dyskinesia;  | Lexapro               |              |            | S           | Oral         | 10 Mg Qhs Po       |                 | Not Reported |
| Feeling Abnormal;        | Lexapro               |              |            | S           | Oral         | 15 Mg Qhs Po       |                 | Not Reported |
| Hyperhidrosis; Insomnia; | Ambien                |              |            | C           |              |                    |                 | Not Reported |
| Paraesthesia             | Seroquel              |              |            | C           |              |                    |                 | Not Reported |
|                          | Zoloft                |              |            | C           |              |                    |                 | Not Reported |
|                          | Concerta              |              |            | C           |              |                    |                 | Not Reported |
|                          | Allegra               |              |            | C           |              |                    |                 | Not Reported |
|                          | Xanax                 |              |            | C           |              |                    |                 | Not Reported |
|                          | Pulmicort Flexhaler   |              |            | C           |              |                    |                 | Not Reported |
|                          | Hydrocodone           |              |            | C           |              |                    |                 | Not Reported |
|                          | Albuterol             |              |            | C           |              |                    |                 | Not Reported |
|                          | Atrovent              |              |            | C           |              |                    |                 | Not Reported |
|                          | Floradil (Formoterol) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2006              | 5959436       | EXPEDITED (15-DAY) | Y                  | OT              | S05-FRA-05747-01     |                      | 23 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mallory-Weiss Syndrome; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Oesophagitis; Vomiting  | Minocin              |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
|                         | Xanax                |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                 | <u>503B Facility</u>                                                                                                                                          | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 23-Feb-2006                                                                                                                                         | 6000380                                                                                                              | EXPEDITED (15-DAY) | Y                  | HO                                        | S06-FRA-00797-01                                                     |                                                                                                                                                               | 35 YR           | Female                                                                                                                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                         | <u>Dosage Text</u>                                                                                                                                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Pyelonephritis Acute;<br>Transaminases Increased                                                                                                    | Escitalopram Oxalate<br>Antibiotics                                                                                  |                    |                    | S<br>C                                    |                                                                      |                                                                                                                                                               |                 | Not Reported<br>Not Reported                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                 | <u>503B Facility</u>                                                                                                                                          | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 23-Feb-2006                                                                                                                                         | 6000941                                                                                                              | EXPEDITED (15-DAY) | N                  | RI                                        | S06-USA-00555-01                                                     |                                                                                                                                                               | 26 YR           | Female                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                         | <u>Dosage Text</u>                                                                                                                                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Caesarean Section;<br>Gestational Diabetes;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Umbilical Cord Around<br>Neck                   | Lexapro<br>Lexapro<br>Toprol XL                                                                                      |                    |                    | S<br>S<br>C                               | Oral<br>Oral                                                         | 10 Mg Qd Po<br>20 Mg Qd Po                                                                                                                                    |                 | Not Reported<br>Not Reported<br>Not Reported                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                 | <u>503B Facility</u>                                                                                                                                          | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 24-Feb-2006                                                                                                                                         | 5888207                                                                                                              | EXPEDITED (15-DAY) | Y                  | DE                                        | DSA_26954_2005                                                       |                                                                                                                                                               | 72 YR           | Male                                                                                                                                         | CHE            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                         | <u>Dosage Text</u>                                                                                                                                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Agitation; Anxiety;<br>Asphyxia; Bipolar I<br>Disorder; Completed<br>Suicide; Depressive<br>Symptom; Feeling<br>Abnormal; Mutism; Sleep<br>Disorder | Lorazepam<br>Lorazepam<br>Lorazepam<br>Lorazepam<br>Lorazepam<br>Lorazepam<br>Cipralelex<br>Cipralelex<br>Cipralelex |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 1 Mg Q Day Po<br>3 Mg Q Day Po<br>2 Mg Q Day Po<br>1.5 Mg Q Day Po<br>1.5 Mg Q Day Po<br>0.5 Mg Q Day Po<br>5 Mg Q Day Po<br>10 Mg Q Day Po<br>15 Mg Q Day Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |         |   |      |                |              |
|--|---------|---|------|----------------|--------------|
|  | Remeron | S | Oral | 30 Mg Q Day Po | Not Reported |
|  | Remeron | S | Oral | 60 Mg Q Day Po | Not Reported |
|  | Haldol  | S |      | Van Q Day      | Not Reported |
|  | Haldol  | S |      | 2 Mg Q Day     | Not Reported |
|  | Haldol  | S |      | 1 Mg Q Day     | Not Reported |
|  | Haldol  | S |      | 2 Mg Q Day     | Not Reported |
|  | Haldol  | S |      | 4 Mg Q Day     | Not Reported |

| <u>FDA Received Date</u>                                                    | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-----------------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 24-Feb-2006                                                                 | 5942869                                         | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-05P-163-0319075-00 |                      |                 | Male                                         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Haemoglobin Decreased;<br>Jaundice; Platelet Count<br>Increased; Tachypnoea | Lexapro<br>Prenatal Vitamins<br>Antidepressants |                    |                    | S<br>C<br>C     |                              |                      |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
|--------------------------|-------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------------------|----------------|
| 24-Feb-2006              | 6001798                                                                                   | EXPEDITED (15-DAY) | Y                  | DE                    | S06-UKI-00626-01     |                      | 48 YR           | Male                                                                         | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Completed Suicide        | Cipralext<br>Co-Phenotrope<br>Tramadol Hydrochloride<br>Pantoprazole Sodium<br>Ranitidine |                    |                    | S<br>C<br>C<br>C<br>C | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------|-----------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------|-----------------|------------------------------|----------------|
| 27-Feb-2006                                                          | 5905524                                                         | EXPEDITED (15-DAY) | N                  | DE, HO          | US-ABBOTT-05P-163-0313788-00 |                              | 55 YR           | Unknown                      | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase | Acetaminophen\Hydrocodone<br>Bitartrate<br>Escitalopram Oxalate |                    |                    | S<br>S          |                              | Not Reported<br>Not Reported |                 | Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                                 |   |              |              |
|---------------------------------------------------------------------|---------------------------------|---|--------------|--------------|
| Increased; Blood Creatine Phosphokinase Increased; Blood Creatinine | Ibuprofen                       | S | Not Reported | Not Reported |
| Increased; Blood Urea                                               | Acetaminophen\Codeine Phosphate | S | Not Reported | Not Reported |
| Increased; Cardiac Failure                                          | Citalopram                      | S | Not Reported | Not Reported |
| Congestive; Cerebral                                                | Nabumetone                      | S | Not Reported | Not Reported |
| Infarction; Coma;                                                   | Celecoxib                       | S | Not Reported | Not Reported |
| Completed Suicide;                                                  | Zolpidem                        | S | Not Reported | Not Reported |
| Hypertension; Intentional                                           | Metronidazole                   | S | Not Reported | Not Reported |
| Overdose; Pneumonia;                                                | Diazepam                        | S | Not Reported | Not Reported |
| Troponin Increased                                                  | Metaxalone                      | S | Not Reported | Not Reported |
|                                                                     | Amitriptyline                   | S | Not Reported | Not Reported |
|                                                                     | Metformin                       | S | Not Reported | Not Reported |
|                                                                     | Acetylsalicylic Acid            | S | Not Reported | Not Reported |
|                                                                     | Bupropion                       | S | Not Reported | Not Reported |
|                                                                     | Codeine\Promethazine            | S | Not Reported | Not Reported |

| <u>FDA Received Date</u>             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Feb-2006                          | 6002401                    | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04943-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alkaline Phosphatase Increased | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
|                                      | Unspecified Ingredient     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Multiple Medications (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 28-Feb-2006               | 5886170        | NON-EXPEDITED    | Y                  | OT              | S05-USA-04021-01     |                      | 26 YR           | Male            | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hepatic Enzyme Increased; | Lamictal       |                  |                    | S               | Oral                 | 75mg Per Day         |                 | Glaxosmithkline |                |
| Nasopharyngitis           | Lexapro        |                  |                    | S               | Oral                 | 2.5mg Per Day        |                 | Forest          |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Feb-2006              | 5993528        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0549616A |                      | 55 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypersensitivity; Rash   | Lamictal       |                  |                    | S               | Oral                                 | 100mg Per Day        | 2 WEEK          | Glaxosmithkline |                |
|                          | Lexapro        |                  |                    | S               | Oral                                 |                      |                 | Not Reported    |                |
|                          | Wellbutrin XI  |                  |                    | C               |                                      |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Feb-2006                                       | 5994338        | NON-EXPEDITED    | Y                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0580822A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Oropharyngeal Blistering;<br>Photopsia; Toothache | Lamictal       |                  |                    | S               | Oral                                 | 175mg Per Day        | 16 MTH          | Glaxosmithkline |                |
|                                                   | Lexapro        |                  |                    | S               | Oral                                 | 5mg At Night         |                 | Not Reported    |                |
|                                                   | Lexapro        |                  |                    | C               | Oral                                 |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Feb-2006                                                                         | 5994452        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0584204A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Bedridden; Depression;<br>Malaise; Nausea; Weight<br>Decreased; Weight<br>Increased | Lamictal       |                  |                    | S               | Oral                                 | 150mg Unknown        |                 | Glaxosmithkline |                |
|                                                                                     | Wellbutrin     |                  |                    | S               | Oral                                 | 300mg Unknown        |                 | Glaxosmithkline |                |
|                                                                                     | Lexapro        |                  |                    | S               | Unknown                              | 20mg Unknown         |                 | Not Reported    |                |
|                                                                                     | Seroquel       |                  |                    | S               | Unknown                              | 100mg Unknown        |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|------------|----------------|
| 28-Feb-2006              | 5994503        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0555421A |                      | 23 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|      |          |   |         |              |       |                 |
|------|----------|---|---------|--------------|-------|-----------------|
| Rash | Lamictal | S | Oral    | 25mg Per Day | 1 MTH | Glaxosmithkline |
|      | Lexapro  | S | Unknown | 10mg Unknown |       | Not Reported    |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>        | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2006                       | 5994685                | NON-EXPEDITED             | N                           |                          | US-<br>GLAXOSMITHKLINE-<br>A0560556A |                               | 31 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Rash                           | Lamictal                |                       |                     | S                    | Oral                  | 200mg Unknown               |                          | Glaxosmithkline     |
|                                | Lexapro                 |                       |                     | S                    | Unknown               | 10mg Unknown                |                          | Not Reported        |
|                                | Ativan                  |                       |                     | S                    | Unknown               | 5mg Unknown                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>        | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2006                       | 5994740                | NON-EXPEDITED             | N                           |                          | US-<br>GLAXOSMITHKLINE-<br>A0562100A |                               | 58 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Balance Disorder;<br>Hyperhidrosis | Lamictal                |                       |                     | S                    | Oral                  | 100mg Twice Per Day         | 1 YR                     | Glaxosmithkline     |
|                                    | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                    | Klonopin                |                       |                     | C                    | Unknown               |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2006                       | 5995241                | NON-EXPEDITED             | N                           |                          | S05-USA-00407-01              |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective; Drug<br>Interaction | Imitrex                 |                       |                     | S                    | Unknown               |                             |                          | Glaxosmithkline     |
|                                       | Lexapro                 |                       |                     | S                    | Oral                  | 10mg Per Day                |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2006                       | 5995361                | NON-EXPEDITED             | N                           |                          | S05-USA-03818-01              |                               | 54 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |          |   |         |              |                 |
|----------------------------|----------|---|---------|--------------|-----------------|
| Anxiety; Asthenia;         | Imitrex  | S | Unknown |              | Glaxosmithkline |
| Disturbance In Attention;  | Lexapro  | S | Oral    | 10mg Per Day | Not Reported    |
| Drug Interaction; Fatigue; | Prevacid | C | Unknown |              | Not Reported    |
| Migraine                   |          |   |         |              |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2006              | 5999036       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-00607-01     |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Drug Interaction; Supraventricular Extrasystoles | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                       | Interferon Alfa      |              |            | S           |              |                    |                 | Not Reported |
|                                                                       | Ribavirin            |              |            | S           |              |                    |                 | Not Reported |
|                                                                       | Levothyroxine Sodium |              |            | S           |              |                    |                 | Not Reported |
|                                                                       | Acetaminophen        |              |            | C           |              |                    |                 | Not Reported |
|                                                                       | Zolpidem             |              |            | C           |              |                    |                 | Not Reported |
|                                                                       | Urbanyl              |              |            | C           |              |                    |                 | Not Reported |
|                                                                       | Domperidone          |              |            | C           |              |                    |                 | Not Reported |
|                                                                       | Diosmin              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2006              | 6004092       | EXPEDITED (15-DAY) | Y                  | OT              | S06-BEL-00806-01     |                      | 98 YR      | Female     | BEL            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Transient Ischaemic Attack | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                            | Loperamide           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2006              | 6004958       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00600-1      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2006              | 6004991       | EXPEDITED (15-DAY) | Y                  | DE, HO          | A001-002-006789      |                      | 87 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;         | Aricept                 |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Aggression; Amnesia;        | Diflucan                |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Anger; Cardiopulmonary      | Seroquel                |              |            | S           |              |                    |                 | Not Reported |
| Failure; Confusional State; | Risperdal               |              |            | S           |              |                    |                 | Not Reported |
| Delusion; Dementia;         | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
| Depression; Frustration     | Naprosyn                |              |            | S           |              |                    |                 | Not Reported |
| Tolerance Decreased;        | Exelon                  |              |            | C           |              |                    |                 | Not Reported |
| Hallucination;              | Atarax                  |              |            | C           |              |                    |                 | Not Reported |
| Hypotension; Muscle         | Lisinopril (Lisinopril) |              |            | C           |              |                    |                 | Not Reported |
| Spasms; Nocturia;           | Lotrel                  |              |            | C           |              |                    |                 | Not Reported |
| Overdose; Screaming;        | Tylenol (Paracetamol)   |              |            | C           |              |                    |                 | Not Reported |
| Urinary Incontinence;       | Vistane                 |              |            | C           |              |                    |                 | Not Reported |
| Urinary Tract Infection     | Depakote                |              |            | C           |              |                    |                 | Not Reported |
|                             | Depakene                |              |            | C           |              |                    |                 | Not Reported |
|                             | Cogentin                |              |            | C           |              |                    |                 | Not Reported |
|                             | Ativan                  |              |            | C           |              |                    |                 | Not Reported |
|                             | Ciprofloxacin           |              |            | C           |              |                    |                 | Not Reported |
|                             | Probiotica              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 02-Mar-2006              | 5991482       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-06P-056-0324872-00 |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Drug | Levothyrox            |              |            | S           |              |                    |                 | Not Reported |
| Interaction;              | Paracetamol           |              |            | C           |              |                    |                 | Not Reported |
| Supraventricular          | Zolpidem              |              |            | C           |              |                    |                 | Not Reported |
| Extrasystoles             | Clobazam              |              |            | C           | Oral         |                    |                 | Not Reported |
|                           | Domperidone           |              |            | C           |              |                    |                 | Not Reported |
|                           | Diosmin               |              |            | C           |              |                    |                 | Not Reported |
|                           | Escitalopram Oxalate  |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Escitalopram Oxalate  |              |            | S           | Oral         |                    |                 | Not Reported |
|                           | Peginterferon Alfa-2a |              |            | S           |              |                    |                 | Not Reported |

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|                                                                                                                                    |                                       |                    |                    |                 |                      |                              |                 |                                              |                |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|----------------------------------------------|----------------|
| Ribavirin                                                                                                                          |                                       |                    | S                  |                 |                      |                              | Not Reported    |                                              |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-Mar-2006                                                                                                                        | 6002981                               | DIRECT             | N                  | LT              |                      |                              | 48 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abnormal Behaviour; Self-Injurious Ideation; Suicide Attempt                                                                       | Lexapro                               |                    |                    | S               |                      | 1/2 Tab X 6 Than 1 Tab After |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-Mar-2006                                                                                                                        | 6005505                               | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-00546-01     |                              | 78 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Blood Magnesium Abnormal; Blood Potassium Abnormal; Blood Sodium Abnormal; Chest Pain; Electrolyte Imbalance; Musculoskeletal Pain | Lexapro<br>Dessicare (Nos)<br>Fosamax |                    |                    | S<br>C<br>C     |                      |                              |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-Mar-2006                                                                                                                        | 6005511                               | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00638-03     |                              |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Arrhythmia                                                                                                                         | Lexapro                               |                    |                    | S               |                      |                              |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-Mar-2006                                                                                                                        | 6005515                               | EXPEDITED (15-DAY) | Y                  | LT, OT          | S06-USA-00638-02     |                              |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Arrhythmia                                                                                                                         | Lexapro                               |                    |                    | S               |                      |                              |                 | Not Reported                                 |                |

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| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2006                                                                         | 6005528        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00641-01     |                      | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Interaction;<br>Alcohol Problem;<br>Completed Suicide;<br>Multiple Injuries | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                     | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                         | 6005530        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00598-03     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                         | 6005532        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00598-02     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                         | 6005534        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00598-01     |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                   | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                         | 6006606        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00638-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia                                                                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 02-Mar-2006                                                                                                                         | 6006608             | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-00648-01     |                         | 30 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Iatrogenic Injury; Inappropriate Antidiuretic Hormone Secretion; Influenza Like Illness; Respiratory Arrest; Seizure | Lexapro             |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                     | Lisinopril          |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                     | Hydrochlorothiazide |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                     | Lorazepam           |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                                                                         | 6006609             | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00645-01     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hernia; Seizure                                                                                                                     | Lexapro             |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2006                                                                                                                         | 6045035             | NON-EXPEDITED      | N                  |                 | S06-USA-00306-01     |                         | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia                                                                                                                          | Campral             |                    |                    | S               | Oral                 | 666 Mg Tid Po           |                 | Not Reported |                |
|                                                                                                                                     | Lexapro             |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                     | Lithium             |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2006                                                                                                                         | 6005900             | EXPEDITED (15-DAY) | Y                  | HO, LT          | SEWYE440601MAR06     |                         | 69 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Hyponatraemia; Seizure                                                                                        | Effexor             |                    |                    | S               | Oral                 | 75 Mg 1x Per 1 Day Oral | 11 DAY          | Not Reported |                |
|                                                                                                                                     | Cipraxel            |                    |                    | S               | Oral                 | 10 Mg 1x Per 1 Day Oral | 9 DAY           | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Mar-2006                                                                                                                              | 6035465                           | EXPEDITED (15-DAY) | Y                  | HO              | CH-JNJFOC-20060300686        |                      | 47 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased;<br>Drug Interaction;<br>Intentional Overdose;<br>Intentional Overdose;<br>Serotonin Syndrome;<br>Suicide Attempt | Tramadol Hydrochloride            |                    |                    | S               | Oral                         | Duration: Once       |                 | Not Reported |                |
|                                                                                                                                          | Cipraxel                          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                          | Bromazepam                        |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                          |                                   |                    |                    |                 |                              |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2006                                                                                                                              | 5893996                           | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04347-01             |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mental Status Changes;<br>Seizure                                                                                                        | Lexapro                           |                    |                    | S               | Oral                         | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                           |                    |                    | S               | Oral                         | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                          | Tegretol                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Lopresor                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Synthroid (Lelvothyroxine Sodium) |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Glipizide                         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Aciphex                           |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Doxycycline                       |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Coumadin                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                          | Reglan                            |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2006                                                                                                                              | 5949477                           | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-05P-163-0319679-00 |                      | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Enterocolitis Infectious                                                                                                                 | Lexapro                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                          | Lexapro                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2006                | 5955052                | EXPEDITED (15-DAY) | N                  | OT              | S05-USA-05178-01     |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dyspepsia;      | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Eructation; Platelet Count | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Decreased; Red Blood       |                        |                    |                    |                 |                      |                      |                 |              |                |
| Cell Macrocytes Present;   | Multi-Vitamin          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Splenomegaly; White        | Folic Acid             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Blood Cell Count           | Calcium Gluconate      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased                  |                        |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2006                | 6007638                | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00597-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Asphyxia; | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Completed Suicide;         | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Disease Recurrence;        | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Fear; Hallucination,       | Lexapro                |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Auditory; Influenza Like   | Lexapro                |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Illness; Nephrolithiasis;  | Lexapro                |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Obsessive Thoughts;        | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Scratch; Treatment         | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Noncompliance              | Lexapro                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2006                | 6007639                | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-006644-01    |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Decreased Appetite;        | Percocet               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Fatigue; Feeling Cold;     | Tramadol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hypersomnia; Nausea;       | Carisoprodol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Somnolence                 |                        |                    |                    |                 |                      |                      |                 |              |                |

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|                                                                         |                | Clorazepate Dipotassium |                    | C               |                      |                      |                 |            | Not Reported   |
|-------------------------------------------------------------------------|----------------|-------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
|                                                                         |                | Premarin                |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Clarinx                 |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Singulair               |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Zantac                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Flovent                 |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Albuterol               |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                         |                | Finacea                 |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Mar-2006                                                             | 6008076        | EXPEDITED (15-DAY)      | N                  | OT              | S06-USA-00596-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Respiration Abnormal;<br>Urticaria                                      | Lexapro        |                         |                    | S               | Oral                 | 20 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Mar-2006                                                             | 6008369        | EXPEDITED (15-DAY)      | Y                  | OT              | S06-GER-00822-01     |                      | 57 YR           | Female     | DEU            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Leukopenia                                                              | Cipralext      |                         |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                         | Cipralext      |                         |                    | S               | Oral                 | 5 Mg Qd Po           |                 |            | Not Reported   |
|                                                                         | Keppra         |                         |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2006                                                             | 5798822        | EXPEDITED (15-DAY)      | N                  | HO              | S05-USA-02268-01     |                      | 44 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour;<br>Bipolar I Disorder; Stress;<br>Suicidal Ideation | Lexapro        |                         |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                         | Lexapro        |                         |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                         | Hormones (Nos) |                         |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2006                                                             | 5992746        | EXPEDITED (15-DAY)      | Y                  | OT              | S06-USA-00347-01     |                      | 30 YR           | Male       | USA            |

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| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Insomnia;<br>Irritability; White Blood<br>Cell Count Increased | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                            | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                            | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Seroquel       |              |            | S           | Oral         | 100 Mg Qhs Po      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2006              | 5996682       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00487-01     |                      | 30 DAY     | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Divorced Parents; Failure<br>To Thrive; Maternal<br>Exposure During Breast<br>Feeding; Suppressed<br>Lactation; Treatment<br>Noncompliance; Weight<br>Gain Poor | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                        | Mircette       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2006              | 6002451       | EXPEDITED (15-DAY) | Y                  | HO              | T06-USA-00793-01     |                      | 73 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diverticulitis Intestinal<br>Haemorrhagic | Escitalopram Oxalate           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                           | Placebo                        |              |            | S           | Oral         | 1 Capsule Qd Po    |                 | Not Reported |
|                                           | Aspirin (Acetylsalicylic Acid) |              |            | S           | Oral         | 650 Mg Bid Po      |                 | Not Reported |
|                                           | Furosemide                     |              |            | C           |              |                    |                 | Not Reported |
|                                           | Lipitor                        |              |            | C           |              |                    |                 | Not Reported |
|                                           | Potassium                      |              |            | C           |              |                    |                 | Not Reported |
|                                           | Diovan                         |              |            | C           |              |                    |                 | Not Reported |
|                                           | Prevacid                       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2006              | 6009025       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00681-02     |                      | 2 DAY      | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Oversedation; Selective Eating Disorder | Lexapro                 |                    |                    | S               | Transplacental       | Mg Transplacental    |                 | Not Reported |                |
|                                                                                                                               | Lexapro                 |                    |                    | S               |                      | Mg Bf                |                 | Not Reported |                |
|                                                                                                                               | Topamax                 |                    |                    | S               | Transplacental       | Mg Transplacental    |                 | Not Reported |                |
|                                                                                                                               | Topamax                 |                    |                    | S               |                      | Mg Bf                |                 | Not Reported |                |
|                                                                                                                               | Abilify                 |                    |                    | S               | Transplacental       | Mg Transplacental    |                 | Not Reported |                |
|                                                                                                                               | Abilify                 |                    |                    | S               |                      | Mg Bf                |                 | Not Reported |                |
|                                                                                                                               | Remeron                 |                    |                    | S               | Transplacental       | Mg Transplacental    |                 | Not Reported |                |
|                                                                                                                               | Remeron                 |                    |                    | S               |                      | Mg Bf                |                 | Not Reported |                |
|                                                                                                                               | Zyprexa                 |                    |                    | S               | Transplacental       | Mg Transplacental    |                 | Not Reported |                |
|                                                                                                                               | Zyprexa                 |                    |                    | S               |                      | Mg Bf                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2006                                                                                                                   | 6009026                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00682-01     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Suicide Attempt                                                                                         | Lexapro                 |                    |                    | S               | Oral                 | 200 Mg Once Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2006                                                                                                                   | 6009029                 | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-00727-01     |                      | 79 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound; Head Injury                                                                                | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                               | Clonazepam              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                               | Temazepam               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                               | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2006                                                                                                                   | 6008867                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-00983-01     |                      | 29 YR           | Female       | DNK            |

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| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Galactorrhoea                                                                                                                                                | Cipralext               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Loratadine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2006                                                                                                                                                  | 6008870                 | EXPEDITED (15-DAY) | Y                  | LT              | S06-UKI-00993-01     |                      | 55 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                             | Cipralext               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Donepezil Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2006                                                                                                                                                  | 6009631                 | EXPEDITED (15-DAY) | Y                  | OT              | 2006-139169-NL       |                      | 2 DAY           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Disorder; Nervous System Disorder; Sedation; Selective Eating Disorder | Remeron                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Topamax                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Abilify                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                              | Zyprexa                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2006                                                                                                                                                  | 6001834                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-00629-01     |                      | 39 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Generalised Tonic-Clonic Seizure; Loss Of Consciousness                                                                                                | Cipralext               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Cipralext               |                    |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2006                                                                                                                                                  | 6002611                 | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | 2006024700           |                      | 87 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Amnesia;<br>Anger; Cardiopulmonary<br>Failure; Condition<br>Aggravated; Confusional<br>State; Delusion; Dementia<br>Alzheimer'S Type;<br>Frustration Tolerance<br>Decreased; Hallucination;<br>Hypotension; Muscle<br>Spasms; Muscle<br>Twitching; Nocturia;<br>Overdose; Urinary Tract<br>Infection; Vomiting | Diflucan                    |              |            | S           | Oral         | 150 Mg, Oral       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Seroquel                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Risperdal                   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Lexapro                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Naprosyn                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Aricept                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Exelon                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Atarax                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Lisinopril (Lisinopril)     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Lotrel                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Tylenol (Paracetamol)       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Unspecified Ingredient      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Depakote                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Depakene                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Cogentin                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Ativan                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Ciprofloxacin Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                            | Unspecified Ingredient      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2006              | 6010700       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-00984-01     |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eosinophilia; Pyrexia; Red<br>Blood Cell Sedimentation<br>Rate Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                          | Tegretol             |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Levothyroxine Sodium |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Oromone (Estradiol)  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2006              | 6010711       | EXPEDITED (15-DAY) | Y                  | OT              | S06-BEL-00982-01     |                      | 69 YR      | Male       | BEL            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Dysarthria; Dyskinesia;<br>Impaired Driving Ability;<br>Muscle Rigidity; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                               | Escitalopram Oxalate |              |            | S           |              | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                               | Prazepam             |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |                                              |             |                                              |
|--------------------------------------------------|----------------------------------------------|-------------|----------------------------------------------|
| Nervousness; Self-Medication; Tardive Dyskinesia | Symbicort<br>Tiotropium Bromide<br>Lorazepam | C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------|----------------------------------------------|-------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2006              | 5920630       | EXPEDITED (15-DAY) | Y                  | OT              | T05-USA-03925-01     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                       | Aleve          |              |            | S           |              | 4180 Mg Once       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2006              | 6007590       | DIRECT           | N                  | DE              |                      |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed Suicide; Partner Stress | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2006              | 6008530       | DIRECT           | Y                  | OT              |                      |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Abortion Spontaneous; Maternal Exposure During Pregnancy | Lexapro        |              |            | S           | Oral         | 1/2 Tablet Once Daily Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2006              | 6010599       | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-00997-01     |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Anxiety; Completed Suicide; Gun Shot Wound | Escitalopram Oxalate               |              |            | S           | Oral                                  | 20 Mg Qd Po        |                 | Not Reported |
|                                            | Seropram (Citalopram Hydrobromide) |              |            | S           | Intravenous (not otherwise specified) | 40 Mg Qd Iv        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |                      |                    |                    |                 |             |                      |                      |                 |              |                |
|----------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                              |                      | Buspar             |                    | C               |             |                      |                      | Not Reported    |              |                |
|                                              |                      | Atarax             |                    | C               |             |                      |                      | Not Reported    |              |                |
|                                              |                      | Anafranil          |                    | C               |             |                      |                      | Not Reported    |              |                |
|                                              |                      | Abilify            |                    | C               |             |                      |                      | Not Reported    |              |                |
|                                              |                      | Oxazepam           |                    | C               |             |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Mar-2006                                  | 6010600              | EXPEDITED (15-DAY) | Y                  | HO              |             | S06-ESP-00996-01     |                      | 26 YR           | Male         | ESP            |
| <u>Preferred Term</u>                        | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Nystagmus; Vertigo | Escitalopram Oxalate |                    |                    |                 | S           | Oral                 | 5 Mg Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2006                                  | 5850803              | EXPEDITED (15-DAY) | Y                  | DE              |             | T05-FIN-02354-01     |                      | 44 YR           | Male         | FIN            |
| <u>Preferred Term</u>                        | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death;                            | Ciprallex            |                    |                    |                 | S           |                      | 20 Mg Qd             |                 | Not Reported |                |
| Accidental Poisoning;                        | Viagra               |                    |                    |                 | C           |                      |                      |                 | Not Reported |                |
| Alcohol Interaction;                         |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Cardiomegaly; Contusion;                     |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Drug Interaction; Drug                       |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Level Below Therapeutic;                     |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Drug Screen Positive;                        |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Hyperglycaemia; Lactic                       |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Acidosis; Scar; Skin                         |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Abrasion; Sudden Death;                      |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| Toxicity To Various Agents                   |                      |                    |                    |                 |             |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2006                                  | 6009023              | EXPEDITED (15-DAY) | Y                  | OT              |             | S06-USA-00709-01     |                      | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoglycaemia                                | Lexapro              |                    |                    |                 | S           | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Lexapro              |                    |                    |                 | S           | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                              | Insulin Nos          |                    |                    |                 | C           |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |              |
|------------------------|---|--------------|
| Actos (Pioglitazone)   | C | Not Reported |
| Crestor (Rosuvastatin) | C | Not Reported |
| Aspirin                | C | Not Reported |
| Plavix                 | C | Not Reported |
| Hydrochlorothiazide    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2006              | 6012038       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-01050-01     |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound; Head Injury | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2006              | 6012040       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01051-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Cancer Female  | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2006              | 6012083       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00750-01     |                      | 75 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2006              | 6012089       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00749-01     |                      | 75 YR      | Male       | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Large Intestinal Ulcer Haemorrhage | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Mar-2006                                                                                                                                                 | 6002642                   | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-03204-01     |                      | 91 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Decreased Appetite;<br>Dehydration; Loss Of<br>Consciousness; Renal<br>Failure; Toxicity To<br>Various Agents; Weight<br>Decreased | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                             | Digoxin                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Inderal                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Celebrex                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Nexium (Esomeprazole)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Statin Medication         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Enlarged Heart Medication |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Vitamins Nos              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2006                                                                                                                                                 | 6011391                   | DIRECT             | Y                  | OT              |                      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fall; Skin<br>Abrasion; Tooth Erosion;<br>Tooth Injury                                                                                           | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2006                                                                                                                                                 | 6013135                   | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01064-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Headache; Malaise                                                                                                              | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                             | Premarin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Lipitor                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2006                                                                                                                                                 | 6015371                   | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-01014-01     |                      | 19 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                 |           |   |      |                |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|------|----------------|--------------|
| Abdominal Pain Upper;<br>Balance Disorder; Chest<br>Discomfort; Diarrhoea;<br>Dizziness; Jaw Disorder;<br>Malaise; Tremor; Visual<br>Impairment | Ciprallex | S | Oral | 20 Mg Daily Po | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|------|----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2006              | 6010753       | DIRECT           | N                  | HO              |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;            | Lexapro        |              |            | S           | Oral         | 1 Daily Po         |                 | Forest       |
| Anaphylactic Reaction;     | Clonazepam     |              |            | C           |              |                    |                 | Not Reported |
| Anxiety; Chest Discomfort; | Prozac         |              |            | C           |              |                    |                 | Not Reported |
| Chest Pain; Dyspnoea;      |                |              |            |             |              |                    |                 |              |
| Muscle Twitching; Panic    |                |              |            |             |              |                    |                 |              |
| Attack; Pruritus; Rash;    |                |              |            |             |              |                    |                 |              |
| Thinking Abnormal;         |                |              |            |             |              |                    |                 |              |
| Tremor                     |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2006              | 6014319       | EXPEDITED (15-DAY) | Y                  | DE, HO          | PAR_0535_2006        |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase   | Ibuprofen                 |              |            | S           |              | Df                 |                 | Not Reported |
| Increased; Aspartate       | Aspirin                   |              |            | S           |              | Df                 |                 | Not Reported |
| Aminotransferase           | Citalopram                |              |            | S           |              | Df                 |                 | Not Reported |
| Increased; Blood Bilirubin | Diazepam                  |              |            | S           |              | Df                 |                 | Not Reported |
| Increased; Blood           | Amitriptyline             |              |            | S           |              | Df                 |                 | Not Reported |
| Creatinine Increased;      | Metformin                 |              |            | S           |              | Df                 |                 | Not Reported |
| Blood Urea Increased;      | Escitalopram Oxalate      |              |            | S           | Oral         | Df Po              |                 | Not Reported |
| Body Temperature           | Acetaminophen And Codeine |              |            | S           |              | Df                 |                 | Not Reported |
| Increased; Cardiac Failure | Acetaminophen\Hydrocodone |              |            | S           |              | Df                 |                 | Not Reported |
| Congestive; Cerebral       | Bitartrate                |              |            |             |              |                    |                 |              |
| Infarction; Coma;          |                           |              |            |             |              |                    |                 |              |
| Completed Suicide; Drug    |                           |              |            |             |              |                    |                 |              |
| Screen Positive;           |                           |              |            |             |              |                    |                 |              |
| Hypertension;              |                           |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                           |                          |   |    |              |
|-----------------------------------------------------------------------------------------------------------|--------------------------|---|----|--------------|
| International Normalised Ratio Increased; Loss Of Consciousness; Pneumonia; Posturing; Troponin Increased | Nabumetone               | S | Df | Not Reported |
|                                                                                                           | Zolpidem                 | S | Df | Not Reported |
|                                                                                                           | Celecoxib                | S | Df | Not Reported |
|                                                                                                           | Metronidazole            | S | Df | Not Reported |
|                                                                                                           | Metaxalone               | S | Df | Not Reported |
|                                                                                                           | Bupropion                | S | Df | Not Reported |
|                                                                                                           | Promethazine And Codeine | S | Df | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Mar-2006                                           | 5987327              | EXPEDITED (15-DAY) | Y                  | DS              | S06-FRA-00090-01     |                      | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Galactorrhoea; Nausea; Photopsia; Vomiting | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Mar-2006                   | 6007015                 | EXPEDITED (15-DAY) | Y                  | OT              | 2006UW04073          |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Flutter; Palpitations | Seroquel                |                    |                    | S               | Oral                 |                      |                 | Zeneca       |                |
|                               | Depakote Er             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                               | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                               | Neurontin               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                               | Trazodone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Mar-2006                                | 6016828        | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-DEN-01202-01     |                      | 69 YR           | Male         | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder; Hyponatraemia; Seizure | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2006              | 6007740       | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20060303621 |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Arrhythmia; Drug Interaction; Electrocardiogram Qt Prolonged; Palpitations; Sinus Tachycardia; Supraventricular Extrasystoles; Vertigo | Flexeril       |              |            | S           |              |                            | 2 DAY           | Not Reported |
|                                                                                                                                        | Clonidine      |              |            | C           | Oral         |                            | 13 DAY          | Not Reported |
|                                                                                                                                        | Valium         |              |            | C           | Oral         | Varying Doses              | 3 DAY           | Not Reported |
|                                                                                                                                        | Vistaril       |              |            | C           | Oral         |                            |                 | Not Reported |
|                                                                                                                                        | Trazodone      |              |            | C           | Oral         |                            |                 | Not Reported |
|                                                                                                                                        | Ibuprofen      |              |            | C           | Oral         |                            | 8 DAY           | Not Reported |
|                                                                                                                                        | Ibuprofen      |              |            | C           | Oral         |                            | 8 DAY           | Not Reported |
|                                                                                                                                        | Toradol        |              |            | C           |              |                            | 4 DAY           | Not Reported |
|                                                                                                                                        | Toradol        |              |            | C           |              | 30 Mg, Once, Intramuscular | 4 DAY           | Not Reported |
|                                                                                                                                        | Keflex         |              |            | C           | Oral         |                            | 8 DAY           | Not Reported |
|                                                                                                                                        | Tigan          |              |            | C           | Oral         |                            | 3 DAY           | Not Reported |
|                                                                                                                                        | Diflucan       |              |            | C           | Oral         |                            |                 | Not Reported |
|                                                                                                                                        | Rozerem        |              |            | S           | Oral         |                            |                 | Not Reported |
|                                                                                                                                        | Seroquel       |              |            | S           | Oral         | 50mg Q8hrs And 100mg Hs    |                 | Not Reported |
|                                                                                                                                        | Lexapro        |              |            | S           | Oral         |                            | 13 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2006              | 6012239       | DIRECT           | Y                  | OT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |
|------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|------------|
| Atrial Fibrillation; Fatigue | Lexapro        |              |            | S           | Oral         | 20 Mg Daily, Hs Po (Intermittent) |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Mar-2006                                                                                                                                                         | 5999423                          | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00518-01     |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Aphasia; Disturbance In<br>Attention; Drug Ineffective;<br>Economic Problem;<br>Emotional Disorder;<br>Musculoskeletal Pain;<br>Speech Disorder | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Aspirin                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2006                                                                                                                                                         | 6005474                          | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00570-01     |                      | 88 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Diastolic Dysfunction;<br>Hyponatraemia                                                                                                    | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Unspecified Ingredient           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Lasix                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Lisinopril                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Lortab                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Aspirin                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Pepcid                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Ativan                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Kay Ciel                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Multi-Vitamin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Mylicon Drops                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Lovenox                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2006                                                                                                                                                         | 6008507                          | EXPEDITED (15-DAY) | Y                  | HO              | 2006PK00508          |                      | 73 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Confusional State;<br>Dehydration;                                                                                                                          | Seroquel                         |                    |                    | S               | Oral                 |                      | 2 MTH           | Zeneca       |                |
|                                                                                                                                                                     | Beloc Mite (Metoprolol Tartrate) |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |                   |   |      |  |  |       |  |              |
|---------------------------------------------------------------------------------------------------------------------------|-------------------|---|------|--|--|-------|--|--------------|
| Disorientation; Drug Interaction; Headache; Hypophagia; Mydriasis; Serotonin Syndrome; Toxicity To Various Agents; Tremor | Aspirin           | C | Oral |  |  |       |  | Not Reported |
|                                                                                                                           | Lorazepam         | C | Oral |  |  |       |  | Not Reported |
|                                                                                                                           | Pravastatin       | C | Oral |  |  |       |  | Not Reported |
|                                                                                                                           | Calcimagon-D3     | C | Oral |  |  |       |  | Not Reported |
|                                                                                                                           | Fosamax           | C | Oral |  |  |       |  | Not Reported |
|                                                                                                                           | Lithium Carbonate | S | Oral |  |  | 2 MTH |  | Not Reported |
|                                                                                                                           | Cipralext         | S | Oral |  |  | 2 MTH |  | Not Reported |
|                                                                                                                           | Remeron           | S | Oral |  |  | 2 MTH |  | Not Reported |
|                                                                                                                           | Valproate Sodium  | S | Oral |  |  | 2 MTH |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2006              | 6019154       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01092-01     |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                        | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2006              | 6019157       | EXPEDITED (15-DAY) | Y                  | HO              | 2006-139622-NL       |                      | 73 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Confusional State; Drug Interaction; Fluid Intake Reduced; Headache; Hypophagia; Mydriasis; Serotonin Syndrome; Toxicity To Various Agents; Tremor | Mirtazapine          |              |            | S           | Oral         | Df                 | 2 MTH           | Not Reported |
|                                                                                                                                                            | Potassium Sulfate    |              |            | S           |              | 660 Mg             | 2 MTH           | Not Reported |
|                                                                                                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              | 2 MTH           | Not Reported |
|                                                                                                                                                            | Valproate Sodium     |              |            | S           | Oral         | Df                 | 2 MTH           | Not Reported |
|                                                                                                                                                            | Quetiapine Fumarate  |              |            | S           | Oral         | 300 Mg             | 2 MTH           | Not Reported |
|                                                                                                                                                            | Metoprolol Tartrate  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                            | Acetylsalicylic Acid |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                            | Lorazepam            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                            | Pravastatin          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                            | Calcimagon-D3        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                            | Alendronate Sodium   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2006              | 5951680       | EXPEDITED (15-DAY) | Y                  | RI, OT          | TPA2005A01628        |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Arrhythmia; Long Qt Syndrome; Palpitations; Sinus Tachycardia; Supraventricular Extrasystoles; Vertigo | Rozerem                 |              |            | S           | Oral         | 8 Mg, Qhs, Per Oral                           |                 | Not Reported |
|                                                                                                        | Seroquel                |              |            | S           | Oral         | 50 Mg, Every 8 Hrs And 100 Mg At Hs, Per Oral |                 | Not Reported |
|                                                                                                        | Lexapro                 |              |            | S           | Oral         | 10 Mg, 1 In 1 D, Per Oral                     |                 | Not Reported |
|                                                                                                        | Flexeril                |              |            | S           |              | 10 Mg, Qam & Qhs                              |                 | Not Reported |
|                                                                                                        | Diflucan                |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Clonidine               |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Valium                  |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Vistaril                |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Trazodone Hydrochloride |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Ibuprofen               |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Toradol                 |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Keflex                  |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                                        | Tigan                   |              |            | C           |              |                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2006              | 6016841       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-01028-01     |                      | 26 YR      | Female     | FRA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Urinary Retention | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                 | Seretide Diskus      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Mar-2006              | 6018281       | EXPEDITED (15-DAY) | N                  | OT              | 2006036438           |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Confusional State; Feeling Abnormal; Haematemesis; Mood Swings; Nausea; Oesophageal Disorder; | Geodon         |              |            | S           |              | 40 Mg (40 Mg, 1 In 1 D), |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D)  |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Retching; Vomiting                                                                             | Klonopin                      |                    |                    | S               |                      | 1 Mg (0.5 Mg, 2 In 1 D), |                 | Not Reported |                |
|------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
|                                                                                                | Biovan "Novartis" (Valsartan) |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2006                                                                                    | 6018591                       | EXPEDITED (15-DAY) | Y                  | OT              | L06-GER-00428-01     |                          | 62 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychotic Disorder;<br>Serotonin Syndrome;<br>Therapy Non-Responder                            | Cipralex                      |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Cipralex                      |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Cipralex                      |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Cipralex                      |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Zotepine                      |                    |                    | S               | Oral                 | 50 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Mesalazine                    |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                | Pantoprazole Sodium           |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                | Propranolol                   |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                | Glimepiride                   |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                | Phenprocoumon                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2006                                                                                    | 6018593                       | EXPEDITED (15-DAY) | Y                  | OT              | S06-ESP-00809-01     |                          | 53 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Hallucination;<br>Paronychia                                                         | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                | Gabapentin                    |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2006                                                                                    | 3914213                       | EXPEDITED (15-DAY) | Y                  | HO, LT          | PHFR2003IE00498      |                          | 31 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Blood<br>Bicarbonate Decreased;<br>Blood Chloride Increased;<br>Blood Electrolytes | Clozaril                      |                    |                    | S               | Oral                 | 450mg/Day                | 2413 DAY        | Novartis     |                |
|                                                                                                | Clozaril                      |                    |                    | S               | Oral                 | 80-100x100mg/Overdose    | 2880 MIN        | Novartis     |                |
|                                                                                                | Clozaril                      |                    |                    | S               | Oral                 | 5.5 G                    |                 | Novartis     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                  |   |      |           |              |
|----------------------------|------------------|---|------|-----------|--------------|
| Abnormal; Blood Urea       | Valproate Sodium | S | Oral | 100mg/Day | Not Reported |
| Abnormal; Blood Urea       | Valproate Sodium | S |      | Overdose  | Not Reported |
| Increased; Carbon Dioxide  | Lexapro          | S |      | Overdose  | Not Reported |
| Decreased; Coma;           |                  |   |      |           |              |
| Haematocrit Decreased;     |                  |   |      |           |              |
| Haemoglobin Decreased;     |                  |   |      |           |              |
| Lymphocyte Count           |                  |   |      |           |              |
| Decreased; Neutrophil      |                  |   |      |           |              |
| Count Increased;           |                  |   |      |           |              |
| Overdose; Pneumonia        |                  |   |      |           |              |
| Aspiration; Po2 Increased; |                  |   |      |           |              |
| Red Blood Cell Count       |                  |   |      |           |              |
| Decreased; Tonic Clonic    |                  |   |      |           |              |
| Movements; Urinary         |                  |   |      |           |              |
| Retention                  |                  |   |      |           |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2006              | 5987475       | EXPEDITED (15-DAY) | N                  | OT              | 2006UW02448          |                      | 30 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Irritability; | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
| White Blood Cell Count    | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Increased                 | Lexapro        |              |            | S           | Oral         |                    | 2 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2006              | 6014446       | DIRECT           | N                  |                 |                      |                      | 80 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Gait Disturbance; | Lexapro        |              |            | S           |              | 20 Mg Once Daily   |                 | Not Reported |
| Medication Error; Product  |                |              |            |             |              |                    |                 |              |
| Dispensing Error; Tremor;  |                |              |            |             |              |                    |                 |              |
| Visual Impairment          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2006              | 5906312       | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-05P-163-0313440-00 |                      | 85 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Mental Status Changes;<br>Seizure   | Lexapro                                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                     | Lexapro                                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                     | Carbamazepine                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Metoprolol Tartrate                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Levothyroxine Sodium                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Glipizide                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Rabeprazole Sodium                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Doxycycline                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                     | Warfarin Sodium                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Metoclopramide                      |                                         |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2006                         | 6018785                                 | DIRECT             | N                  | RI              |                      |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Hypotrichosis             | Lexapro                                 |                    |                    | S               |                      | 10 Mg 1 Each Day     |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2006                         | 6020034                                 | EXPEDITED (15-DAY) | N                  | RI              |                      | S06-USA-01156-01     | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Glaucoma                            | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2006                         | 6019104                                 | EXPEDITED (15-DAY) | Y                  | OT              |                      | S06-USA-01098-01     | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure | Lexapro                                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                     | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | S               |                      | 200 Mg Bid           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Mar-2006                                                                                                      | 6024452        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01230-01     |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Amniotic Fluid Volume<br>Increased; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                  | Albuterol      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 5960387                | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04689-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Asthenopia; Back<br>Injury; Bipolar Disorder;<br>Condition Aggravated;<br>Crying; Depression; Drug<br>Interaction; Dry Eye; Eye<br>Irritation; Eye Pruritus;<br>Family Stress; Fatigue;<br>Feeling Abnormal; Food<br>Craving; Idiosyncratic<br>Drug Reaction; Impaired<br>Driving Ability; Impaired<br>Work Ability; Irritability;<br>Muscle Spasms;<br>Obsessive-Compulsive<br>Disorder; Photosensitivity<br>Reaction; Self-Injurious<br>Ideation; Sinusitis; Vision<br>Blurred | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro                |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Claritin               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prilosec               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Niacin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Calcium                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Pamelor                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ativan                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lamictal (Lamotrigine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ability (Aripiprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Celexa                 |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Mar-2006              | 5998782        | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00517-01     |                      | 42 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |         |   |      |             |              |
|---------|---------|---|------|-------------|--------------|
| Seizure | Lexapro | S | Oral | 20 Mg Qd Po | Not Reported |
|         | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|         | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|         | Lexapro | S | Oral | 15 Mg Qd Po | Not Reported |
|         | Lexapro | S | Oral | 20 Mg Qd Po | Not Reported |
|         | Xanax   | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2006              | 6015437       | EXPEDITED (15-DAY) | Y                  | HO              | 2006PK00569          |                      | 27 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Epilepsy;<br>Generalised Tonic-Clonic<br>Seizure | Seroquel             |              |            | S           | Oral         |                    | 17 DAY          | Zeneca       |
|                                                                                                          | Levothyroxine Sodium |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Enalapril            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Seroquel             |              |            | S           | Oral         |                    | 10 DAY          | Zeneca       |
|                                                                                                          | Seroquel             |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                          | Fluctine             |              |            | S           | Oral         |                    | 15 DAY          | Not Reported |
|                                                                                                          | Fluctine             |              |            | S           | Oral         |                    | 1 DAY           | Not Reported |
|                                                                                                          | Melperone            |              |            | S           | Oral         |                    | 15 DAY          | Not Reported |
|                                                                                                          | Melperone            |              |            | S           | Oral         |                    | 12 DAY          | Not Reported |
|                                                                                                          | Melperone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Cipralelex           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2006              | 6016826       | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-01029-01     |                      | 75 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bifascicular Block; Bundle<br>Branch Block Left; Bundle<br>Branch Block Right;<br>Coronary Artery Disease; | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                            | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                            | Cipralelex     |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |                                |   |      |             |              |
|----------------------------------------|--------------------------------|---|------|-------------|--------------|
| Depression; Treatment<br>Noncompliance | Pipamperone                    | S | Oral | 25 Mg Qd Po | Not Reported |
|                                        | Pipamperone                    | S | Oral | 50 Mg Qd Po | Not Reported |
|                                        | Valproate Sodium               | C |      |             | Not Reported |
|                                        | Pantozol (Pantoprazole Sodium) | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2006              | 6016842       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01201-01     |                      | 55 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Prostatic Adenoma;<br>Urinary Retention | Escitalopram Oxalate    |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                         | Diazepam                |              |            | S           |              |                    |                 | Not Reported |
|                                         | Mianserin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2006              | 6025023       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00836-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6012036       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01048-01     |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neuropathy Peripheral | Lexapro                      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Cholesterol Medciation (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6016591       | EXPEDITED (15-DAY) | Y                  | HO              | DE-JNJFOC-20060305526 |                      | 68 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Parkinsonism;         | Haldol         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |                              |   |      |              |
|----------------|------------------------------|---|------|--------------|
| Pleurothotonus | Haldol                       | S | Oral | Not Reported |
|                | Haldol                       | S | Oral | Not Reported |
|                | Cipralelex                   | S | Oral | Not Reported |
|                | Cipralelex                   | S | Oral | Not Reported |
|                | Beloc-Zok                    | C | Oral | Not Reported |
|                | Losartan Potassium           | C | Oral | Not Reported |
|                | Amiodarone Hydrochloride     | C | Oral | Not Reported |
|                | Kalinor (Potassium Chloride) | C |      | Not Reported |
|                | Aspirin                      | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6025335       | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-01279-01     |                      | 41 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Dizziness;<br>Dysaesthesia; Feeling Of<br>Body Temperature<br>Change; Insomnia;<br>Musculoskeletal Stiffness;<br>Nausea; Tachycardia;<br>Vomiting | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6025338       | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-01280-01     |                      | 38 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Aphonia; Confusional<br>State; Dizziness; Drug<br>Withdrawal Syndrome;<br>Euphoric Mood; Muscle<br>Twitching; Panic Reaction;<br>Paraesthesia; Suicidal<br>Ideation; Vomiting | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                      | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6025345       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01305-01     |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder;<br>Urinary Retention | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2006              | 6025359       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-00644-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Decreased Appetite;<br>Fatigue; Feeling Cold;<br>Nausea; Somnolence | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Percocet                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Tramadol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Carisoprodol            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Clorazepate Dipotassium |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Premarin                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Clarinet                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Singulair               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Zantac                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Flovent                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Albuterol               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Finacea                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Apr-2006              | 5996252       | EXPEDITED (15-DAY) | Y                  | OT              | S06-SAF-00423-01     |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bronchospasm; Chest<br>Discomfort; Face<br>Oedema; Throat Irritation;<br>Urticaria | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                    | Ferrimed       |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 03-Apr-2006                                                                                                                                                                         | 6024168        | DIRECT             | N                  | OT              |                      |                          | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Flat Affect; Hyposmia; Loss Of Personal Independence In Daily Activities                                                                                                | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Daily In Evening Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2006                                                                                                                                                                         | 5955540        | EXPEDITED (15-DAY) | Y                  | HO              | S05-NOR-05682-01     |                          | 81 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Drug Withdrawal Syndrome; Fatigue; General Physical Health Deterioration; Listless; Sleep Disorder                                                              | Ciprallex      |                    |                    | S               | Ophthalmic           | 5 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                                                                     | Valsartan      |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                     | Anastrozole    |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                     | Plavix         |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2006                                                                                                                                                                         | 6015376        | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-01017-01     |                          | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Cervical Incompetence; Complication Of Pregnancy; Gestational Diabetes; Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Premature Labour | Ciprallex      |                    |                    | S               | Oral                 | 20 Mg Daily Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Apr-2006                                                                                   | 6024572                     | DIRECT             | Y                  | OT              |                      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Suicide Attempt                                                                   | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2006                                                                                   | 6061420                     | NON-EXPEDITED      | Y                  | HO              | 2005139095           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Polydipsia                                                                                    | Geodon                      |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                               | Lexapro                     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2006                                                                                   | 6061476                     | NON-EXPEDITED      | Y                  | OT              | 2005095397           |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Intolerance; Feeling Hot; Flushing; Heart Rate Increased; Hypertension; Malaise; Pyrexia | Geodon                      |                    |                    | S               | Oral                 | (2 In 1 D), Oral     |                 | Not Reported |                |
|                                                                                               | Lexapro                     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                               | Klonopin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Amitriptyline Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Ritalin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2006                                                                                   | 5957086                     | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-05219-01     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Chest Pain; Nausea; Sinus Tachycardia                               | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 05-Apr-2006                                                           | 6028191                | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00875-01             |                      | 51 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Tuberculosis                                                          | Lexapro                |                    |                    | S               | Oral                         | 40 Mg Qd Po          |                 | Not Reported    |                |
|                                                                       | Strattera              |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                       | Ritalin                |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                                       | Imitrex (Sumatriptan)  |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 06-Apr-2006                                                           | 6029093                | EXPEDITED (15-DAY) | Y                  | OT              | 2006042057                   |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Bladder Hypertrophy;<br>Condition Aggravated;<br>Urinary Retention    | Neurontin              |                    |                    | S               |                              | 1500 Mg (1 D)        |                 | Not Reported    |                |
|                                                                       | Clozapine              |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                       | Abilify                |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                       | Lexapro                |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                       | Seroquel               |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 06-Apr-2006                                                           | 6064994                | NON-EXPEDITED      | Y                  | OT              | SUS1-2006-00046              |                      |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure Increased                                              | Adderall Xr            |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                                       | Lexapro                |                    |                    | S               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Apr-2006                                                           | 6020784                | EXPEDITED (15-DAY) | N                  | HO              | FR-GLAXOSMITHKLINE-B0419288A |                      | 73 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dehydration; Diarrhoea;<br>Hyponatraemia;<br>Orthostatic Hypotension; | Clamoxyl (Amoxicillin) |                    |                    | S               | Oral                         | 1g Twice Per Day     | 6 DAY           | Glaxosmithkline |                |
|                                                                       | Inexium                |                    |                    | S               |                              | 20mg Per Day         | 12 DAY          | Unknown         |                |

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|          |                      |   |         |                    |        |         |
|----------|----------------------|---|---------|--------------------|--------|---------|
| Vomiting | Perindopril Erbumine | S | Oral    | 4mg Per Day        | 55 DAY | Unknown |
|          | Escitalopram Oxalate | S | Oral    | 10mg Twice Per Day | 44 DAY | Unknown |
|          | Vastarel             | C | Oral    | 35mg Twice Per Day | 57 DAY | Unknown |
|          | Carvedilol           | C | Oral    | 25mg Per Day       |        | Unknown |
|          | Aspirin Lysine       | C | Oral    | 75mg Per Day       |        | Unknown |
|          | Risperdal            | C | Unknown | 1.5mg Per Day      |        | Unknown |
|          | Stilnox              | C | Oral    | 1tab Per Day       |        | Unknown |
|          | Econazole Nitrate    | C | Other   |                    | 21 DAY | Unknown |
|          | Pravastatin Sodium   | C | Oral    | 20mg Per Day       |        | Unknown |
|          | Omeprazole           | C | Oral    | 20mg Per Day       |        | Unknown |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2006              | 6031427       | EXPEDITED (15-DAY) | N                  | OT              | 2006045197           |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Confusional State;        | Lyrica                 |              |            | S           |              | 150 Mg (75 Mg, 2 In 1 D), |                 | Not Reported |
| Contusion; Fall;          | Lexapro                |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D),  |                 | Not Reported |
| Haematocrit Decreased;    | Metoprolol Tartrate    |              |            | C           |              |                           |                 | Not Reported |
| Haemoglobin Decreased;    | Synthroid              |              |            | C           |              |                           |                 | Not Reported |
| Platelet Count Decreased; | Tramadol Hydrochloride |              |            | C           |              |                           |                 | Not Reported |
| Red Blood Cell Count      | Miacalcin              |              |            | C           |              |                           |                 | Not Reported |
| Abnormal; Red Cell        |                        |              |            |             |              |                           |                 |              |
| Distribution Width        |                        |              |            |             |              |                           |                 |              |
| Increased; Skin           |                        |              |            |             |              |                           |                 |              |
| Laceration; Wheelchair    |                        |              |            |             |              |                           |                 |              |
| User                      |                        |              |            |             |              |                           |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2006              | 5936959       | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04945-02     |                      | 7 DAY      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident; | Lexapro           |              |            | S           |              |                    |                 | Not Reported |
| Foetal Disorder;          | Lexapro           |              |            | S           |              |                    |                 | Not Reported |
| Haemoglobin Decreased;    | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported |

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|                                                                                                                                                                                                                   |                        |   |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---|--------------|
| Jaundice Neonatal;<br>Maternal Exposure During<br>Breast Feeding; Maternal<br>Exposure During<br>Pregnancy; Neonatal<br>Disorder; Neonatal<br>Tachypnoea; Nervous<br>System Disorder; Platelet<br>Count Increased | Unspecified Ingredient | C | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2006              | 6019107       | EXPEDITED (15-DAY) | Y                  | HO, OT          | L06-USA-01021-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Depressed Mood; Dry<br>Mouth; Dystonia; Suicidal<br>Ideation; Weight<br>Decreased | Escitalopram Oxalate |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2006              | 6022535       | EXPEDITED (15-DAY) | Y                  | OT              | 2006037513           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Brain Operation; Cardiac<br>Operation; Depression;<br>Gingival Swelling; Weight<br>Decreased | Dilantin       |              |            | S           |              |                          |                 | Not Reported |
|                                                                                                                       | Lipitor        |              |            | S           |              | 40 Mg (40 Mg, 1 In 1 D), |                 | Not Reported |
|                                                                                                                       | Xalatan        |              |            | S           |              |                          |                 | Not Reported |
|                                                                                                                       | Lexapro        |              |            | S           |              |                          |                 | Not Reported |
|                                                                                                                       | Valium         |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Dyazide        |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Armour Thyroid |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Metoprolol     |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Klor-Con       |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Aspirin        |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                       | Trusopt        |              |            | C           |              |                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------|-----------------|--------------|----------------|
| 11-Apr-2006                                                                                                         | 6022878              | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-JNJFOC-20060305521 |                       |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Acidosis; Dependence On Respirator; Fatigue; Gastrointestinal Sounds Abnormal; Overdose; Seizure; Suicide Attempt   | Risperdal            |                    |                    | S               | Oral                  |                       |                 | Not Reported |                |
|                                                                                                                     | Ciprallex            |                    |                    | S               | Oral                  |                       |                 | Not Reported |                |
|                                                                                                                     | Cymbalta             |                    |                    | S               | Oral                  |                       |                 | Not Reported |                |
|                                                                                                                     | Trimipramine Maleate |                    |                    | S               | Oral                  |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2006                                                                                                         | 6024422              | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-01163-01      |                       | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death; Fatigue; Loss Of Consciousness; Malaise; Toxicity To Various Agents                               | Lexapro              |                    |                    | S               | Oral                  | 20 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                     | Synthroid            |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                     | Aricept              |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                     | Aldactone            |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                     | Effexor              |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                     | Vitamin B Complex    |                    |                    | C               |                       |                       |                 | Not Reported |                |
|                                                                                                                     | Folate               |                    |                    | C               |                       |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2006                                                                                                         | 6026284              | DIRECT             | Y                  | OT              |                       |                       | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Diarrhoea; Drug Interaction; Gallbladder Disorder; Gastrooesophageal Reflux Disease; Vomiting | Lexapro              |                    |                    | S               | Oral                  | 1 Tab Daily Po        |                 | Forest       |                |
|                                                                                                                     | Omeprazole           |                    |                    | S               | Oral                  | 2 Tabs Twice A Day Po |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Apr-2006                                                                             | 6027066              | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00834-01     |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Urticaria | Lexapro              |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                         | Lexapro              |                    |                    | S               | Oral                 | 1 MI Qd Po           |                 | Not Reported |                |
|                                                                                         | Lexapro              |                    |                    | S               | Oral                 | 0.5 MI Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2006                                                                             | 6032140              | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-01352-01     |                      | 36 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Discomfort;<br>Galactorrhoea;<br>Hyperprolactinaemia                             | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2006                                                                             | 6032201              | EXPEDITED (15-DAY) | Y                  | HO              | S06-NOR-01350-01     |                      | 81 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug<br>Interaction; Hyperreflexia;<br>Muscle Rigidity               | Ciprallex            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Lithium              |                    |                    | S               | Oral                 | 42 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Alopam (Oxazepam)    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                         | Imovane (Zopiclone)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2006                                                                             | 5964790              | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-00114-01     |                      | 88 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Condition<br>Aggravated; Fall;<br>Hangover; Head Injury;                      | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                       |   |      |                  |              |
|---------------------------|-----------------------|---|------|------------------|--------------|
| Humerus Fracture; Injury; | Lexapro               | S | Oral | 5 Mg Qd Po       | Not Reported |
| Insomnia; Nightmare;      | Lexapro               | S | Oral | 10 Mg Qd Po      | Not Reported |
| Pain; Somnambulism;       | Ambien Cr             | S | Oral | 25 Mg Once Po    | Not Reported |
| Somnolence; Syncope       | Ambien Cr             | S | Oral | 12.5 Mg Qhs Po   | Not Reported |
|                           | Ambien Cr             | S | Oral | 12.5 Mg Qhs Po   | Not Reported |
|                           | Ambien Cr             | S | Oral | 18.75 Mg Once Po | Not Reported |
|                           | Risperdal             | C |      |                  | Not Reported |
|                           | Lunesta               | C |      |                  | Not Reported |
|                           | Avapro                | C |      |                  | Not Reported |
|                           | Sotalol Hydrochloride | C |      |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2006              | 6007636       | EXPEDITED (15-DAY) | N                  | HO, LT          | S06-USA-00647-01     |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress Syndrome; Asthenia;                   | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Coma; Diffuse Alveolar Damage; Dizziness; Drug Hypersensitivity; | Lopresor            |              |            | C           |              |                    |                 | Not Reported |
| Respiratory Failure; Toxicity To Various Agents; Viral Infection | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2006              | 6007637       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-00637-01     |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;      | Lexapro                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Aggression; Mania;       | Lexapro                    |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Muscle Twitching;        | Moban                      |              |            | C           |              |                    |                 | Not Reported |
| Obsessive Thoughts;      | Multiple Medications (Nos) |              |            | C           |              |                    |                 | Not Reported |
| Pneumonia; Seizure;      |                            |              |            |             |              |                    |                 |              |
| Speech Disorder; Tic;    |                            |              |            |             |              |                    |                 |              |
| Urosepsis; Verbigeration |                            |              |            |             |              |                    |                 |              |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 12-Apr-2006                                                                        | 6023929                            | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-SANOFI-SYNTHELABO-A02200600883 |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Drug Interaction; Haematemesis; Haemobilia; Peritoneal Haemorrhage; Shock | Plavix                             |                    |                    | S               | Oral                              |                      | 20 DAY          | Not Reported |                |
|                                                                                    | Selokeen                           |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Digitaline                         |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Pravastatin Sodium                 |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Omeprazole                         |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Nicorandil                         |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Vastarel                           |                    |                    | C               | Oral                              | 3 Unit               |                 | Not Reported |                |
|                                                                                    | Ramipril                           |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Unspecified Ingredient             |                    |                    | C               | Oral                              | Unk                  |                 | Not Reported |                |
|                                                                                    | Doliprane                          |                    |                    | C               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                                                                    | Bicarbonate Ion\Sodium Bicarbonate |                    |                    | C               | Buccal                            | Unk                  |                 | Not Reported |                |
|                                                                                    | Eludril                            |                    |                    | C               | Buccal                            | Unk                  |                 | Not Reported |                |
|                                                                                    | Fungizone                          |                    |                    | C               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                                                                    | Aspirin Lysine                     |                    |                    | S               | Oral                              |                      | 8 YR            | Not Reported |                |
|                                                                                    | Escitalopram Oxalate               |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                                    | Previscan (Fluindione)             |                    |                    | S               | Oral                              |                      | 19 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2006                                                                        | 6029244                            | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-FRA-01316-01                  |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Overdose; Suicide Attempt                                                    | Escitalopram Oxalate               |                    |                    | S               | Oral                              | 1 Tablet Once Po     |                 | Not Reported |                |
|                                                                                    | Lexomil (Bromazepam)               |                    |                    | S               | Oral                              | 15 Tablet Once Po    |                 | Not Reported |                |
|                                                                                    | Alcohol                            |                    |                    | S               |                                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                | <u>Case #</u>                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------------------|----------------|
| 12-Apr-2006                                                                                                                                                                                                                                                                             | 6034545                                                                                          | EXPEDITED (15-DAY) | Y                  | HO                    | S06-UKI-01326-01     |                      | 46 YR           | Male                                                                         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u>                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Hallucination, Auditory;<br>Mental Disorder;<br>Overdose; Paranoia;<br>Psychotic Disorder                                                                                                                                                                                               | Cipralelex                                                                                       |                    |                    | S                     | Oral                 | Tablet Po            |                 | Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                | <u>Case #</u>                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
| 13-Apr-2006                                                                                                                                                                                                                                                                             | 5959505                                                                                          | EXPEDITED (15-DAY) | Y                  | LT                    | S05-PRT-05743-01     |                      | 36 YR           | Male                                                                         | PRT            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u>                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Alveolitis; Depressed<br>Level Of Consciousness;<br>Dizziness; Drug Abuser;<br>Drug Interaction;<br>Headache; Herpes<br>Simplex; Hypotension;<br>Loss Of Consciousness;<br>Malaise; Respiratory<br>Acidosis; Respiratory<br>Arrest; Respiratory<br>Distress; Somnolence;<br>Tachycardia | Cipralelex<br>Methadone<br>Mirtazapine<br>Oxazepam<br>Triazolam                                  |                    |                    | S<br>S<br>C<br>C<br>C | Oral                 | 40 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                | <u>Case #</u>                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
| 13-Apr-2006                                                                                                                                                                                                                                                                             | 5999464                                                                                          | EXPEDITED (15-DAY) | Y                  | DE, HO                | S06-USA-00510-01     |                      | 74 YR           | Female                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u>                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Abdominal Pain Upper;<br>Anxiety; Aortic<br>Arteriosclerosis; Asthenia;<br>Atonic Urinary Bladder;<br>Blood Pressure Systolic<br>Increased; Cardiac Failure                                                                                                                             | Lexapro<br>Insulin Nos<br>Cholesterol Medication (Nos)<br>Congestive Heart Failure<br>Medication |                    |                    | S<br>C<br>C<br>C      | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                                |   |              |
|-----------------------------|--------------------------------|---|--------------|
| Congestive;                 | Aspirin                        | C | Not Reported |
| Cardiomegaly; Condition     | Plavix                         | C | Not Reported |
| Aggravated; Confusional     | Imdur                          | C | Not Reported |
| State; Coronary Artery      | Lovastatin                     | C | Not Reported |
| Disease; Decreased          | Coreg                          | C | Not Reported |
| Appetite; Disorientation;   | Digoxin                        | C | Not Reported |
| Fatigue; Formication;       | Procrit                        | C | Not Reported |
| Gastrooesophageal Reflux    | Ferrous Sulfate                | C | Not Reported |
| Disease; Heart Rate         | Humibid (Guaifenesin)          | C | Not Reported |
| Decreased; Heart Sounds     | Rocephin                       | C | Not Reported |
| Abnormal; Hypoxia;          | Zithromax                      | C | Not Reported |
| Insomnia; Mental Status     | Lasix                          | C | Not Reported |
| Changes; Muscle             | Protonix                       | C | Not Reported |
| Twitching; Nausea;          | Os-Cal Plus Vitamin D (Calcium | C | Not Reported |
| Osteoporosis; Pleural       | Carbonate/Vitamin D)           |   |              |
| Effusion; Pneumonia;        | Reglan                         | C | Not Reported |
| Pulmonary Oedema;           | Vasotec                        | C | Not Reported |
| Renal Artery Stenosis;      | Lantus                         | C | Not Reported |
| Renal Failure; Renal        | Demadex                        | C | Not Reported |
| Impairment; Respiratory     | Flonase                        | C | Not Reported |
| Failure; Restlessness;      | Bumex                          | C | Not Reported |
| Rhinitis Allergic; Staring; | Hycodan [Hydrocodone           | C | Not Reported |
| Tremor; Urinary Retention;  | Bitartrate]                    |   |              |
| Vomiting; Weight            | Avelox                         | C | Not Reported |
| Increased                   | Novolin N                      | C | Not Reported |
|                             | Hydralazine                    | C | Not Reported |
|                             | Folate                         | C | Not Reported |
|                             | Niaspan                        | C | Not Reported |
|                             | Keflex                         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2006              | 6034039       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00972-01     |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Steatosis;    | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Pancreatitis; Sepsis  | Requip         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2006              | 6034043       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00957-01     |                      | 72 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| Hyponatraemia                                                                                                                                                                                                                                                                                         | Lexapro                      |                    |                    | S               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2006                                                                                                                                                                                                                                                                                           | 6930039                      | EXPEDITED (15-DAY) | Y                  | DS, HO          | 2006-BP-03613RO      |                                                              | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Urea Increased;<br>Confusional State;<br>Decreased Appetite;<br>Dehydration; Delirium;<br>Depressed Mood;<br>Disturbance In Attention;<br>Drug Interaction; Fall;<br>Hypersomnia;<br>Hyponatraemia;<br>Hypophagia; Impaired<br>Self-Care; Lethargy;<br>Memory Impairment;<br>Pneumonia; Staring | Methadone Hydrochloride      |                    |                    | S               |                      | High 20mg/D Decr To<br>10mg/D Then Tapered To<br>Discontinue |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Dextromethorphan\Guaifenesin |                    |                    | S               |                      | 600mg/30 Mg Bid (2 In 1<br>D)                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Sertraline                   |                    |                    | S               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Escitalopram Oxalate         |                    |                    | S               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Acetaminophen\Hydrocodone    |                    |                    | S               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Bitartrate                   |                    |                    |                 |                      |                                                              |                 |              |                |
|                                                                                                                                                                                                                                                                                                       | Ipratropium Bromide          |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Metoclopramide Hydrochloride |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                       | Metolazone                   |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
| Warfarin Sodium                                                                                                                                                                                                                                                                                       |                              |                    | C                  |                 |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Apr-2006                                                                                                                                                                                                                                                                                           | 5939176                      | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-05006-02     |                                                              | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;                                                                                                                                                                                                                                                                                    | Lexapro                      |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental                                      |                 | Not Reported |                |
| Hyperbilirubinaemia                                                                                                                                                                                                                                                                                   | Lexapro                      |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental                                      |                 | Not Reported |                |
| Neonatal; Hypertension                                                                                                                                                                                                                                                                                | Lexapro                      |                    |                    | S               | Transmammary         | 10 Mg Qd Bf                                                  |                 | Not Reported |                |
| Neonatal; Hypoglycaemia                                                                                                                                                                                                                                                                               | Prenatal Vitamins            |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
| Neonatal; Large For Dates                                                                                                                                                                                                                                                                             |                              |                    |                    |                 |                      |                                                              |                 |              |                |
| Baby; Maternal Exposure                                                                                                                                                                                                                                                                               |                              |                    |                    |                 |                      |                                                              |                 |              |                |
| During Breast Feeding;                                                                                                                                                                                                                                                                                |                              |                    |                    |                 |                      |                                                              |                 |              |                |
| Maternal Exposure During                                                                                                                                                                                                                                                                              |                              |                    |                    |                 |                      |                                                              |                 |              |                |
| Pregnancy                                                                                                                                                                                                                                                                                             |                              |                    |                    |                 |                      |                                                              |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|----------------------------------------------|----------------|
| 14-Apr-2006                                | 5954087                               | EXPEDITED (15-DAY) | Y                  | HO, OT          | S05-UKI-05679-01     |                                 | 61 YR           | Female                                       | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Hypotension; Loss Of Consciousness; Pallor | Cipralext<br>Rivastigmine             |                    |                    | S<br>C          | Oral                 | 10 Mg Po                        |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Apr-2006                                | 6001836                               | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-00627-01     |                                 |                 | Male                                         | DEU            |
| <u>Preferred Term</u>                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Csf Pressure Increased; Overdose           | Cipralext                             |                    |                    | S               |                      | 40 Mg                           |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Apr-2006                                | 6025213                               | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-GER-00070-01     |                                 | 74 YR           | Male                                         | DEU            |
| <u>Preferred Term</u>                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Focal Dyscognitive Seizures                | Cipralext<br>Cipralext<br>Mirtazapine |                    |                    | S<br>S<br>C     | Oral<br>Oral         | 20 Mg Daily Po<br>5 Mg Daily Po |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Apr-2006                                | 6031853                               | DIRECT             | Y                  |                 |                      |                                 |                 | Male                                         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Rash; Scratch                              | Lexapro                               |                    |                    | S               | Oral                 | 10mg Daily Po                   |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 14-Apr-2006                                | 6035547                               | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-01340-01     |                                 | 60 YR           | Female                                       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                              | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Drug Interaction;<br>International Normalised<br>Ratio Increased;<br>Somnolence; Vomiting | Escitalopram Oxalate                         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Previscan (Fluindione)                       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Previscan (Fluindione)                       |              |            | S           | Oral         | 20 Mg Bid Po       |                 | Not Reported |
|                                                                                                                    | Previscan (Fluindione)                       |              |            | S           | Oral         | 20 Mg Daily Po     |                 | Not Reported |
|                                                                                                                    | Previscan (Fluindione)                       |              |            | S           | Oral         | 20 Mg Qod Po       |                 | Not Reported |
|                                                                                                                    | Previscan (Fluindione)                       |              |            | S           | Oral         | 30 Mg Qod Po       |                 | Not Reported |
|                                                                                                                    | Anafranil                                    |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
|                                                                                                                    | Ciprofloxacin Hydrochloride                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Parkinane (Trihexyphenidyl<br>Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Cyamemazine                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Haloperidol                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Imovane (Zopiclone)                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Tranxene T-Tab                               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Effexor                                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Valproate Sodium                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Risperdal                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Zolpidem                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                    | Lexomil (Bromazepam)                         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2006              | 6064562       | NON-EXPEDITED    | N                  |                 | 2005SP004452         |                      | 83 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Hangover;<br>Therapeutic Product Effect<br>Decreased | Lunesta        |              |            | S           | Oral         | 3 Mg;Hs;Oral       |                 | Not Reported |
|                                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Simvastatin    |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Multivitamins  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2006              | 6068160       | NON-EXPEDITED    | Y                  |                 | 2006SP000025         |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                      |   |      |               |              |
|------------------|----------------------|---|------|---------------|--------------|
| Nausea; Retching | Lunesta              | S | Oral | Oral          | Not Reported |
|                  | Lexapro              | S | Oral | 10 Mg;Qd;Oral | Not Reported |
|                  | Uroxatal             | C |      |               | Not Reported |
|                  | Depakote             | C |      |               | Not Reported |
|                  | Tricor               | C |      |               | Not Reported |
|                  | Atorvastatin         | C |      |               | Not Reported |
|                  | Metoprolol Succinate | C |      |               | Not Reported |
|                  | Nexium               | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2006              | 6068471       | NON-EXPEDITED    | Y                  | OT              | US-JNJFOC-20050600763 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Drug Interaction; Seizure | Ultram         |              |            | S           |              |                               |                 | Not Reported |
|                           | Lexapro        |              |            | S           |              | Generic: Escitalopram Oxalate |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2006              | 5998785       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-00506-01     |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Back Pain; Body Temperature Increased; Drug Abuser; Drug Screen Positive; Drug Withdrawal Syndrome; Erythema; Serotonin Syndrome; Ventricular Fibrillation; Ventricular Tachycardia | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                | Cocaine        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                | Xanax          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2006              | 6035832       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01365-01     |                      | 75 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Chest | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Pain; Cholecystitis;  
International Normalised  
Ratio Increased;  
Prothrombin Time  
Prolonged

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 17-Apr-2006                                                                                                                                                                             | 6036066        | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-01349-01     |                         | 22 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Psychiatric Symptom;<br>Self-Injurious Ideation                                                                                                                     | Cipralelex     |                    |                    | S               | Oral                 | 5 Mg Qod Po             |                 | Not Reported |                |
|                                                                                                                                                                                         | Cipralelex     |                    |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                                                                         | Artane         |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2006                                                                                                                                                                             | 5992432        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00384-01     |                         | 8 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety;<br>Depression; Educational<br>Problem; Incorrect Dose<br>Administered                                                                                                   | Lexapro        |                    |                    | S               | Oral                 | 7.5 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2006                                                                                                                                                                             | 6032435        | DIRECT             | Y                  | OT              |                      |                         | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Eye Movement Disorder;<br>Fatigue; Feeling<br>Abnormal; Nausea;<br>Nervous System Disorder;<br>Nightmare; Sleep Disorder | Lexapro        |                    |                    | S               | Oral                 | 10 Mg 1 Time Per Day Po |                 | Forest       |                |
|                                                                                                                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 20 Mg 1 Time Per Day Po |                 | Forest       |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------|--------------------|------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
| 18-Apr-2006                                                                                                                                                                                                                                                | 6035315                                                                 | EXPEDITED (15-DAY) | N                  | OT               | 2006031609           |                      |                 | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Accidental Overdose;<br>Back Pain; Condition<br>Aggravated; Depressed<br>Level Of Consciousness;<br>Depression; Exostosis;<br>Insomnia; Off Label Use;<br>Sedation; Somnolence;<br>Spinal Osteoarthritis;<br>Suicidal Ideation;<br>Treatment Noncompliance | Neurontin<br>Ambien<br>Lexapro                                          |                    |                    | S<br>S<br>S      |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 18-Apr-2006                                                                                                                                                                                                                                                | 6036556                                                                 | EXPEDITED (15-DAY) | Y                  | HO               | S06-FRA-01382-01     |                      | 55 YR           | Male                                                         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Aggression; Drug<br>Withdrawal Syndrome;<br>Physical Assault                                                                                                                                                                                               | Ciprallex                                                               |                    |                    | S                |                      |                      |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 18-Apr-2006                                                                                                                                                                                                                                                | 6036558                                                                 | EXPEDITED (15-DAY) | Y                  | OT               | S06-FRA-01376-01     |                      | 47 YR           | Female                                                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Epistaxis; Sinusitis                                                                                                                                                                                                                                       | Escitalopram Oxalate<br>Beconase Aq<br>Desloratadine<br>Serevent Diskus |                    |                    | S<br>S<br>C<br>C | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 18-Apr-2006                                                                                                                                                                                                                                                | 6036899                                                                 | EXPEDITED (15-DAY) | Y                  | OT               | S06-USA-01444-01     |                      |                 | Unknown                                                      | USA            |

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| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
|--------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Cerebrovascular Accident       | Lexapro<br>Plavix       |                    |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Apr-2006                    | 6037221                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01459-01     |                      | 77 YR           | Unknown                      | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Electrocardiogram Qt Prolonged | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Apr-2006                    | 6030429                 | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-01309-01     |                      |                 | Male                         | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide; Overdose    | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                | Acepromazine            |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                | Maleate\Meprobamate     |                    |                    |                 |                      |                      |                 |                              |                |
|                                | Oxetorone Fumarate      |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                | Bromazepam              |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Apr-2006                    | 6036144                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-NLD-01354-01     |                      | 46 YR           | Female                       | NLD            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Epilepsy; Hypoglycaemia        | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                | Clorazepate Dipotassium |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Glyceril Trinitrate     |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Folic Acid              |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Carbasalate Calcium     |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Isosorbide Mononitrate  |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Simvastatin             |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Ranitidine              |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Insulin Nos             |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                | Insulin Glargine        |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
| Diltiazem Hydrochloride        |                         |                    | C                  |                 |                      |                      | Not Reported    |                              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Apr-2006                                                                        | 6038684                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01448-01     |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness;<br>Supraventricular<br>Tachycardia; Syncope;<br>Ventricular Tachycardia | Lexapro                  |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2006                                                                        | 6038690                  | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01447-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Stress Test                                                                | Lexapro                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Abnormal; Condition                                                                | Anti-Seizure Medications |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Aggravated; Drug                                                                   | Doxepin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Ineffective; Fatigue;                                                              | Restless Leg Syndrome    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Gastrooesophageal Reflux                                                           | Medication               |                    |                    |                 |                      |                      |                 |              |                |
| Disease; Headache; Mood                                                            | Unspecified Ingredient   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Swings; Oesophageal                                                                | Potassium                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Spasm                                                                              |                          |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2006                                                                        | 6041014                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01378-01     |                      | 73 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature                                                                   | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
| Decreased; Dehydration;                                                            | Clamoxyl (Amoxicillin)   |                    |                    | S               | Oral                 | 1 G Bid Po           |                 | Not Reported |                |
| Diarrhoea; Hypokalaemia;                                                           | Inexium (Esomeprazole)   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Hyponatraemia;                                                                     | Perindopril Erbumine     |                    |                    | S               | Oral                 | 4 Mg Qd Po           |                 | Not Reported |                |
| Orthostatic Hypotension;                                                           | Vastarel                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Vomiting                                                                           | Carvedilol               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                    | Aspirin Lysine           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                    | Risperdal                |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                             |   |              |
|-----------------------------|---|--------------|
| Zolpidem Tartrate           | C | Not Reported |
| Pevaryl (Econazole Nitrate) | C | Not Reported |
| Pravastatin                 | C | Not Reported |
| Mopral (Omeprazole)         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2006              | 6037156       | DIRECT           | N                  | DS, HO, LT      |                      |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Alcohol Use; Intentional Overdose; Loss Of Consciousness; Respiratory Arrest; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 20 Mg Once Daily Po |                 | Cvs Caremark |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2006              | 5951964       | EXPEDITED (15-DAY) | Y                  | OT              | S05-IRL-05648-01     |                      | 82 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypokinesia; Hypotension; Pupil Fixed; Salivary Hypersecretion; Seizure; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Aripiprazole         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Amlodipine Besylate  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2006              | 6022641       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01095-02     |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Agitation Neonatal; Caesarean Section; Maternal Exposure During Pregnancy; Pulmonary Oedema Neonatal | Lexapro        |              |            | S           | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported |
|                                                                                                      | Prenatabs Fa   |              |            | C           |                |                         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 25-Apr-2006                                   | 6031649                | EXPEDITED (15-DAY) | Y                  | HO              | US-GLAXOSMITHKLINE-A0600926A |                      | 40 YR           | Male            | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hepatic Steatosis; Pain; Pancreatitis; Sepsis | Requip                 |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                               | Lexapro                |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                               | Unspecified Ingredient |                    |                    | C               |                              |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 25-Apr-2006               | 6034915                   | EXPEDITED (15-DAY) | Y                  | HO              | 2006048301           |                          | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Urea Increased;     | Sertraline                |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Confusional State;        | Methadone Hydrochloride   |                    |                    | S               |                      | 20 Mg (1 D)              |                 | Not Reported |                |
| Decreased Appetite;       | Guaifenesin               |                    |                    | S               |                      | 60 Mg (30 Mg, 2 In 1 D), |                 | Not Reported |                |
| Dehydration; Delirium;    | Escitalopram Oxalate      |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Depressed Mood;           | Acetaminophen\Hydrocodone |                    |                    | S               |                      | (As Necessary)           |                 | Not Reported |                |
| Disturbance In Attention; | Bitartrate                |                    |                    |                 |                      |                          |                 |              |                |
| Drug Interaction; Fall;   | Ipratropium Bromide       |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Hypersomnia;              | Metoclopramide            |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Hyponatraemia;            | Metolazone                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Hypophagia; Lethargy;     | Warfarin Sodium           |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Memory Impairment;        |                           |                    |                    |                 |                      |                          |                 |              |                |
| Pneumonia; Staring        |                           |                    |                    |                 |                      |                          |                 |              |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Apr-2006                                           | 6037342        | DIRECT           | Y                  | HO              |                      |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactoid Reaction;                               | Lamictal       |                  |                    | S               | Oral                 | 25 Daily Po          |                 | Not Reported |                |
| Diplopia; Keratopathy;                                | Lexapro        |                  |                    | S               | Oral                 | 5 Daily Po           |                 | Not Reported |                |
| Staphylococcal Infection;                             |                |                  |                    |                 |                      |                      |                 |              |                |
| Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; |                |                  |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vision Blurred

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2006              | 6041679       | EXPEDITED (15-DAY) | Y                  | HO              | S06-GER-01552-01     |                      | 40 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acidosis; Dependence On Respirator; Fatigue; Gastrointestinal Sounds Abnormal; Overdose; Seizure; Suicide Attempt | Ciprallex            |              |            | S           | Oral         | 400 Mg Qd Po       |                 | Not Reported |
|                                                                                                                   | Risperdal            |              |            | S           | Oral         | 45 Mg Qd Po        |                 | Not Reported |
|                                                                                                                   | Cymbalta             |              |            | S           | Oral         | 4800 Mg Qd Po      |                 | Not Reported |
|                                                                                                                   | Trimipramine Maleate |              |            | S           | Oral         | 250 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2006              | 6042920       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-01443-01     |                      | 43 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; Agitation; Amnesia; Anhedonia; Anxiety; Completed Suicide; Gun Shot Wound; Hypoaesthesia; Irritability; Pain; Self-Injurious Ideation; Weight Decreased | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2006              | 6043001       | EXPEDITED (15-DAY) | N                  | HO, OT          | S06-USA-01144-01     |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gait Disturbance; Mental Disorder; Nausea; Tremor | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2006              | 6034912       | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2006046439           |                      | 30 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Accidental Overdose;<br>Alcohol Use; Belligerence;<br>Cardio-Respiratory Arrest;<br>Completed Suicide; Drug<br>Abuser; Hostility;<br>Insomnia; Paranoia | Geodon         |              |            | S           | Oral         | 160 Mg (80 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                         | Lexapro        |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D),          |                 | Not Reported |
|                                                                                                                                                         | Lamictal       |              |            | C           |              |                                   |                 | Not Reported |
|                                                                                                                                                         | Seroquel       |              |            | C           |              |                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2006              | 6043026       | EXPEDITED (15-DAY) | N                  |                 | TPA2006A00679        |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Depression; Drug<br>Ineffective; Feeling Jittery | Rozerem                             |              |            | S           | Oral         | See Image                 |                 | Not Reported |
|                                                  | Lunesta                             |              |            | S           | Oral         | 2 Tab., Qhs, Per Oral     |                 | Not Reported |
|                                                  | Lexapro                             |              |            | S           | Oral         | 10 Mg, 2 In 1 D, Per Oral |                 | Not Reported |
|                                                  | Xanax (Alprazolam) (0.25 Milligram) |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2006              | 6033706       | EXPEDITED (15-DAY) | Y                  | HO              | DE-ABBOTT-06P-062-0331308-00 |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acidosis; Dependence On<br>Respirator; Fatigue;<br>Gastrointestinal Sounds<br>Abnormal; Intentional<br>Overdose; Seizure;<br>Suicide Attempt | Ciprallex            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Risperidone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Cymbalta             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                              | Trimipramine Maleate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2006              | 6045020       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04736-01     |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |                                    |   |      |             |              |
|--------------------------------------------------------------|------------------------------------|---|------|-------------|--------------|
| Asthenia; Cerebrovascular Accident; Dizziness; Hyponatraemia | Lexapro                            | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                              | Glipizide                          | C |      |             | Not Reported |
|                                                              | Avandamet (Rosglitazone/Metformin) | C |      |             | Not Reported |
|                                                              | Lotensin                           | C |      |             | Not Reported |
|                                                              | Mobic                              | C |      |             | Not Reported |
|                                                              | Ativan                             | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2006              | 6045207       | EXPEDITED (15-DAY) |                    | OT              | HQWYE871419APR06     |                      | 60 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Epistaxis; Platelet Aggregation Abnormal; Rectal Haemorrhage; Serum Serotonin Increased | Effexor                   |              |            | S           |              | See Image          | 4 WEEK          | Not Reported |
|                                                                                                           | Escitalopram Oxalate      |              |            | S           |              | See Image          | 1 WEEK          | Not Reported |
|                                                                                                           | Mirtazapine (Mirtazapine) |              |            | S           |              | See Image          | 4 WEEK          | Not Reported |
|                                                                                                           | Omeprazole                |              |            | C           |              | See Image          | 1 WEEK          | Not Reported |
|                                                                                                           | Irbesartan                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2006              | 6045154       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01536-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Serotonin Syndrome | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                      | Tramadol Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2006              | 6045159       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01535-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abscess; Condition Aggravated; Crohn'S Disease | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                | Zyprexa        |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-May-2006                                                                                                                                                                       | 6036061                       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S06-FRA-01366-01     |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Cardiac Arrest;<br>Drug Interaction;<br>Haematemesis;<br>International Normalised<br>Ratio Increased; Intra-<br>Abdominal Haematoma;<br>Peritoneal Haemorrhage;<br>Shock | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                   | Aspirin Lysine                |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                   | Previscan (Fluindione)        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                   | Plavix                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Selokeen                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Digoxine Nativelle (Digoxine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Pravastatin                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Mopral (Omeprazole)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Ikorel (Nicorandil)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Trimetazidine Hydrochloride   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Ramipril                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Unspecified Ingredient        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Acetaminophen                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Eludril                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                   | Fungizone                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2006                                                                                                                                                                       | 6042661                       | DIRECT             | N                  |                 |                      |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain                                                                                                                                                                        | Lexapro                       |                    |                    | S               | Oral                 | 10mg 1 Daily Po      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2006                                                                                                                                                                       | 6043226                       | DIRECT             | N                  | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Bruxism;<br>Depression; Feeling<br>Abnormal; Hyperhidrosis;<br>Hypersomnia; Product                                                                                      | Lexapro                       |                    |                    | S               | Oral                 | 5-10 Mgs Sid Po      |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quality Issue; Thirst;  
Tinnitus; Treatment  
Noncompliance

| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------|-----------------|-----------------|----------------|
| 02-May-2006                                                                                                                                         | 5963238                                  | EXPEDITED (15-DAY) | Y                  | OT              | 2005173641                   |                                 |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Arterial Occlusive Disease; Blood Cholesterol Increased; Chest Pain; Depression; Electrocardiogram Abnormal; Malaise; Pain; Treatment Noncompliance | Celebrex                                 |                    |                    | S               | Oral                         | 200 Mg (200 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |
|                                                                                                                                                     | Lexapro                                  |                    |                    | S               | Unknown                      | Unknown                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-May-2006                                                                                                                                         | 6036031                                  | EXPEDITED (15-DAY) | N                  | HO              | FR-GLAXOSMITHKLINE-B0421412A |                                 | 39 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Abuser                                                                                                                                         | Ventolin                                 |                    |                    | S               | Respiratory (inhalation)     |                                 |                 | Glaxosmithkline |                |
|                                                                                                                                                     | Acetaminophen\Propoxyphene Hydrochloride |                    |                    | S               | Unknown                      |                                 |                 | Unknown         |                |
|                                                                                                                                                     | Oxazepam                                 |                    |                    | S               | Unknown                      |                                 |                 | Unknown         |                |
|                                                                                                                                                     | Risperdal                                |                    |                    | S               | Unknown                      |                                 |                 | Unknown         |                |
|                                                                                                                                                     | Methadone Hydrochloride                  |                    |                    | S               | Unknown                      |                                 |                 | Unknown         |                |
|                                                                                                                                                     | Escitalopram Oxalate                     |                    |                    | S               | Oral                         |                                 |                 | Unknown         |                |
|                                                                                                                                                     | Codeine                                  |                    |                    | C               | Oral                         |                                 |                 | Unknown         |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-May-2006                                                                                                                                         | 6043160                                  | DIRECT             | Y                  | HO              |                              |                                 | 76 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                               |                    |                    |                     |                      |                      |                 |                                              |                |
|----------------------------------------------------------------------|-------------------------------|--------------------|--------------------|---------------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| Fall; Inappropriate<br>Antidiuretic Hormone<br>Secretion             | Lexapro<br>Evista<br>Klonopin | S<br>C<br>C        | Oral               | One Tablet Daily Po |                      |                      |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>     | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-May-2006                                                          | 6046806                       | EXPEDITED (15-DAY) | Y                  | DE                  | S06-USA-01613-01     |                      |                 | Male                                         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>         | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Completed Suicide;<br>Overdose                                       | Lexapro                       |                    |                    | S                   |                      |                      |                 |                                              | Not Reported   |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>     | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 02-May-2006                                                          | 6046815                       | EXPEDITED (15-DAY) | Y                  | OT                  | S06-USA-01612-01     |                      |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>         | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Malaise; Seizure                                                     | Lexapro                       |                    |                    | S                   |                      |                      |                 |                                              | Not Reported   |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>     | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 03-May-2006                                                          | 6047337                       | EXPEDITED (15-DAY) | Y                  | HO                  | S06-USA-01615-01     |                      | 37 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>         | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Gastric Perforation;<br>Haematemesis; Pyrexia;<br>Retching; Vomiting | Lexapro                       |                    |                    | S                   | Oral                 | 10 Mg Qhs Po         |                 |                                              | Not Reported   |
|                                                                      | Lexapro                       |                    |                    | S                   | Oral                 | 10 Mg Qhs Po         |                 |                                              | Not Reported   |
|                                                                      | Lithium                       |                    |                    | C                   |                      |                      |                 |                                              | Not Reported   |
|                                                                      | Trileptal                     |                    |                    | C                   |                      |                      |                 |                                              | Not Reported   |
|                                                                      | Nexium (Esomeprazole)         |                    |                    | C                   |                      |                      |                 |                                              | Not Reported   |
|                                                                      | Tricor                        |                    |                    | C                   |                      |                      |                 |                                              | Not Reported   |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>     | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 04-May-2006                                                          | 6045156                       | EXPEDITED (15-DAY) | Y                  | OT                  | S06-USA-01529-01     |                      | 55 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>         | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Confusional                                                 | Lexapro                       |                    |                    | S                   |                      |                      |                 |                                              | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                               |                        |        |  |  |  |  |  |  |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------|--|--|--|--|--|--|------------------------------|
| State; Depression;<br>Disturbance In Attention;<br>Hallucination, Visual;<br>Hepatic Pain; Influenza<br>Like Illness; Insomnia;<br>Post Procedural<br>Complication; Psoriasis | Pegintron<br>Ribavirin | S<br>S |  |  |  |  |  |  | Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------|--|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2006              | 6047361       | EXPEDITED (15-DAY) | Y                  | HO              | S06-DEN-01310-01     |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Blood Potassium<br>Decreased;<br>Hyponatraemia; Seizure | Ciprallex<br>Salures-K<br>Amlodipine |              |            | S<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2006              | 6047963       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-01637-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|----------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Drug Dependence; Drug<br>Withdrawal Syndrome | Lexapro<br>Lexapro<br>Lexapro |              |            | S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2006              | 6047968       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01639-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| White Blood Cell Count<br>Decreased | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2006              | 6048489       | EXPEDITED (15-DAY) | Y                  | HO              | S06-UKI-01584-01     |                      | 23 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                       |              |   |      |                |              |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------|---|------|----------------|--------------|
| Balance Disorder; Cold Sweat; Confusional State; Coordination Abnormal; Dysarthria; Intentional Overdose; Malaise; Somnolence; Tremor | Ciprallex    | S | Oral | 20 Mg Qd Po    | Not Reported |
|                                                                                                                                       | Ciprallex    | S | Oral | 400 Mg Once Po | Not Reported |
|                                                                                                                                       | Ciprallex    | S |      |                | Not Reported |
|                                                                                                                                       | Risperidone  | S | Oral | 0.5 Mg Bid Po  | Not Reported |
|                                                                                                                                       | Risperidone  | S | Oral | 10 Mg Once Po  | Not Reported |
|                                                                                                                                       | Risperidone  | S |      |                | Not Reported |
|                                                                                                                                       | Lansoprazole | C |      |                | Not Reported |
|                                                                                                                                       | Zopiclone    | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2006              | 5951255       | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-05128-01     |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Decreased; Blood Potassium Increased; Blood Sodium Increased; Blood Urea Increased; Carbon Dioxide Abnormal; Completed Suicide; Drug Level Increased; Ovarian Cyst | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                  | Lamictal       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Topamax        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Vitamin K      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2006              | 6062460       | DIRECT           | N                  | DE              |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-May-2006              | 7385666       | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-06P-163-0331919-00 |                      | 72 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 08-May-2006                                                                                                                                     | 5992741           | EXPEDITED (15-DAY) | Y                  | HO, RI          | S06-USA-00451-01     |                         | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchial Hyperreactivity;<br>Maternal Exposure During<br>Pregnancy; Pneumonia;<br>Pre-Eclampsia;<br>Pregnancy; Premature<br>Labour             | Lexapro           |                    |                    | S               | Oral                 | 30 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                 | Hydroxyzine       |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2006                                                                                                                                     | 5992929           | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00451-02     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotonia Neonatal;<br>Maternal Exposure During<br>Pregnancy; Premature<br>Baby; Resuscitation                                                  | Lexapro           |                    |                    | S               | Transplacental       | 30 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                 | Magnesium Sulfate |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                 | Hydroxyzine       |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                 | Rocephin          |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2006                                                                                                                                     | 6001861           | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-01297-01     |                         | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Hypotonia<br>Neonatal; Maternal<br>Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Somnolence<br>Neonatal; Treatment<br>Noncompliance | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                 | Prenatal Vitamins |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2006                                                                                                                                     | 6007635           | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00588-01     |                         |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Headache;<br>Hyperaesthesia; Insomnia;<br>Irritability; Lethargy;<br>Muscle Tightness;<br>Nausea; Pain;<br>Photophobia;<br>Restlessness | Lexapro                            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                                                                                                                                                    | Lexapro                            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                    | Loratadine\Pseudoephedrine Sulfate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2006              | 6049688       | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-01754-01     |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Change;<br>Electrocardiogram Qt Prolonged | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2006              | 6005525       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-00636-01     |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haemorrhage; Injury Corneal | Lexapro                |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                  | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2006              | 6039199       | EXPEDITED (15-DAY) | Y                  | HO              | PHEH2006US05418      |                      | 91 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                         | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------|------------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;                           | Stalevo                                                          |                    |                    | S               | Oral                     | 150 Mg, Qd           |                 | Orion        |                |
| Depressed Level Of Consciousness;             | Lexapro                                                          |                    |                    | S               |                          | 10 Mg, Qd            |                 | Not Reported |                |
| Hallucination; Product Administration Error;  | Lexapro                                                          |                    |                    | S               |                          | 5 Mg, Qd             |                 | Not Reported |                |
| Sedation; Somnolence;                         | Aricept                                                          |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Unresponsive To Stimuli                       | Zyprexa                                                          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | Oxybutynin                                                       |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2006                                   | 6041069                                                          | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20060500545    |                      | 39 YR           | Female       | FRA            |
| <u>Preferred Term</u>                         | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuser                                   | Risperdal                                                        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                               | Acetaminophen\Propoxyphene Hydrochloride                         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                               | Acetaminophen\Propoxyphene Hydrochloride                         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                               | Oxazepam                                                         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | Ventolin                                                         |                    |                    | S               | Respiratory (inhalation) |                      |                 | Not Reported |                |
|                                               | Methadone Hydrochloride                                          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | Escitalopram Oxalate                                             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2006                                   | 6627381                                                          | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01752-01         |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                         | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchial Obstruction;                        | Escitalopram Oxalate                                             |                    |                    | S               | Oral                     | 1 Units Qd Po        |                 | Not Reported |                |
| Lactic Acidosis; Oxygen Saturation Decreased; | Acetaminophen                                                    |                    |                    | S               | Oral                     | 500 Mg Qd Po         |                 | Not Reported |                |
| Respiratory Distress                          | Acetaminophen\Biclotymol\Chlorpheniramine\Eucalyptol\Guaifenesin |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | Ramipril                                                         |                    |                    | S               | Oral                     | 5 Mg Qd Po           |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                                                                                     |                    |                    |                 |                                 |                      |                 |                 |                |
|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|-----------------|----------------|
| Metformin Hydrochloride                                                        |                                                                                     |                    | S                  | Oral            | 850 Mg Tid Po                   |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-May-2006                                                                    | 6042656                                                                             | EXPEDITED (15-DAY) | Y                  | HO              | US-KINGPHARMUSA00001-K200600550 |                      | 78 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Lactic Acidosis                                                                | Altace                                                                              |                    |                    | S               | Oral                            | 5 Mg, Qd             |                 | King            |                |
|                                                                                | Dafalgan                                                                            |                    |                    | S               | Oral                            | 500 Mg, Qd           |                 | Not Reported    |                |
|                                                                                | Escitalopram Oxalate                                                                |                    |                    | S               | Oral                            | 1 U, Qd              |                 | Not Reported    |                |
|                                                                                | Acetaminophen\Chlorpheniramine Maleate\Guaifenesin\Phenylephrine Metformine "Merck" |                    |                    | S               | Oral                            | 850 Mg, Tid          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-May-2006                                                                    | 6043404                                                                             | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0604964A    |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Event; Anger; Bipolar Disorder; Euphoric Mood; Feeling Abnormal; Mania | Wellbutrin                                                                          |                    |                    | S               | Oral                            |                      |                 | Glaxosmithkline |                |
|                                                                                | Lexapro                                                                             |                    |                    | S               | Oral                            |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 12-May-2006                                                                    | 5795994                                                                             | NON-EXPEDITED      | N                  |                 | S05-USA-02246-01                |                      | 27 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Screen False Positive                                                     | Relafen                                                                             |                    |                    | S               | Oral                            | 750mg Twice Per Day  |                 | Glaxosmithkline |                |
|                                                                                | Lexapro                                                                             |                    |                    | S               | Oral                            | 20mg Per Day         |                 | Not Reported    |                |
|                                                                                | Cyproheptadine Hydrochloride                                                        |                    |                    | C               | Unknown                         | 4mg Per Day          |                 | Not Reported    |                |
|                                                                                | Claritin                                                                            |                    |                    | C               | Unknown                         | 10mg Per Day         |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |             |   |         |               |  |              |
|--|-------------|---|---------|---------------|--|--------------|
|  | Hydroxyzine | C | Unknown |               |  | Not Reported |
|  | Inderal     | C | Unknown | 160mg Per Day |  | Not Reported |
|  | Doxycycline | C | Unknown |               |  | Not Reported |
|  | Melatonin   | C | Unknown | 3mg Per Day   |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2006              | 5959449       | EXPEDITED (15-DAY) | Y                  | LT              | S05-PRT-05742-01     |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Eyelid Oedema; Metabolic Acidosis; Respiratory Distress; Somnolence | Ciprallex               |              |            | S           |              |                    |                 | Not Reported |
|                                                                                          | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                          | Lorazepam               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                          | Triazolam               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                          | Oxazepam                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                          | Zyprexa                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2006              | 6045015       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01530-01     |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract; Eye Disorder; Somnolence | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2006              | 6050992       | DIRECT           | Y                  |                 |                      |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Nausea; Palpitations | Lexapro        |              |            | S           | Oral         | One Daily 10mg P.O |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2006              | 6053368       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01593-01     |                      | 73 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                        |   |      |               |              |
|--------------------------|------------------------|---|------|---------------|--------------|
| Dehydration; Diarrhoea;  | Escitalopram Oxalate   | S | Oral | 20 Mg Qd Po   | Not Reported |
| Hypokalaemia;            | Perindopril Erbumine   | S | Oral | 4 Mg Qd Po    | Not Reported |
| Hyponatraemia; Malaise;  | Inexium (Esomeprazole) | S | Oral | 20 Mg Qd Po   | Not Reported |
| Orthostatic Hypotension; | Clamoxyl (Amoxicillin) | S | Oral | 2 Units Qd Po | Not Reported |
| Vomiting                 | Vastarel               | C |      |               | Not Reported |
|                          | Inexium (Esomeprazole) | C |      |               | Not Reported |
|                          | Zolpidem Tartrate      | C |      |               | Not Reported |
|                          | Carvedilol             | C |      |               | Not Reported |
|                          | Pravastatin            | C |      |               | Not Reported |
|                          | Duphalac               | C |      |               | Not Reported |
|                          | Aspirin Lysine         | C |      |               | Not Reported |
|                          | Risperdal              | C |      |               | Not Reported |
|                          | Mopral (Omeprazole)    | C |      |               | Not Reported |
|                          | Pevaryl                | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2006              | 4103820       | EXPEDITED (15-DAY) | Y                  | DE              | S04-USA-00729-01     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Completed       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Suicide; Condition       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Aggravated; Depression;  | Protonix       |              |            | C           |              |                    |                 | Not Reported |
| Dizziness; Fatigue;      | Elavil         |              |            | C           |              |                    |                 | Not Reported |
| Gastrooesophageal Reflux | Paxil          |              |            | C           |              |                    |                 | Not Reported |
| Disease; Gun Shot        |                |              |            |             |              |                    |                 |              |
| Wound; Insomnia          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2006              | 5871570       | EXPEDITED (15-DAY) | Y                  | HO, OT          | T05-JPN-03077-01     |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Depression;     | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Disease Recurrence; Drug | Luvox                |              |            | S           | Oral         | 50 Mg Qd Po        |                 | Not Reported |
| Withdrawal Syndrome;     | Luvox                |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
| Electroencephalogram     | Lorazepam            |              |            | C           |              |                    |                 | Not Reported |
| Abnormal;                |                      |              |            |             |              |                    |                 |              |
| Hyperventilation;        |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Insomnia; Intentional  
Overdose; Intentional Self-  
Injury; Joint Injury; Loss Of  
Consciousness;  
Nasopharyngitis; Pruritus  
Generalised; Rash  
Generalised

| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-May-2006                                       | 6027752                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-NLD-01246-01     |                      | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Work Ability;<br>Nephrolithiasis; Pain   | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2006                                       | 6047608                  | EXPEDITED (15-DAY) | Y                  | HO              | L06-TUR-01591-01     |                      | 38 YR           | Male         | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Parkinsonism                           | Cipralext                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Sertraline Hydrochloride |                    |                    | S               |                      | 50 Mg Qd             |                 | Not Reported |                |
|                                                   | Tianeptine               |                    |                    | S               | Oral                 | 12.5 Mg Tid Po       |                 | Not Reported |                |
|                                                   | Tianeptine               |                    |                    | S               |                      | 12.5 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2006                                       | 6080216                  | NON-EXPEDITED      | N                  |                 | S06-USA-01466-01     |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Diarrhoea; Nausea;<br>Vomiting | Namenda                  |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                   | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Zocor                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                   | Levoxyl                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                   | Lanoxin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                   | K-Dur                    |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |              |
|----------|---|--------------|
| Coreg    | C | Not Reported |
| Vicodin  | C | Not Reported |
| Prevacid | C | Not Reported |
| Lasix    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2006              | 6081038       | NON-EXPEDITED    | N                  |                 | S06-USA-00697-01     |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nausea                | Namenda                         |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                       | Namenda                         |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lexapro                         |              |            | S           |              |                    |                 | Not Reported |
|                       | Xanax                           |              |            | C           |              |                    |                 | Not Reported |
|                       | Elavil                          |              |            | C           |              |                    |                 | Not Reported |
|                       | Vistaril (Hydroxyzine Embonate) |              |            | C           |              |                    |                 | Not Reported |
|                       | Premarin                        |              |            | C           |              |                    |                 | Not Reported |
|                       | Synthroid                       |              |            | C           |              |                    |                 | Not Reported |
|                       | Prevacid                        |              |            | C           |              |                    |                 | Not Reported |
|                       | Atenolol                        |              |            | C           |              |                    |                 | Not Reported |
|                       | Reglan                          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-May-2006              | 7385667       | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-06P-163-0332658-00 |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;   | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Nausea; Suicide Attempt | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2006              | 6019106       | EXPEDITED (15-DAY) | Y                  | HO, RI          | S06-USA-01099-01     |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Priapism              | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 16-May-2006                                                                                                                                                                                                                                                                                                 | 6046540              | EXPEDITED (15-DAY) | Y                  | HO              | GB-JNJFOC-20060502055 |                      | 23 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Cold Sweat; Confusional State; Coordination Abnormal; Dysarthria; Malaise; Overdose; Overdose; Somnolence; Tremor                                                                                                                                                                         | Risperidone          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Risperidone          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Zopiclone            |                    |                    | S               |                       | As Necessary         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Lansoprazole         |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2006                                                                                                                                                                                                                                                                                                 | 6047073              | EXPEDITED (15-DAY) | Y                  | DE, HO          | S06-FRA-01387-01      |                      | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Blood Creatine Phosphokinase Increased; Cardio-Respiratory Arrest; Chills; Delusion; Feeling Hot; Human Chorionic Gonadotropin Positive; Lactic Acidosis; Malaise; Maternal Exposure During Pregnancy; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Retained Placenta Or Membranes; Sepsis | Escitalopram Oxalate |                    |                    | S               | Oral                  | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Tiaprider            |                    |                    | S               | Oral                  | 100 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Aripiprazole         |                    |                    | S               | Oral                  | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Cytotec              |                    |                    | S               |                       | 400 Mcg Bid          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Mifepristone         |                    |                    | S               | Oral                  | 600 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Prazepam             |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                             | Imovane (Zopiclone)  |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2006                                                                                                                                                                                                                                                                                                 | 6054211              | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01729-01      |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                          |         |   |      |              |              |
|----------------------------------------------------------------------------------------------------------|---------|---|------|--------------|--------------|
| Attention<br>Deficit/Hyperactivity<br>Disorder; Bipolar Disorder;<br>Skin Laceration; Suicide<br>Attempt | Lexapro | S | Oral | 10 Mg Bid Po | Not Reported |
|----------------------------------------------------------------------------------------------------------|---------|---|------|--------------|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-May-2006                       | 6054219                | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-01817-01              |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Tardive Dyskinesia             | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Once Po               |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2006                       | 5980478                | EXPEDITED (15-DAY)        | Y                           | HO                       | US016653                      |                               | 42 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Acne; Drug Ineffective;                                    | Provigil                |                       |                     | S                    | Oral                  | 100 Mg Qd Oral              |                          | Not Reported        |
| Feeling Abnormal;                                          | Risperdal               |                       |                     | S                    |                       |                             |                          | Not Reported        |
| Stevens-Johnson<br>Syndrome; Toxic<br>Epidermal Necrolysis | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-May-2006                       | 6055366                | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-01830-01              |                               | 18 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                | Neurontin               |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Ritalin                 |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-May-2006                       | 6015379                | EXPEDITED (15-DAY)        | Y                           | HO                       | T06-IND-01018-01              |                               | 37 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |                                             |   |      |                |              |
|------------------------------------------------|---------------------------------------------|---|------|----------------|--------------|
| Akathisia; Decreased<br>Appetite; Restlessness | Cipralext                                   | S | Oral | 10 Mg Daily Po | Not Reported |
|                                                | Cipralext                                   | S | Oral | 20 Mg Qd Po    | Not Reported |
|                                                | Larpose (Lorazepam)                         | C |      |                | Not Reported |
|                                                | Vinturin                                    | C |      |                | Not Reported |
|                                                | Haloperidol Decanoate                       | C |      |                | Not Reported |
|                                                | Sizodon                                     | C |      |                | Not Reported |
|                                                | Becosules                                   | C |      |                | Not Reported |
|                                                | Topaz                                       | C |      |                | Not Reported |
|                                                | Qutipin                                     | C |      |                | Not Reported |
|                                                | Pacitane (Trihexyphenidyl<br>Hydrochloride) | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2006              | 6082046       | NON-EXPEDITED    | N                  | OT              | 2005092466           |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Conversion Disorder;<br>Headache; Osteoporosis | Depo-Provera   |              |            | S           | Intramuscular | See Image          |                 | Not Reported |
|                                                |                |              |            |             | Intramuscular | See Image          |                 |              |
|                                                |                |              |            |             | Intramuscular | See Image          |                 |              |
|                                                | Lexapro        |              |            | S           |               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2006              | 6076132       | NON-EXPEDITED    | N                  | HO              | ZONI002161           |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Ankle Fracture; Fall;<br>Hypersensitivity; Rash | Zonegran       |              |            | S           | Oral         | Oral                  |                 | Not Reported |
|                                                 | Lexapro        |              |            | S           | Oral         | 40 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                 | Morphine       |              |            | S           |              |                       |                 | Not Reported |
|                                                 | Bextra         |              |            | S           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 22-May-2006              | 5923798       | EXPEDITED (15-DAY) | Y                  | DE              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13171186 |                      | 54 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                                 |   |      |              |
|-------------------------|---------------------------------|---|------|--------------|
| Completed Suicide; Pain | Abilify                         | S | Oral | Not Reported |
|                         | Escitalopram Oxalate            | S | Oral | Not Reported |
|                         | Levomepromazine                 | C | Oral | Not Reported |
|                         | Oxazepam                        | C | Oral | Not Reported |
|                         | Oxazepam                        | C | Oral | Not Reported |
|                         | Meprobamate                     | C | Oral | Not Reported |
|                         | Acetaminophen\Codeine Phosphate | C | Oral | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2006                                                                                                                                                   | 6057238                | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01876-01     |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Condition Aggravated; Depression; Frustration Tolerance Decreased; Intentional Self-Injury; Irritability; Nervousness; Self-Injurious Ideation; Tremor | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Lexapro                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Unspecified Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Trileptal              |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2006                                            | 6057245        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01891-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Breast Feeding; Polycythaemia | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-May-2006              | 6057544        | EXPEDITED (15-DAY) | Y                  | DE, LT          | 2006063621           |                      | 26 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                      |   |         |                                      |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|---------|--------------------------------------|--------------|
| Accident; Anoxia; Back Pain; Blood Creatine Phosphokinase Increased; Cardiac Failure; Cardiac Procedure Complication; Cardio-Respiratory Arrest; Chills; Cyanosis; Delirium; Dyspnoea; Feeling Cold; Feeling Hot; Human Chorionic Gonadotropin Positive; Lactic Acidosis; Malaise; Maternal Exposure During Pregnancy; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Necrotising Colitis; Obstetric Procedure Complication; Pallor; Pyrexia; Retained Placenta Or Membranes; Rhabdomyolysis; Seizure; Troponin Increased | Cytotec              | S | Vaginal | 800 Mcg (200 Mcg, 2 In 2 D), Vaginal | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Tiaprider            | S | Oral    | 100 Mg (100 Mg, 1 In 1 D), Oral      | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Escitalopram Oxalate | S | Oral    | 15 Mg (15 Mg, 1 In 1 D), Oral        | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Abilify              | S | Oral    | 15 Mg (15 Mg, 1 In 1 D), Oral        | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prazepam             | C |         |                                      | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Imovane (Zopiclone)  | C |         |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2006              | 6050289       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01684-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperkalaemia         | Lexapro                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Multiple Medications (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2006              | 6056083       | DIRECT           | Y                  | DE              |                      |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alcohol Use; Completed Suicide | Lexapro        |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-May-2006                                                                                           | 6058883                | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-01894-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Bipolar Disorder;<br>Euphoric Mood; Feeling<br>Abnormal; Incorrect Dose<br>Administered; Mania | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                       | Wellbutrin XI          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Wellbutrin XI          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2006                                                                                           | 6032141                | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-01324-01     |                      | 17 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Olfactory                                                                              | Cipralext              |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                       | Cipralext              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2006                                                                                           | 6044105                | EXPEDITED (15-DAY) |                    | HO              | 2006-141460-NL       |                      | 31 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Ectopic Pregnancy;<br>Maternal Exposure During<br>Pregnancy                  | Mirtazapine            |                    |                    | S               | Oral                 | 15 Mg/Df             |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate   |                    |                    | S               |                      | Df/20 Mg             |                 | Not Reported |                |
|                                                                                                       | Terbutaline Sulfate    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Budesonide             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Fluticasone Propionate |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                       | Clemastine Fumarate    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2006                                                                                           | 6058109                | DIRECT             | N                  | DE              |                      |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                            |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|----------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Completed Suicide; Ill-Defined Disorder; Nervousness                       |                         | Lexapro                   | S                           |                          | 10 Mg Tablet 1 A Day          |                               |                             | Not Reported             |                         |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 25-May-2006                                                                | 6058900                 | DIRECT                    | Y                           | OT                       |                               |                               | 19 YR                       | Male                     | USA                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Computerised Tomogram Abnormal; Generalised Tonic-Clonic Seizure           | Lexapro                 |                           |                             |                          | S                             | Oral                          | One Daily Po                |                          | Not Reported            |
|                                                                            | Lexapro                 |                           |                             |                          | S                             | Oral                          | One Daily Po                |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 26-May-2006                                                                | 6059155                 | EXPEDITED (15-DAY)        | Y                           | HO                       | ENTC2006-0132                 |                               | 91 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Hallucination, Visual; Loss Of Consciousness; Obsessive Thoughts; Sedation | Stalevo                 |                           |                             |                          | S                             | Oral                          | 600 Mg, 4 In 1 D, Oral      |                          | Not Reported            |
|                                                                            | Lexapro                 |                           |                             |                          | S                             |                               | 50 Mg, 1 In 1 D,            |                          | Not Reported            |
|                                                                            | Zyprexa                 |                           |                             |                          | S                             |                               |                             |                          | Not Reported            |
|                                                                            | Aricept                 |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-May-2006                                                                | 5992727                 | NON-EXPEDITED             | N                           |                          | US-GLAXOSMITHKLINE-A0587079A  |                               | 44 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Constipation; Drug Ineffective; Fatigue; Medication Error; Somnolence      | Wellbutrin XI           |                           |                             |                          | S                             | Oral                          | 150mg Per Day               | 4 MTH                    | Glaxosmithkline         |
|                                                                            | Lexapro                 |                           |                             |                          | S                             | Oral                          |                             |                          | Not Reported            |
|                                                                            | Valtrex                 |                           |                             |                          | C                             |                               |                             |                          | Glaxosmithkline         |
|                                                                            | Nordette                |                           |                             |                          | C                             |                               |                             |                          | Not Reported            |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-May-2006                                                                | 6054468                 | NON-EXPEDITED             | Y                           | OT                       | US-GLAXOSMITHKLINE-A0597343A  |                               | 65 YR                       | Male                     | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Irritability; Suicidal Ideation; Tremor            | Wellbutrin XI  |                    |                    | S               | Oral                 | 150mg Per Day        |                 | Glaxosmithkline |                |
|                                                    | Lexapro        |                    |                    | S               | Oral                 | 10mg Per Day         |                 | Not Reported    |                |
|                                                    | Flomax         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Glipizide      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Metformin      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Lipitor        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Tricor         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Oxaprozin      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                    | Cialis         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| Aspirin                                            |                |                    | C                  |                 |                      |                      | Glaxosmithkline |                 |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-May-2006                                        | 6054850        | EXPEDITED (15-DAY) | N                  | OT              | US017195             |                      | 19 YR           | Male            | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Depressed Level Of Consciousness; Drug Interaction | Wellbutrin XI  |                    |                    | S               | Oral                 | 300mg Per Day        |                 | Glaxosmithkline |                |
|                                                    | Provigil       |                    |                    | S               | Oral                 | 200mg Per Day        |                 | Not Reported    |                |
|                                                    | Lexapro        |                    |                    | S               | Oral                 | 10mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-May-2006                                        | 6063555        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01929-01     |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coagulopathy                                       | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                    | Multi-Vitamin  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-May-2006                                        | 6053109        | EXPEDITED (15-DAY) | Y                  | DE              | S06-NLD-01788-01     |                      | 55 YR           | Male            | NLD            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Behaviour; Anger; Completed Suicide;      | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Indifference                           | Zyprexa                                                                                              |                    | S                  | Oral            | 5 Mg Qd Po           |                                 | Not Reported    |              |                |
|----------------------------------------|------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
|                                        | Xanax                                                                                                |                    | C                  |                 |                      |                                 | Not Reported    |              |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2006                            | 6065367                                                                                              | EXPEDITED (15-DAY) | Y                  | HO              | S06-UKI-01998-01     |                                 | 88 YR           | Male         | GBR            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Urinary Tract Infection | Ciprallex                                                                                            |                    |                    | S               | Oral                 | 10 Mg Qd Po                     |                 | Not Reported |                |
|                                        | Amitriptyline                                                                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Calfovit D3                                                                                          |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Codeine Phosphate                                                                                    |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Docusate                                                                                             |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Ferrous Sulfate                                                                                      |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Ranitidine                                                                                           |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Risedronate Sodium                                                                                   |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Temazepam                                                                                            |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2006                            | 6083167                                                                                              | NON-EXPEDITED      | N                  | OT              | 2005098254           |                                 | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                         | Colestipol Hydrochloride                                                                             |                    |                    | S               | Oral                 | 2 Gram (1 Gram, 2 In 1 D), Oral |                 | Not Reported |                |
|                                        | Lexapro                                                                                              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                        | Nortriptyline Hydrochloride                                                                          |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Hydrochlorothiazide/Triamterene (Hydrochlorothiazide, Triamterene)                                   |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Norvasc                                                                                              |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                        | Centrum Silver (Ascorbic Acid, Calcium, Minerals Nos, Retinol, Tocopheryl Acetate, Vitamin B Nos...) |                    |                    | C               |                      |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Jun-2006                                                 | 6044528              | EXPEDITED (15-DAY) | Y                  | HO              | 2006CG00789          |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health<br>Deterioration;<br>Rhabdomyolysis | Omeprazole           |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                             | Cyamemazine          |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                             | Zopiclone            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Zyprexa              |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                             | Tareg                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                             | Pinaverium Bromide   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Esberiven            |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2006                                                 | 6063902              | DIRECT             | Y                  | OT              |                      |                      | 87 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Head Titubation; Tremor                                     | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qam Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2006                                                 | 6089915              | NON-EXPEDITED      | N                  |                 | 2006PV007552         |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Hunger;<br>Insomnia                       | Byetta               |                    |                    | S               | Subcutaneous         | 5 Mcg;Bid;Sc         |                 | Not Reported |                |
|                                                             | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2006                                                 | 7136028              | NON-EXPEDITED      | Y                  |                 | US200603006324       |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                   |           |   |           |       |              |
|---------------------------------------------------------------------------------------------------|-----------|---|-----------|-------|--------------|
| Abdominal Pain; Blood Glucose Decreased; Blood Glucose Increased; Gastroesophageal Reflux Disease | Cymbalta  | S | See Image | 3 DAY | Not Reported |
|                                                                                                   | Lexapro   | S | See Image | 3 DAY | Not Reported |
|                                                                                                   | Strattera | C | See Image | 3 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2006              | 6066451       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02019-01     |                      | 29 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; Abdominal Distension; Hepatic Steatosis; Weight Increased | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Inderal La     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2006              | 6066794       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-02031-01     |                      | 70 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2006              | 6067392       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-ITA-02163-01     |                      | 55 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine Phosphokinase Abnormal; Condition Aggravated; Discomfort; Job Dissatisfaction; Loss Of Consciousness; Muscle Spasms; Neuralgia | Ciprallex      |              |            | S           | Oral         | 10 Mg Qod Po       |                 | Not Reported |
|                                                                                                                                               | Diazepam       |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|----------------------|----------------|
| 06-Jun-2006                                                                                                                                                                                                                                            | 5845453                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13044078 |                                                                                                                 | 55 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>           |                |
| Constipation; Diarrhoea;<br>Dyspnoea; Fatigue;<br>Pulmonary Embolism                                                                                                                                                                                   | Cetuximab                  |                    |                    | S               | Intravenous (not<br>otherwise specified)        | Init Tx:02-Jun-05 400<br>Mg/M2/Act Dose:800 Mg.<br>Actual Dose This Inf:<br>500mg/Tot This Course =<br>1500 Mg. |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Cisplatin                  |                    |                    | S               | Intravenous (not<br>otherwise specified)        | Initiated 02-June-2005 60<br>Mg/Reduced To Level 1<br>Due To Fatigue/50 Mg 23-<br>Jun & 30 Jun.                 |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                                                                                        | Effexor                    |                    |                    | S               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Lexapro                    |                    |                    | S               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Prevacid                   |                    |                    | S               |                                                 |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Propoxyphene Hydrochloride |                    |                    | S               |                                                 |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Xanax                      |                    |                    | S               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Klonopin                   |                    |                    | C               |                                                 |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Wellbutrin                 |                    |                    | C               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Jun-2006                                                                                                                                                                                                                                            | 6020029                    | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01100-01                                |                                                                                                                 | 41 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Disorder; Cardio-<br>Respiratory Arrest;<br>Conversion Disorder;<br>Crying; Gastric Disorder;<br>Heart Rate Decreased;<br>Heart Rate Increased;<br>Heart Rate Irregular;<br>Insomnia; Muscle<br>Spasms; Myocardial<br>Infarction; Nervousness; | Lexapro                    |                    |                    | S               | Oral                                            | 10 Mg Qd Po                                                                                                     |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Lexapro                    |                    |                    | S               | Oral                                            | 20 Mg Qd Po                                                                                                     |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Protonix                   |                    |                    | C               |                                                 |                                                                                                                 |                 | Not Reported         |                |
|                                                                                                                                                                                                                                                        | Lorazepam                  |                    |                    | C               |                                                 |                                                                                                                 |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Procedural Complication;  
Seizure; Thrombosis

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2006              | 6037222       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01441-01     |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Face Injury; Fall; Heart Rate Decreased; Hypotension; Loss Of Consciousness; Tooth Fracture; Tooth Injury | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                           | Prozac         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2006              | 6068746       | EXPEDITED (15-DAY) | Y                  | HO, OT          | HQWYE547725MAY06     |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Asthenia; Blood Catecholamines Increased; Chest Pain; Drug Interaction; Drug Intolerance; Lethargy; Pallor; Pharyngeal Erythema; Serotonin Syndrome | Effexor Xr                |              |            | S           |              | See Image                            | 2 DAY           | Not Reported |
|                                                                                                                                                     |                           |              |            |             |              | See Image                            | 1 DAY           |              |
|                                                                                                                                                     |                           |              |            |             |              | See Image                            | 4 DAY           |              |
|                                                                                                                                                     | Escitalopram Oxalate      |              |            | S           |              | 10 Mg 1x Per 1 Day                   | 2 DAY           | Not Reported |
|                                                                                                                                                     | Methylphenidate           |              |            | S           |              | 10 Mg (2 Doses), Given 3 Hours Apart |                 | Not Reported |
|                                                                                                                                                     | Mirtazapine (Mirtazapine) |              |            | S           |              | 15 Mg 1x Per 1 Day                   | 3 DAY           | Not Reported |
|                                                                                                                                                     | Trazodone Hydrochloride   |              |            | S           |              | 100 Mg 1x Per 1 Day                  | 6 DAY           | Not Reported |
|                                                                                                                                                     | Lamotrigine               |              |            | C           |              |                                      |                 | Not Reported |
|                                                                                                                                                     | Gabapentin                |              |            | C           |              |                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2006              | 5993296       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00351-01     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Albumin Decreased; Blood Alkaline | Lexapro        |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
|                                         | Provigil       |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                        |           |   |  |  |  |  |  |              |
|------------------------------------------------------------------------------------------------------------------------|-----------|---|--|--|--|--|--|--------------|
| Phosphatase Decreased;<br>Hypophagia; Scab;<br>Somnolence; Stevens-<br>Johnson Syndrome; Toxic<br>Epidermal Necrolysis | Risperdal | S |  |  |  |  |  | Not Reported |
|------------------------------------------------------------------------------------------------------------------------|-----------|---|--|--|--|--|--|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Jun-2006                       | 6014950                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-FRA-01011-01              |                               | 45 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Food Allergy                      | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Lexomil (Bromazepam)    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Zolpidem Tartrate       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jun-2006                              | 5919693                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-FRA-03870-01              |                               | 37 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Psychomotor<br>Hyperactivity | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                          | Stresam (Etifoxine)     |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jun-2006                                                                                  | 5981743                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | US-JNJFOC-<br>20060200563     |                               | 42 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal;<br>Somnolence; Stevens-<br>Johnson Syndrome; Toxic<br>Epidermal Necrolysis | Risperdal               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                              | Provigil                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                              | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jun-2006                       | 6004068                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-FRA-00802-01              |                               | 68 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                |                                                                                       |                  |      |             |                                                              |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|
| Drug Interaction;<br>Epistaxis; International<br>Normalised Ratio<br>Increased; Prothrombin<br>Level Decreased | Escitalopram Oxalate<br>Previscan (Fluindione)<br>Xanax<br>Aceprometazine\Meprobamate | S<br>S<br>C<br>C | Oral | 20 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2006              | 6070589       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-02170-01     |                      | 50 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Blood Osmolarity<br>Decreased; Cerebral<br>Atrophy; Epilepsy;<br>Hypokalaemia;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion; Loss<br>Of Consciousness;<br>Seizure | Escitalopram Oxalate<br>Equanil<br>Haldol<br>Aceprometazine\Meprobamate |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2006              | 5928950       | EXPEDITED (15-DAY) | Y                  | HO              | S05-ISL-04800-01     |                      | 17 YR      | Male       | ISL            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Psychosis;<br>Delusional Disorder,<br>Unspecified Type;<br>Paranoia | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2006              | 6035673       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-01437-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|----------------------------------------------|
| Adrenal Disorder;<br>Amnesia; Arthralgia; Blood<br>Glucose Decreased;<br>Chest Pain; Disturbance In | Lexapro<br>Lexapro<br>Trileptal |              |            | S<br>S<br>S | Oral         | 20 Mg Qd Po<br>450 Mg Qd |                 | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |                      |        |                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------|------------------------------|
| Attention; Drug Interaction;<br>Fatigue; Feeling Cold;<br>Intervertebral Disc<br>Protrusion; Laboratory<br>Test Abnormal; Road<br>Traffic Accident | Flexeril<br>Ultracet | S<br>S | Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2006              | 6051622       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-01783-01     |                      | 39 YR      | Female     | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Drug Abuser;<br>Intentional Overdose | Escitalopram Oxalate               |              |            | S           | Oral         | 100 Mg Once Po     |                 | Not Reported |
|                                                   | Acetaminophen\Codeine<br>Phosphate |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Oxazepam                           |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Ventolin                           |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Risperdal                          |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Methadone Hydrochloride            |              |            | S           |              |                    |                 | Not Reported |
|                                                   | Codeine                            |              |            | S           |              | 2 Tablet Qd        |                 | Not Reported |
|                                                   | Alcohol                            |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2006              | 6061824       | EXPEDITED (15-DAY) | N                  | OT              | 2006UW11450          |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Heart<br>Rate Decreased | Toprol XL      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jun-2006              | 6045005       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01516-02     |                      | 1 DAY      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Insomnia; Maternal    | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                     |         |   |              |
|-------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|
| Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Restlessness; Screaming | Lexapro | S | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jun-2006              | 6064540       | EXPEDITED (15-DAY) | Y                  | DE              | T06-CAN-02004-01     |                      | 22 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jun-2006              | 6071373       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02149-01     |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ejaculation Failure; Progressive Multiple Sclerosis; Sexual Dysfunction | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                         | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                         | Rebif          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jun-2006              | 6064031       | EXPEDITED (15-DAY) | Y                  | HO              | 2006UW11453          |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Decreased; Anxiety; Blood Urea Nitrogen/Creatinine Ratio Decreased; Depression; Drug Interaction; Family Stress; Homicidal Ideation; Insomnia; Suicidal Behaviour; Suicidal | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                                                                                                                      | Zonegran       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                      | Zonegran       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                      | Wellbutrin XL  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                      | Lexapro        |              |            | S           | Oral         |                    | 186 DAY         | Not Reported |
|                                                                                                                                                                                                      | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                      | Marijuana      |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Ideation; Tearfulness;  
Weight Decreased

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2006              | 6074788        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02236-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiomegaly             | Campral        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Klonopin       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2006                                             | 6075010        | EXPEDITED (15-DAY) | Y                  | OT              | S06-ITA-02360-01     |                      | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion; Maternal Exposure During Pregnancy; Pregnancy | Ciprallex      |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jun-2006                                              | 6075011                         | EXPEDITED (15-DAY) | Y                  | HO, OT          | L06-IND-02195-01     |                      |                 | Female       | IND            |
| <u>Preferred Term</u>                                    | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Insomnia; Restlessness; Therapy Non-Responder | Escitalopram Oxalate            |                    |                    | S               |                      | 20 Mg Qd             |                 | Not Reported |                |
|                                                          | Olanzapine                      |                    |                    | S               |                      | 7.5 Mg Qd            |                 | Not Reported |                |
|                                                          | Lamotrigine                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Thyroxin (Levothyroxine Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 16-Jun-2006              | 5989406        | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00349-01     |                      | 77 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                |                        |   |      |             |              |
|------------------------------------------------------------------------------------------------|------------------------|---|------|-------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Jaundice Cholestatic | Lexapro                | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                | Unspecified Ingredient | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2006              | 6076275       | EXPEDITED (15-DAY) | Y                  | OT              | T06-USA-02371-01     |                      | 13 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Alcohol Poisoning; Crying; Intentional Self-Injury; Malaise; Suicidal Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |
|                                                                                            | Lexapro              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Lexapro              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Placebo              |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2006              | 5999439       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00458-01     |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood Cholesterol Increased; Blood Triglycerides Increased; Bronchoscopy Abnormal; Chest X-Ray Abnormal; Condition Aggravated; Fatigue; Fungal Infection; Hyperlipidaemia; Low Density Lipoprotein Increased; Lung Infection; Lung Infiltration; Lung Neoplasm; Lung Neoplasm Malignant; Lymphadenopathy Mediastinal; Metastatic Neoplasm; Osteopenia; Platelet Count Increased; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Rheumatoid Arthritis;  
Sarcoidosis; Sinusitis;  
Staphylococcal Infection;  
Systemic Lupus  
Erythematosis; Treatment  
Noncompliance; Turner'S  
Syndrome; Type 2  
Diabetes Mellitus; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2006              | 6044971       | EXPEDITED (15-DAY) | Y                  | OT              | S06-ITA-01558-01     |                      | 55 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bipolar I Disorder;<br>Condition Aggravated;<br>Depression; Family<br>Stress; Homicide | Cipralext                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                        | Carbolithium (Lithium Carbonate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2006              | 6054845       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S06-USA-01700-01     |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Antidepressant Drug Level<br>Below Therapeutic;<br>Completed Suicide;<br>Suicidal Ideation | Wellbutrin              |              |            | S           | Oral         | 150mg Per Day      |                 | Glaxosmithkline |
|                                                                                            | Lexapro                 |              |            | S           | Oral         |                    |                 | Not Reported    |
|                                                                                            | Celexa                  |              |            | S           | Oral         | 40mg Per Day       |                 | Not Reported    |
|                                                                                            | Klonopin                |              |            | S           | Oral         | 1mg At Night       |                 | Not Reported    |
|                                                                                            | Trazodone Hydrochloride |              |            | S           |              | 100mg At Night     |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2006              | 6073474       | EXPEDITED (15-DAY) | Y                  | OT              | S06-HRV-02352-01     |                      | 48 YR      | Female     | HRV            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Female Orgasmic       | Cipralext      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                      |   |              |
|----------------------------|----------------------|---|--------------|
| Disorder; Libido Increased | Cilazil (Cilazapril) | C | Not Reported |
|                            | Atenolol             | C | Not Reported |
|                            | Furosemide           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2006              | 6076365       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-02306-01     |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During Pregnancy; Premature Labour | Lexapro                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                      | Methadone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2006              | 6010591       | EXPEDITED (15-DAY) | Y                  | CA, OT          | S06-GER-01001-01     |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Drug Interaction; Paternal Drugs Affecting Foetus; Trisomy 21 | Ciprallex      |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
|                                                               | Lithium        |              |            | S           | Oral           | 900 Mg Qd Po            |                 | Not Reported |
|                                                               | Quetiapine     |              |            | S           | Oral           | 300 Mg Qd Po            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2006              | 6020542       | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-01001-02     |                      | 40 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During Pregnancy; Paternal Drugs Affecting Foetus; Sperm Analysis Abnormal; Trisomy 21 | Ciprallex      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                          | Lithium        |              |            | S           | Oral         | 900 Mg Qd Po       |                 | Not Reported |
|                                                                                                          | Quetiapine     |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2006              | 6069469       | EXPEDITED (15-DAY) | Y                  | DE              | 2006CG01064          |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |                      |   |      |        |              |
|--------------------------------|----------------------|---|------|--------|--------------|
| Asphyxia; Completed<br>Suicide | Inexium              | S | Oral | 84 DAY | Astrazeneca  |
|                                | Cyamemazine          | S | Oral |        | Not Reported |
|                                | Escitalopram Oxalate | S | Oral |        | Not Reported |
|                                | Ramipril             | S | Oral |        | Not Reported |
|                                | Glucophage           | S | Oral |        | Not Reported |
|                                | Tahor                | S | Oral |        | Not Reported |
|                                | Aspirin              | C |      |        | Not Reported |
|                                | Lasix                | C |      |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2006              | 5749953       | EXPEDITED (15-DAY) | Y                  | DS              | S05-NOR-00571-01     |                      | 41 YR      | Male       | NOR            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Condition                            | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Aggravated; Depression;<br>Dyskinesia; Muscle | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Contractions Involuntary;<br>Torticollis      | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2006              | 6039439       | EXPEDITED (15-DAY) | N                  | OT              | PHEH2006US05401      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adrenal Disorder;                                                                        | Trileptal      |              |            | S           | Oral         | 450 Mg, Qd         |                 | Novartis     |
| Amnesia; Arthralgia; Blood<br>Glucose Decreased;                                         | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
| Chest Pain; Disturbance In<br>Attention; Drug Interaction;                               | Lexapro        |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
| Fatigue; Feeling Cold;                                                                   | Flexeril       |              |            | S           |              | Unk, Unk           |                 | Not Reported |
| Intervertebral Disc<br>Protrusion; Laboratory<br>Test Abnormal; Road<br>Traffic Accident | Ultracet       |              |            | S           |              | Unk, Unk           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jun-2006                                                                          | 6077793                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWE-02400-01     |                      | 31 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Ectopic Pregnancy;<br>Maternal Exposure During<br>Pregnancy | Cipralext                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Remeron                  |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Bricanyl                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Rhinocort                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Flutide                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Tavegyl (Clemastine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2006                                                                          | 6077799                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-GER-02398-01     |                      | 44 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Generalised                                                                     | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                      | Clozapine                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Abilify                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                      | Nervendragees-Ratiopharm |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2006                                                                          | 6425863                  | EXPEDITED (15-DAY) | Y                  | OT              | 8017325              |                      | 45 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Seizure; Suicide<br>Attempt                                                    | Keppra                   |                    |                    | S               | Oropharyngeal        | Once Po              |                 | Not Reported |                |
|                                                                                      | Cipralext                |                    |                    | S               | Oral                 | Once Po              |                 | Not Reported |                |
|                                                                                      | Lyrica                   |                    |                    | S               | Oral                 | Once Po              |                 | Not Reported |                |
|                                                                                      | Mirtazapine              |                    |                    | S               | Oral                 | Once Po              |                 | Not Reported |                |
|                                                                                      | Nexium                   |                    |                    | S               | Oral                 | Once Po              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jun-2006                  | 6075253                       | EXPEDITED (15-DAY) | Y                  | HO              | L06-USA-02193-01     |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Chest Pain;        | Escitalopram Oxalate          |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
| Confusional State;           | Methylphenidate Hydrochloride |                    |                    | S               |                      | 10 Mg Bid            |                 | Not Reported |                |
| Dizziness; Drug              | Venlafaxine Hydrochloride     |                    |                    | S               |                      | 75 Mg Qd             |                 | Not Reported |                |
| Interaction; Fall; Flushing; | Venlafaxine Hydrochloride     |                    |                    | S               |                      | 150 Mg Qd            |                 | Not Reported |                |
| Hallucination;               | Venlafaxine Hydrochloride     |                    |                    | S               |                      | 225 Mg Qd            |                 | Not Reported |                |
| Hyperventilation; Labile     | Lamotrigine                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Blood Pressure; Lethargy;    | Gabapentin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Muscle Rigidity; Pain;       | Trazodone Hydrochloride       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Pallor; Pharyngeal           | Mirtazapine                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Erythema; Pyrexia;           |                               |                    |                    |                 |                      |                      |                 |              |                |
| Serotonin Syndrome;          |                               |                    |                    |                 |                      |                      |                 |              |                |
| Tremor                       |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2006                  | 6075254                       | EXPEDITED (15-DAY) | Y                  | DS, OT          | S06-HRV-02168-01     |                      | 47 YR           | Male         | HRV            |
| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Anxiety; Gastric  | Ciprallex                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Disorder; Headache;          | Ciprallex                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Insomnia; Restless Legs      | Oxazepam                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Syndrome; Tension;           | Cerson (Nitrazepam)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Tremor                       |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2006                  | 6076174                       | DIRECT             | N                  | HO, LT          |                      |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased     | Lexapro                       |                    |                    | S               | Oral                 | 20 Mg Once A Day Po  |                 | Fleming      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 26-Jun-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6079377                               | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-02325-01     |                               | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Lexapro                               |                    |                    | S               | Oral                 | 10 Mg Qd Po                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Unspecified Ingredient                |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 4155085                               | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | 2004035108           |                               | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Abscess; Alanine Aminotransferase Increased; Anger; Anxiety; Arthralgia; Arthropod Bite; Asthenia; Blood Creatine Phosphokinase Increased; Blood Pressure Systolic Increased; Bowel Movement Irregularity; Burning Sensation; Cerebral Disorder; Chills; Confusional State; Constipation; Cough; Crying; Decreased Appetite; Diarrhoea; Discomfort; Disturbance In Attention; Diverticulum Intestinal; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Erythema; Exercise Tolerance Decreased; Fatigue; Feeling Abnormal; Feeling Drunk; | Lipitor                               |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Meclizine                             |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Keflex                                |                    |                    | S               |                      | 500 Mg (500 Mg, 1 In 1 D)     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Trazodone Hydrochloride               |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prozac                                |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Lexapro                               |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Ritalin                               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prednisone                            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Effexor Xr                            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Amitriptyline Hydrochloride           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Provigil                              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Minocycline\Minocycline Hydrochloride |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Namenda                               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Carnitor (Levocarnitine)              |                    |                    | C               |                      |                               |                 | Not Reported |                |

Fibrocystic Breast  
Disease; Fibromyalgia;  
Frustration Tolerance  
Decreased; Gait  
Disturbance;  
Gastrointestinal  
Hypermotility; Goitre;  
Hepatic Lesion;  
Hyperhidrosis;  
Hypoaesthesia;  
Hypotonia; Inflammation;  
Influenza Like Illness;  
Intervertebral Disc  
Degeneration; Loss Of  
Personal Independence In  
Daily Activities; Lymphoid  
Tissue Hyperplasia; Major  
Depression; Malaise;  
Mass; Mitochondrial  
Myopathy; Muscle  
Atrophy; Muscle Injury;  
Muscle Spasms; Myalgia;  
Nausea; Neuropathy  
Peripheral; Oedema  
Peripheral; Oropharyngeal  
Pain; Osteochondroma;  
Pelvic Inflammatory  
Disease; Pruritus;  
Psychomotor  
Hyperactivity; Rash;  
Rhinorrhoea; Sneezing;  
Soft Tissue Disorder;  
Spinal Osteoarthritis;  
Swelling; Tearfulness;  
Therapy Non-Responder;  
Tinnitus; Tremor; Urine  
Output Decreased;  
Vertigo; Weight  
Fluctuation

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# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 28-Jun-2006                                                                                                                | 6057600                       | EXPEDITED (15-DAY) | Y                  | OT              | S06-TUR-01973-01     |                             | 21 YR           | Female       | TUR            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Intentional Overdose; Photophobia; Suicide Attempt; Tinnitus                                                     | Cipralelex                    |                    |                    | S               | Oral                 | 22 Tablet Once Po           |                 | Not Reported |                |
|                                                                                                                            | Cipralelex                    |                    |                    | S               | Oral                 | 10 Mg Qd Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2006                                                                                                                | 6079474                       | EXPEDITED (15-DAY) | Y                  | DE              | S06-DEN-02592-01     |                             |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose                                                                                                                   | Citalopram                    |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Citalopram                    |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Cipralelex                    |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Cipralelex                    |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Chlorprothixene Hydrochloride |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Chlorprothixene Hydrochloride |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2006                                                                                                                | 6082725                       | EXPEDITED (15-DAY) | Y                  | OT              | 2006077913           |                             | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Diabetes Mellitus; Drug Interaction; liird Nerve Paralysis; Mitochondrial Myopathy Acquired; Tinnitus | Lipitor                       |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                            | Lexapro                       |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                            | Starlix                       |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2006                                                                                                                | 6082822                       | EXPEDITED (15-DAY) | Y                  | OT              | S06-HRV-02596-01     |                             | 49 YR           | Male         | HRV            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                                     |             |      |            |                                              |
|-----------------------------------------------------------------|-------------------------------------|-------------|------|------------|----------------------------------------------|
| Ejaculation Failure;<br>Erectile Dysfunction; Loss<br>Of Libido | Ciprallex<br>Thiamazole<br>Atenolol | S<br>C<br>C | Oral | 5 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------|-------------------------------------|-------------|------|------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jul-2006              | 6076975       | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13421599 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Platelet Count Decreased;<br>White Blood Cell Count<br>Decreased | Abilify<br>Lexapro |              |            | S<br>S      | Oral         |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2006              | 6022642       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01131-02     |                      | < 1 DAY    | Unknown    | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                   | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------------------------|----------------------------------------|-----------------|----------------------------------------------|
| Apgar Score Low; Infantile<br>Apnoea; Maternal<br>Exposure During<br>Pregnancy; Premature<br>Baby | Lexapro<br>Lexapro<br>Zyprexa |              |            | S<br>S<br>C | Transplacental<br>Transmammary | 40 Mg Qd Transplacental<br>40 Mg Qd Bf |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2006              | 6022644       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01131-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Premature Labour | Lexapro<br>Zyprexa |              |            | S<br>C      | Oral         | 40 Mg Qd Po        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2006              | 6077621       | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2006US08337      |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |         |   |            |           |              |
|--------------------------------|---------|---|------------|-----------|--------------|
| Catheter Placement; Drug       | Ritalin | S | 10 Mg, Bid | 15840 MIN | Novartis     |
| Interaction; Urinary Retention | Lexapro | S | 20 Mg, Qd  |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2006              | 6081849       | DIRECT           | Y                  | HO              |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertensive Crisis   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2006              | 6084759       | EXPEDITED (15-DAY) |                    | HO, OT          | DEWYE800826JUN06     |                      | 67 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Delirium; Disorientation;<br>Disturbance In Attention;<br>Drug Interaction; Memory<br>Impairment; Restlessness;<br>Sleep Disorder; Speech<br>Disorder; Thinking<br>Abnormal | Venlafaxine Hydrochloride          |              |            | S           | Oral         | See Image          | 1 DAY           | Not Reported |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 18 DAY          |              |
|                                                                                                                                                                                                   | Akineton                           |              |            | S           |              |                    | 3 DAY           | Not Reported |
|                                                                                                                                                                                                   | Aricept                            |              |            | S           |              | 5 Mg               | 8 DAY           | Not Reported |
|                                                                                                                                                                                                   | Ciprallex                          |              |            | S           |              | 5 Mg               | 4 DAY           | Not Reported |
|                                                                                                                                                                                                   | Lithium Carbonate                  |              |            | S           |              |                    |                 |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           | Not Reported |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 6 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          |                 |              |
|                                                                                                                                                                                                   | Seroquel                           |              |            | S           | Oral         | See Image          | 13 DAY          | Not Reported |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 3 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 2 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 1 DAY           |              |
|                                                                                                                                                                                                   |                                    |              |            |             | Oral         | See Image          | 11 DAY          |              |
|                                                                                                                                                                                                   | Zoloft                             |              |            | S           |              | See Image          |                 | Not Reported |
|                                                                                                                                                                                                   |                                    |              |            |             |              | See Image          | 6 DAY           |              |
|                                                                                                                                                                                                   | Presomen (Estrogens<br>Conjugated) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Iodide (Iodide)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                        | C                  |                    | Not Reported    |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Tavor (Lorazepam)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 6040717                | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-FRA-01380-01     |                      | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress Syndrome; Blood Calcium Decreased; Blood Chloride Decreased; Cardio-Respiratory Arrest; Cardiogenic Shock; Cardiomyopathy; Cerebral Disorder; Confusional State; Dialysis; Ejection Fraction Decreased; Hypokalaemia; Liver Disorder; Lung Infection; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Nosocomial Infection; Paraesthesia; Protein Total Decreased; Renal Failure; Renal Tubular Necrosis; Status Epilepticus; Syncope; Torsade De Pointes; Ventricular Fibrillation; Ventricular Tachycardia; Vomiting | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Unspecified Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 6064542                | EXPEDITED (15-DAY) | Y                  | DE              | S06-BRA-02000-01     |                      | 45 YR           | Male         | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |                                                       |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Suicide                                                                       | Clonazepam                                            |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                               | Valproate Sodium                                      |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2006                                                                   | 6070591                                               | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-02185-01     |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gamma-Glutamyltransferase Increased                                           | Escitalopram Oxalate                                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                               | Effexor                                               |                    |                    | S               |                      | 75 Mg Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2006                                                                   | 6070593                                               | EXPEDITED (15-DAY) | Y                  | LT              | S06-FRA-02186-01     |                      | 68 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Chloride Decreased; Generalised Oedema; Hyponatraemia; Weight Increased | Escitalopram Oxalate                                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                               | Gaviscon                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Brompheniramine Maleate\Pseudoephedrine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Iperfen (Manidipine Hydrochloride)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Seretide                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Furosemide                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Fozitec (Fosinopril)                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Rilmenidine                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Inipomp                                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Xalatan                                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Permixon (Serenoa Repens)                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2006                                                                   | 6077801                                               | EXPEDITED (15-DAY) | Y                  | HO              | S06-AUT-02401-01     |                      | 74 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Benign Prostatic Hyperplasia;                                 | Cipralext                                             |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Blood Lactate  
Dehydrogenase  
Increased; Colitis;  
Depression;  
Hyperuricaemia; Large  
Intestine Polyp;  
Megacolon; Pancreatic  
Atrophy; Subileus;  
Supraventricular  
Tachycardia; Weight  
Decreased

| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 07-Jul-2006                                                     | 6078663        | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0594771A |                      | 51 YR           | Female          | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Product<br>Quality Issue; Tension<br>Headache | Lotronex       |                  |                    | S               | Oral                                 | 1mg Per Day          |                 | Glaxosmithkline |                |
|                                                                 | Lexapro        |                  |                    | S               | Unknown                              |                      |                 | Not Reported    |                |
|                                                                 | Uniretic       |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                 | Premarin       |                  |                    | C               |                                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2006                                                                                                                | 6085095                         | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02478-01     |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Anaemia; Colitis<br>Ischaemic; Hypersomnia;<br>Hypothyroidism; Infection;<br>Malaise; Rash Pruritic;<br>Urticaria | Lexapro                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                            | Pegasys (Peginterferon Alfa-2a) |                    |                    | S               | Subcutaneous         | 180 Mcg Qw Sc        |                 | Not Reported |                |
|                                                                                                                            | Ribavirin                       |                    |                    | S               | Oral                 | 800 Mg Qd Po         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Jul-2006              | 6086128        | EXPEDITED (15-DAY) | Y                  | HO              | S06-GER-02616-01     |                      | 22 YR           | Male       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                          |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction; Seizure;<br>Weight Increased                 | Ciprallex                |                    | S                  | Oral            | 20 Mg Qd Po          |                      | Not Reported    |              |                |
|                                                                | Topamax                  |                    | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2006                                                    | 5996732                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-00445-01     |                      | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokalaemia; Overdose;<br>Weight Decreased                    | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Aripiprazole             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Heptaminol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Imovane (Zopiclone)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2006                                                    | 6044172                  | EXPEDITED (15-DAY) | Y                  | HO              | 2006-141543-NL       |                      | 44 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatocellular Injury;<br>Ultrasound Biliary Tract<br>Abnormal | Mirtazapine              |                    |                    | S               | Oral                 | 30 Mg Qd Oral        | 32 YR           | Not Reported |                |
|                                                                | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
|                                                                | Zolpidem Tartrate        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Codeine/Phenyltoloxamine |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jul-2006                                                    | 6090099                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-02625-01     |                      | 81 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Duodenal Ulcer                         | Ciprallex                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Meloxicam                |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                | Alprazolam               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Atenolol                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Flovent                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Folic Acid               |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |              |
|-----------|---|--------------|
| Lorazepam | C | Not Reported |
| Norvasc   | C | Not Reported |
| Phenytoin | C | Not Reported |
| Albuterol | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2006              | 6062218       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01901-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Decreased; Anxiety; Blood Urea Nitrogen/Creatinine Ratio Decreased; | Lexapro        |              |            | S           | Oral         | 30 Mg Qd; Po       |                 | Not Reported |
| Condition Aggravated;                                                                        | Lexapro        |              |            | S           | Oral         | 20 Mg Qd; Po       |                 | Not Reported |
| Depression; Divorced;                                                                        | Seroquel       |              |            | S           |              | 200 Mg Qhs         |                 | Not Reported |
| Drug Interaction;                                                                            | Marijuana      |              |            | S           |              |                    |                 | Not Reported |
| Homicidal Ideation;                                                                          | Zonegran       |              |            | C           |              |                    |                 | Not Reported |
| Insomnia; Legal Problem;                                                                     | Wellbutrin XL  |              |            | C           |              |                    |                 | Not Reported |
| Loss Of Employment;                                                                          |                |              |            |             |              |                    |                 |              |
| Stress; Suicidal Behaviour; Suicidal Ideation; Tearfulness;                                  |                |              |            |             |              |                    |                 |              |
| Treatment Noncompliance; Weight Decreased                                                    |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2006              | 6063882       | EXPEDITED (15-DAY) | Y                  | OT              | 8016846              |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;                 | Keppra         |              |            | S           | Oral         | 1000 Mg 2/D Po     |                 | Not Reported |
| Craniocerebral Injury;                 | Abilify        |              |            | S           | Oral         | 10 Mg /D Po        |                 | Not Reported |
| Depression; Dysstasia;                 | Lexapro        |              |            | S           | Oral         | D Po               |                 | Not Reported |
| Lethargy; Memory Impairment; Sedation; | Carbatrol      |              |            | C           |              |                    |                 | Not Reported |
| Status Epilepticus                     |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Jul-2006                 | 6069578                  | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-02081-01     |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anuria; Asthenia;           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
| Dehydration; Drug           | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
| Ineffective; Gun Shot       | Lexapro                  |                    |                    | S               | Oral                 | 20 Mg Qd; Po         |                 | Not Reported |                |
| Wound; Hallucination;       | Insulin Nos              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Headache; Increased         | Unknown Antihypertensive |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Insulin Requirement;        | Medication               |                    |                    |                 |                      |                      |                 |              |                |
| Nausea; Psychotic           |                          |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Pyrexia; Suicidal |                          |                    |                    |                 |                      |                      |                 |              |                |
| Ideation; Suicide Attempt;  |                          |                    |                    |                 |                      |                      |                 |              |                |
| Urinary Retention; Weight   |                          |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Weight           |                          |                    |                    |                 |                      |                      |                 |              |                |
| Increased; White Blood      |                          |                    |                    |                 |                      |                      |                 |              |                |
| Cell Count Increased        |                          |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2006                 | 6079711                  | EXPEDITED (15-DAY) | Y                  | HO              | 2006PK01460          |                      | 35 YR           | Female       | CHE            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Hepatitis;  | Seroquel                 |                    |                    | S               | Oral                 |                      | 387 DAY         | Zeneca       |                |
| Hepatocellular Injury;      | Exjade                   |                    |                    | S               | Oral                 |                      | 50 DAY          | Not Reported |                |
| Jaundice; Nausea            | Ciprallex                |                    |                    | S               | Oral                 |                      | 2 YR            | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2006                 | 6088726                  | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02525-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Fluctuation   | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
|                             | Lantus                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Humalog                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Fexofenadine             |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |              |
|---------------|---|--------------|
| Furosemide    | C | Not Reported |
| Lisinopril    | C | Not Reported |
| Levothyroxine | C | Not Reported |
| Potassium     | C | Not Reported |
| Iron          | C | Not Reported |
| Vitamin C     | C | Not Reported |
| Aspirin       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2006              | 6088979       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02524-01     |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Insomnia;<br>Nausea; Seizure; Tremor;<br>Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2006              | 6080512       | EXPEDITED (15-DAY) | Y                  | DE              | US-KINGPHARMUSA000001-K200600865 |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Paranoia | Altace               |              |            | S           | Oral         | 2.5 Mg, Qd         |                 | King         |
|                                | Cyamemazine          |              |            | S           | Oral         | 1 U, Qd            | 11520 MIN       | Not Reported |
|                                | Cyamemazine          |              |            | S           | Oral         | Iu, Unk            | 11520 MIN       | Not Reported |
|                                | Glucophage           |              |            | S           | Oral         | 1700 Mg, Qd        |                 | Not Reported |
|                                | Tahor                |              |            | S           | Oral         | 40 Mg, Qd          |                 | Not Reported |
|                                | Inexium              |              |            | S           | Oral         | 20 Mg, Qd          |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Qd          | 84 DAY          | Not Reported |
|                                | Lasix                |              |            | C           |              |                    |                 | Not Reported |
|                                | Aspirin              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2006              | 6085861       | DIRECT           | Y                  | HO              |                      |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |         |   |      |                  |        |
|----------------------------------------------------|---------|---|------|------------------|--------|
| Decreased Appetite; Dry Mouth; Dysphagia; Insomnia | Lexapro | S | Oral | 10 Mg Q Day Oral | Forest |
|----------------------------------------------------|---------|---|------|------------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2006              | 6039773       | EXPEDITED (15-DAY) | Y                  | HO              | T06-AUT-00057-01     |                      | 29 YR      | Male       | AUT            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Decreased; Body Temperature Decreased; Brain Oedema; Delirium; Disorientation; Drug Level Increased; Eosinophil Percentage Increased; Hallucination, Visual; Obsessive-Compulsive Personality Disorder; Restlessness | Ciprallex              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Ciprallex              |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 200 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 350 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 500 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 600 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Clozapine              |              |            | S           | Oral         | 800 Mg Qd Po       |                 | Novartis     |
|                                                                                                                                                                                                                                                                                     | Augmentin              |              |            | S           | Oral         | 3000 Mg Qd Po      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Solian (Amisulpride)   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Nexium (Esomeprazole)  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Aerius (Desloratadine) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Zolpidem               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2006              | 6041554       | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-01557-01     |                      | 85 YR      | Female     | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemoptysis; Nausea   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2006              | 5904066       | EXPEDITED (15-DAY) | Y                  | LT              | S05-UKI-03649-01     |                      | 61 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Cerebrovascular Accident; Cipralelex S Oral 10 Mg Qd Po Not Reported  
 Deep Vein Thrombosis;  
 Myocardial Infarction

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2006              | 6116252       | NON-EXPEDITED    | Y                  |                 | 2006SP002390         |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;                         | Lunesta        |              |            | S           | Oral         | Prn Oral           |                 | Not Reported |
| Dysgeusia;                                | Lexapro        |              |            | S           | Oral         | 10 Mg; Oral        |                 | Not Reported |
| Hypoaesthesia; Muscle Spasms; Nervousness | Remeron        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2006              | 6119081       | NON-EXPEDITED    | N                  |                 | 2006SP002286         |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Drug Ineffective; Middle Insomnia | Lunesta                  |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                              |                          |              |            |             | Oral         | See Image          |                 |              |
|                                              |                          |              |            |             | Oral         | See Image          |                 |              |
|                                              |                          |              |            |             | Oral         | See Image          |                 |              |
|                                              | Hydroxyzine              |              |            | S           | Oral         | Hs;Oral            |                 | Not Reported |
|                                              | Lexapro                  |              |            | S           | Oral         | Hs;Oral            |                 | Not Reported |
|                                              | Tamsulosin Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2006              | 5987601       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00290-01     |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Asthenia; Blood Creatinine Increased; | Lexapro        |              |            | S           | Oral         | 22.5 Mg Qd Po      |                 | Not Reported |
| Blood Urea Increased;                         | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Decreased Appetite;                           | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Hypersomnia; Malaise; Renal Impairment;       | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                                     |   |              |
|------------------------------|-------------------------------------|---|--------------|
| Tubulointerstitial Nephritis | Aciphex                             | S | Not Reported |
|                              | Aciphex                             | S | Not Reported |
|                              | Lotrel                              | S | Not Reported |
|                              | Triamterene And Hydrochlorothiazide | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2006              | 6083155       | EXPEDITED (15-DAY) | Y                  | HO              | 2006PK01488          |                      | 54 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine                                                      | Seroquel       |              |            | S           | Oral         |                    | 17 DAY          | Zeneca       |
| Phosphokinase Increased; Fall; Medication Error;                    | Amisulpride    |              |            | S           | Oral         |                    | 92 DAY          | Not Reported |
| Muscle Rigidity;                                                    | Ciprallex      |              |            | S           | Oral         |                    | 81 DAY          | Not Reported |
| Myoclonus; Overdose; Serotonin Syndrome; Toxicity To Various Agents | Edronax        |              |            | S           | Oral         |                    | 52 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2006              | 6091925       | DIRECT           | Y                  | OT              |                      |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alopecia              | Lexapro        |              |            | S           | Oral         | 1 Tablet Daily Po  | 6 WEEK          | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2006              | 5998357       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00149-01     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anticonvulsant Drug Level Decreased; Blood Glucose Decreased; Brain Natriuretic Peptide Decreased; Dementia; Disorientation; | Namenda        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Generalised Tonic-Clonic Seizure; Granulocyte                                                                                | Namenda        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                              | Namenda        |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                                                              | Namenda        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                              | Namenda        |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |           |   |      |              |              |
|-----------------------------|-----------|---|------|--------------|--------------|
| Count Increased;            | Namenda   | S | Oral | 5 Mg Qd Po   | Not Reported |
| Monocyte Count              | Namenda   | S | Oral | 5 Mg Bid Po  | Not Reported |
| Increased; Myoglobin        | Namenda   | S | Oral | 15 Mg Qd Po  | Not Reported |
| Blood Increased; Nasal      | Namenda   | S | Oral | 10 Mg Bid Po | Not Reported |
| Cyst; Postictal State; Road | Namenda   | S | Oral | 10 Mg Qd Po  | Not Reported |
| Traffic Accident;           | Lexapro   | S | Oral | 10 Mg Qd Po  | Not Reported |
| Screaming; Treatment        | Risperdal | C |      |              | Not Reported |
| Noncompliance; White        |           |   |      |              |              |
| Blood Cell Count            |           |   |      |              |              |
| Increased                   |           |   |      |              |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2006              | 6077039       | EXPEDITED (15-DAY) | Y                  | HO              | T06-SWI-02396-01     |                      | 70 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Gait Inability;<br>Impaired Self-Care;<br>Parkinsonism | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                | Aricept        |              |            | C           |              |                    |                 | Not Reported |
|                                                                | Marcumar       |              |            | C           |              |                    |                 | Not Reported |
|                                                                | Insulin Nos    |              |            | C           |              |                    |                 | Not Reported |
|                                                                | Aldactone      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jul-2006              | 6086186       | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-02604-01     |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed<br>Suicide; Paranoia | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                          | Glucophage             |              |            | S           | Oral         | 1700 Mg Qd Po      |                 | Not Reported |
|                                          | Cyamemazine            |              |            | S           | Oral         | 0.5 Units Bid Po   |                 | Not Reported |
|                                          | Atorvastatin Calcium   |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                          | Inexium (Esomeprazole) |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                          | Ramipril               |              |            | S           | Oral         | 1.25 Mg Bid Po     |                 | Not Reported |
|                                          | Aspirin                |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
|                                          | Lasilix (Furosemide)   |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Jul-2006              | 6091893                       | DIRECT             | N                  | DE              |                      |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Lexapro                       |                    |                    | S               | Oral                 | 20 Mg Daily Po       | 10 DAY          | Forest       |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2006              | 6093124                       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-02722-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Pain    | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                          | Aripiprazole                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2006              | 6081508                       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-02576-01     |                      | 54 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;    | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 1 Units Qd Po        |                 | Not Reported |                |
| Blood Albumin Increased; | Buflomedil Hydrochloride      |                    |                    | S               | Oral                 | 300 Mg Bid Po        |                 | Not Reported |                |
| Blood Chloride           | Lansoprazole                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Blood Glucose | Levothyroxine Sodium          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Increased; Blood Sodium  | Oxazepam                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Blood Urea    | Polyethylene Glycols          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Clonus;       | Acetaminophen\Caffeine\Dextro |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Confusional State;       | propoxyphene                  |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Dizziness; Hot Flush;    | Sedatif Pc                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyperhidrosis;           |                               |                    |                    |                 |                      |                      |                 |              |                |
| Hyponatraemia; Malaise;  |                               |                    |                    |                 |                      |                      |                 |              |                |
| Myoclonus; Nausea;       |                               |                    |                    |                 |                      |                      |                 |              |                |
| Neurological Examination |                               |                    |                    |                 |                      |                      |                 |              |                |
| Abnormal; Pco2           |                               |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Salivary      |                               |                    |                    |                 |                      |                      |                 |              |                |
| Hypersecretion; Seizure; |                               |                    |                    |                 |                      |                      |                 |              |                |
| Speech Disorder;         |                               |                    |                    |                 |                      |                      |                 |              |                |
| Tachypnoea; Tremor       |                               |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 19-Jul-2006                                                                                                                                           | 6088983                | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02484-01                     |                      | 53 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Confusional State;<br>Headache; Pain; Postictal<br>State; Seizure                                                                                     | Lexapro                |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Tramadol Hydrochloride |                    |                    | S               | Oral                                 | 50 Mg Po             |                 | Not Reported    |                |
|                                                                                                                                                       | Lortab                 |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Lisinopril             |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Claritin               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Nabumetone (Relafen)   |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jul-2006                                                                                                                                           | 6093584                | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-02856-01                     |                      | 46 YR           | Male            | DEU            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dermatitis Bullous; Rash                                                                                                                              | Cipralax               |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                       | Atorvastatin Calcium   |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Zolpidem               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Jul-2006                                                                                                                                           | 5798218                | EXPEDITED (15-DAY) | N                  | OT              | US-<br>GLAXOSMITHKLINE-<br>A0558615A |                      | 40 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain Upper;<br>Aggression; Disturbance<br>In Attention; Dizziness;<br>Drug Withdrawal<br>Syndrome; Fatigue;<br>Headache; Nausea;<br>Vertigo | Paxil                  |                    |                    | S               | Oral                                 | 20mg Per Day         |                 | Glaxosmithkline |                |
|                                                                                                                                                       | Paxil Cr               |                    |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                       | Lexapro                |                    |                    | S               | Oral                                 | 10mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                       | Celexa                 |                    |                    | S               | Oral                                 | 20mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                       | Hyoscyamine            |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Clonazepam             |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                       | Valium                 |                    |                    | C               |                                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|------------------|------------------------------|-------------------------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 20-Jul-2006                                                                                                                                                                      | 6016668                                        | EXPEDITED (15-DAY) | Y                  | OT               | ES-MERCK-0603ESP00042        |                                                             |                 | Unknown                                                      | ESP            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hypocalcaemia                                                                                                                                                                    | Aldomet<br>Escitalopram Oxalate                |                    |                    | S<br>S           |                              |                                                             |                 | Merck<br>Not Reported                                        |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 20-Jul-2006                                                                                                                                                                      | 6086112                                        | EXPEDITED (15-DAY) | Y                  | OT               | S06-GER-02617-01             |                                                             | 33 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Leukopenia; Neutrophil Count Decreased                                                                                                                                           | Cipraxel<br>Mirtazapine<br>Tavor (Lorazepam)   |                    |                    | S<br>C<br>C      | Oral                         | 10 Mg Qd Po                                                 |                 | Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 20-Jul-2006                                                                                                                                                                      | 6094265                                        | EXPEDITED (15-DAY) | Y                  | HO               | S06-SWI-02698-01             |                                                             | 54 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Blood Creatine Phosphokinase Increased; Depressed Level Of Consciousness; Fall; Hyperhidrosis; Medication Error; Muscle Rigidity; Myoclonus; Pyrexia; Toxicity To Various Agents | Cipraxel<br>Seroquel<br>Amisulpride<br>Edronax |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | 20 Mg Qd Po<br>800 Mg Qd Po<br>600 Mg Qd Po<br>600 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 20-Jul-2006                                                                                                                                                                      | 6094665                                        | EXPEDITED (15-DAY) | Y                  | OT               | L06-GER-02656-02             |                                                             | 28 YR           | Female                                                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Drug Interaction; Myoclonus                                                                                                                                                      | Escitalopram Oxalate                           |                    |                    | S                |                              | 10 Mg Qd                                                    |                 | Not Reported                                                 |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |           |              |
|--|----------------------|---|-----------|--------------|
|  | Escitalopram Oxalate | S | 20 Mg Qd  | Not Reported |
|  | Lamotrigine          | S | 200 Mg Qd | Not Reported |
|  | Lamotrigine          | S | 300 Mg Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2006              | 6095506       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02766-01     |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Anhedonia;<br>Arthralgia; Asthenia;<br>Condition Aggravated;<br>Fatigue; Loss Of Control<br>Of Legs; Loss Of Personal<br>Independence In Daily<br>Activities; Pain In<br>Extremity | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                             | Effexor Xr     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                             | Allegra        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                             | Prilosec       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2006              | 6096438       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-GER-02877-01     |                      | 60 YR      | Female     | DEU            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Activity;<br>Delirium; Hyponatraemia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                | Solvex               |              |            | C           |              |                    |                 | Not Reported |
|                                                | Exelon               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jul-2006              | 6025330       | EXPEDITED (15-DAY) | Y                  | HO, LT          | T06-UKI-01264-01     |                      | 69 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Blindness<br>Unilateral; Road Traffic<br>Accident; Ruptured<br>Cerebral Aneurysm | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Omeprazole           |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 25-Jul-2006                                                                                                                         | 6075217                                       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02249-01          |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Dyspnoea;<br>Fatigue; Feeling<br>Abnormal; Heart Rate<br>Irregular; Respiratory<br>Tract Congestion; Sinus<br>Congestion | Lexapro                                       |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                     | Lexapro                                       |                    |                    | S               | Oral                      | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                     | Lexapro                                       |                    |                    | C               | Oral                      | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                     | Vytorin (Exetimibe/Simvastatin)               |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                     | Prevacid                                      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                     | Warfarin Sodium                               |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                     | Pacerone                                      |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                     | Ambien                                        |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                     | Centrum Sliver<br>(Multivitamin/Multimineral) |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2006                                                                                                                         | 6083425                                       | EXPEDITED (15-DAY) | N                  | DE              | DK-ROCHE-454316           |                      | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                                                        | Xenical                                       |                    |                    | S               | Oral                      |                      |                 | Roche        |                |
|                                                                                                                                     | Cipralex                                      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jul-2006                                                                                                                         | 6090661                                       | EXPEDITED (15-DAY) | Y                  | DE              | FR-MERCK-<br>0607FRA00047 |                      | 55 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                                                        | Zocor                                         |                    |                    | S               | Oral                      |                      |                 | Merck        |                |
|                                                                                                                                     | Escitalopram Oxalate                          |                    |                    | S               | Oral                      |                      | 20 DAY          | Not Reported |                |
|                                                                                                                                     | Metformin                                     |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                     | Labetalol Hydrochloride                       |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                     | Labetalol Hydrochloride                       |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |      |              |
|-----------------------|---|------|--------------|
| Valsartan             | C | Oral | Not Reported |
| Clopidogrel Bisulfate | C | Oral | Not Reported |
| Aspirin               | C | Oral | Not Reported |
| Repaglinide           | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2006              | 6100007       | EXPEDITED (15-DAY) | Y                  | OT              | 2006088984           |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gait Disturbance; Oedema<br>Peripheral; Pain; Skin<br>Discolouration; Venous<br>Occlusion | Cabergoline            |              |            | S           | Oral         | 6 Mg, Oral         |                 | Not Reported |
|                                                                                           | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                           | Levothyroxine Sodium   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                           | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 26-Jul-2006              | 6091506       | EXPEDITED (15-DAY) | Y                  | DE              | FR-SANOFI-SYNTHELABO-A02200601867 |                      | 55 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Cough;<br>Myocardial Ischaemia;<br>Sudden Death | Plavix               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Escitalopram Oxalate |              |            | S           | Oral         |                    | 20 DAY          | Not Reported |
|                                                           | Tareg                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Zocor                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                           | Trandate             |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                           | Metformin            |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                           | Repaglinide          |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                           | Aspirin              |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2006              | 6086788       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-02618-01     |                      | 64 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                      |   |      |             |              |
|--------------------------------------------|----------------------|---|------|-------------|--------------|
| Loss Of Consciousness;<br>Malaise; Seizure | Escitalopram Oxalate | S | Oral | 20 Mg Qd Po | Not Reported |
|                                            | Buspar               | C |      |             | Not Reported |
|                                            | Levothyroxine Sodium | C |      |             | Not Reported |
|                                            | Zolpidem Tartrate    | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2006              | 6090750       | EXPEDITED (15-DAY) | Y                  | OT              | S06-HRV-02674-01     |                      | 33 YR      | Male       | HRV            |

| <u>Preferred Term</u>                         | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Male Orgasmic Disorder;<br>Sexual Dysfunction | Cipralelex            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                               | Alofalk (Mesalazine)  |              |            | C           |              |                    |                 | Not Reported |
|                                               | Imuran                |              |            | C           |              |                    |                 | Not Reported |
|                                               | Decortin (Prednisone) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2006              | 6101555       | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWI-02900-01     |                      | 94 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                     | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Delirium; Disorientation;<br>Fatigue; Hallucination | Cipralelex                  |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                           | Tramadol Hydrochloride      |              |            | S           | Oral         | 100 Mg Qd Po       |                 | Not Reported |
|                                                                           | Buprenorphine Hydrochloride |              |            | S           | Sublingual   | 0.4 Mg Qd SI       |                 | Not Reported |
|                                                                           | Trileptal                   |              |            | S           | Oral         | 150 Mg Qd Po       |                 | Not Reported |
|                                                                           | Surmontil                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Brufen (Ibuprofen)          |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Xatral (Alfuzosin)          |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Risperdal                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Lyrica                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2006              | 6101557       | EXPEDITED (15-DAY) | Y                  | OT              | S06-SWI-02899-01     |                      | 54 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Epistaxis;<br>Formication; Hepatic Pain; | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypotension; Nausea

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2006              | 6093275       | EXPEDITED (15-DAY) | Y                  | HO              | CH-JNJFOC-20060705583 |                      | 93 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                               | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Delirium; Disorientation; Fatigue; Hallucination; Sleep Disorder | Tramadol Hydrochloride      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Buprenorphine Hydrochloride |              |            | S           | Sublingual   |                    |                 | Not Reported |
|                                                                                     | Trileptal                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Cipralext                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                     | Surmontil                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                     | Ibuprofen                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                     | Xatral                      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                     | Risperdal                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                     | Lyrica                      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2006              | 6100786       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-02794-01     |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed Suicide; Economic Problem; Loss Of Employment | Lexapro                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                   | Toprol XL                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Altacor                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | Hyzaar                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                   | (Losartan/Hydrochlorothiazide) |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2006              | 6100798       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02791-01     |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cyanosis; Drug Interaction; Heart Rate | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                   |                                          |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Decreased; Loss Of Consciousness; Syncope                                                                                         | Trileptal                                |                    |                    | S               |                      | 150 Mg Bid           |                 | Not Reported |                |
|                                                                                                                                   | Strattera                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2006                                                                                                                       | 6100140                                  | DIRECT             | N                  | OT              |                      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Pain Of Skin; Pruritus; Skin Disorder                                                                                   | Lexapro                                  |                    |                    | S               |                      | 10mg Once A Day 047  |                 | Not Reported |                |
|                                                                                                                                   | Advair Diskus                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                   | Synthroid                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                   | Leena 28 (Birth Control)                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2006                                                                                                                       | 6102717                                  | EXPEDITED (15-DAY) | Y                  | OT              | 2006S1006538         |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Loss Of Consciousness; Pain; Postictal Headache; Postictal State; Seizure                                      | Lexapro                                  |                    |                    | S               | Oral                 | 20 Mg;Qd;Po          |                 | Not Reported |                |
|                                                                                                                                   | Tramadol Hydrochloride                   |                    |                    | S               | Oral                 | 50 Mg; Po            |                 | Not Reported |                |
|                                                                                                                                   | Hydrocodone Bitartrate And Acetaminophen |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                   | Lisinopril                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                   | Loratadine                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                   | Nabumetone                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2006                                                                                                                       | 5986542                                  | EXPEDITED (15-DAY) |                    | OT              | PHEH2006US01749      |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Asthenia; Blood Creatinine Increased; Blood Urea Increased; Decreased Appetite; Hypersomnia; Tubulointerstitial Nephritis | Lotrel                                   |                    |                    | S               | Oral                 |                      |                 | Novartis     |                |
|                                                                                                                                   | Aciphex                                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                   | Aciphex                                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                                  |                    |                    | S               |                      | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                                  |                    |                    | S               |                      | 20 Mg, Qd            |                 | Not Reported |                |

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|                                                                                                                          | Lexapro                              |                    | S                  | Oral            | 20 Mg, Qd            |                      | Not Reported    |              |                |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                          | Lexapro                              |                    | S                  | Oral            | 22.5 Mg, Qd          |                      | Not Reported    |              |                |
|                                                                                                                          | Lexapro                              |                    | S                  | Oral            | 15 Mg, Qd            |                      | Not Reported    |              |                |
|                                                                                                                          | Hydrochlorothiazide<br>W/Triamterene |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2006                                                                                                              | 6061031                              | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-01993-01     |                      | 36 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Brain Injury;<br>Cognitive Disorder;<br>Homicidal Ideation;<br>Overdose; Parkinsonism;<br>Tardive Dyskinesia | Ciprallex                            |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Citalopram Hydrobromide              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2006                                                                                                              | 6078561                              | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-02374-01     |                      | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis; Rash; Skin<br>Burning Sensation; Skin<br>Discolouration; Vascular<br>Skin Disorder                           | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Caltrate                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Actonel                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Alprazolam                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Arimidex                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2006                                                                                                              | 6092666                              | EXPEDITED (15-DAY) | Y                  | LT              | GXKR2006DK03939      |                      | 32 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Decreased;<br>Sensory Loss                                                                                 | Citalopram Hydrobromide              |                    |                    | S               | Oral                 | 20 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                                                                          | Insulin Nos                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Isophane Insulin (Isophane           |                    |                    | C               |                      |                      |                 | Not Reported |                |

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Insulin) Injection)

| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Aug-2006                | 6101564                      | EXPEDITED (15-DAY) | Y                  | DS              | S06-UKI-02901-01     |                      | 46 YR           | Female       | GBR            |
| <u>Preferred Term</u>      | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;        | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Dehydration;               | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Disorientation; Hepatic    | Stilnoct (Zolpidem Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Enzyme Abnormal;           |                              |                    |                    |                 |                      |                      |                 |              |                |
| Nausea; Polydipsia;        |                              |                    |                    |                 |                      |                      |                 |              |                |
| Tremor                     |                              |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2006                | 6105925                      | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02935-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia         | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2006                | 6028186                      | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00892-01     |                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Blood   | Lexapro                      |                    |                    | S               | Oral                 | 5 Mg Once Po         |                 | Not Reported |                |
| Pressure Increased; Chest  | Ativan                       |                    |                    | S               |                      | 0.5 Mg Qid           |                 | Not Reported |                |
| Discomfort; Condition      | Cardizem                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Aggravated; Dry Mouth;     | Dyazide                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Headache; Heart Rate       | Tenormin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Increased; Incorrect Dose  | Aspirin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Administered; Nausea;      | Vitamin E                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Palpitations; Sensation Of | Calcium Gluconate            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Foreign Body; Treatment    |                              |                    |                    |                 |                      |                      |                 |              |                |
| Noncompliance              |                              |                    |                    |                 |                      |                      |                 |              |                |



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| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 02-Aug-2006                                                                                                 | 6078559                       | EXPEDITED (15-DAY) | Y                  | DE              | S06-ISR-02567-01                                |                      | 81 YR           | Male                 | ISR            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide;<br>Depression; Suicidal<br>Ideation                                                      | Cipralext                     |                    |                    | S               | Oral                                            | 5 Mg Qd Po           |                 | Not Reported         |                |
|                                                                                                             | Cipralext                     |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported         |                |
|                                                                                                             | Verapamil Hydrochloride       |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Vitamin D Nos                 |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Calcimore (Calcium Carbonate) |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Ipratropium Bromide           |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Tamsulosin Hydrochloride      |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Aug-2006                                                                                                 | 6097019                       | NON-EXPEDITED      | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13290234 |                      | 18 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>International Normalised<br>Ratio Increased                                            | Coumadin                      |                    |                    | S               |                                                 |                      |                 | Bristol Myers Squibb |                |
|                                                                                                             | Lexapro                       |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Aug-2006                                                                                                 | 6097094                       | NON-EXPEDITED      | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13331293 |                      | 86 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Gastrointestinal<br>Haemorrhage;<br>Haematocrit Decreased;<br>Platelet Count Decreased | Coumadin                      |                    |                    | S               |                                                 |                      |                 | Bristol Myers Squibb |                |
|                                                                                                             | Verapamil Hydrochloride       |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Arsenic Trioxide              |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Melphalan                     |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Aspirin                       |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                                                                             | Lexapro                       |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 02-Aug-2006                               | 6097168                  | NON-EXPEDITED      | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13370374 |                      |                 | Male                 | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Dreams;                          | Coumadin                 |                    |                    | S               |                                                 |                      |                 | Bristol Myers Squibb |                |
| Dizziness; Fall;                          | Lexapro                  |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
| Haemorrhage;                              | Cytomel                  |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| Hallucination, Visual; Skin<br>Laceration | Strattera                |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Aug-2006                               | 6104354                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-02919-01                                |                      | 20 YR           | Female               | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Condition Aggravated;                     | Seropram (Citalopram     |                    |                    | S               | Oral                                            | 20 Mg Bid Po         |                 | Not Reported         |                |
| Neutropenia; White Blood                  | Hydrobromide)            |                    |                    |                 |                                                 |                      |                 |                      |                |
| Cell Count Decreased                      | Escitalopram Oxalate     |                    |                    | S               | Oral                                            | 20 Mg Qd Po          |                 | Not Reported         |                |
|                                           | Xanax                    |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Aug-2006                               | 6104359                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWI-03091-01                                |                      | 37 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Haematoma; Petechiae;                     | Ciprallex                |                    |                    | S               | Oral                                            | 5 Mg Qd Po           |                 | Not Reported         |                |
| Platelet Disorder                         | Ciprallex                |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported         |                |
|                                           | Paroxetine Hydrochloride |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Aug-2006                               | 6104520                  | DIRECT             | Y                  |                 |                                                 |                      | 80 YR           | Male                 | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Ineffective; Nausea                  | Lexapro                  |                    |                    | S               |                                                 | Q Day # 30           |                 | Not Reported         |                |

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|------------------------------|----------------|
| 03-Aug-2006                                                                                                                                                                                     | 6094683                             | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2006080082           |                                      | 69 YR           | Male                         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide;<br>Condition Aggravated;<br>Coronary Artery Bypass;<br>Paranoia                                                                                                              | Atorvastatin                        |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D),<br>Oral     |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Glucophage                          |                    |                    | S               | Oral                 | 1700 Mg (1700 Mg, 1 In 1<br>D), Oral |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Cyamemazine                         |                    |                    | S               | Oral                 | 1 Dose Form (2 In 1 D),<br>Oral      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Inexium (Esomeprazole<br>Magnesium) |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral     |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Ramipril                            |                    |                    | S               | Oral                 | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Aspirin<br>Lasix (Furosemide)       |                    |                    | C<br>C          |                      |                                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 04-Aug-2006                                                                                                                                                                                     | 6033240                             | EXPEDITED (15-DAY) | Y                  | OT              | S06-FIN-01353-01     |                                      | 32 YR           | Male                         | FIN            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aura; Cerebral Infarction;<br>Depression; Hepatitis;<br>Hepatotoxicity;<br>Musculoskeletal<br>Discomfort; Neck Pain;<br>Paraesthesia;<br>Vertebrobasilar<br>Insufficiency; Visual<br>Impairment | Ciprallex                           |                    |                    | S               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Fragmin                             |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Fragmin-Marevan (Warfarin)          |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Alprazolam                          |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Voltaren                            |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Burana (Ibuprofen)                  |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Panacod                             |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Dolan                               |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                 | Para-Tabs (Paracetamol)             |                    |                    | C               |                      |                                      |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 04-Aug-2006                                                                                                                                                                                                                                                                                       | 6082870              | EXPEDITED (15-DAY) | Y                  | OT              | 2006-06-2113         |                          | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Blood Thyroid Stimulating Hormone Increased; Depression; Diarrhoea; Drug Hypersensitivity; Fluid Intake Reduced; Goitre; Headache; Heart Rate Increased; Hypophagia; Hypothyroidism; Impaired Work Ability; Neck Pain; Somnolence; Stress; Throat Irritation; Ulcer; Urticaria; Vomiting | Pegintron            |                    |                    | S               | Subcutaneous         | 120 Mcg Qwk Subcutaneous |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Rebetol              |                    |                    | S               | Oral                 | 1000 Mg Qd Oral          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Effexor              |                    |                    | S               | Oral                 | 37.5 Mg Qd               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Lexapro              |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Protonix             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Aspirin              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Advil                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2006                                                                                                                                                                                                                                                                                       | 6099241              | EXPEDITED (15-DAY) |                    | DE              | PHRM2006FR02218      |                          | 55 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Fatigue; Ischaemia; Productive Cough; Sudden Death                                                                                                                                                                                                                                         | Tareg                |                    |                    | S               | Oral                 | 80 Mg, Qd                |                 | Novartis     |                |
|                                                                                                                                                                                                                                                                                                   | Metformin            |                    |                    | S               | Oral                 | Unk, Unk                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Trandate             |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Zocor                |                    |                    | S               | Oral                 | 40 Mg, Qd                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg, Qd                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Plavix               |                    |                    | S               | Ophthalmic           | 75 Mg, Qd                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Aspirin              |                    |                    | C               | Oral                 |                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                   | Repaglinide          |                    |                    | C               | Oral                 |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2006                                                                                                                                                                                                                                                                                       | 6104612              | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01052-01     |                          | 44 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Abdominal Discomfort;<br>Blood Pressure Increased;<br>Chest Pain; Diarrhoea;<br>Heart Rate Increased;<br>Hypertension; Neutrophil<br>Count Increased; Panic<br>Attack; Tachycardia; White<br>Blood Cell Count<br>Increased | Wellbutrin Sr  |              |            | S           | Oral         | 150mg At Night     | 9 DAY           | Glaxosmithkline |
|                                                                                                                                                                                                                            | Dyazide        |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                            | Lexapro        |              |            | S           | Oral         |                    | 8 DAY           | Not Reported    |
|                                                                                                                                                                                                                            | Lasix          |              |            | C           |              | 20mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                                                                                                                            | Estrostep      |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2006              | 6010148       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00723-01     |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bifascicular Block; Blood<br>Pressure Increased;<br>Electrocardiogram Qrs<br>Complex Prolonged;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram Qt<br>Prolonged; Qrs Axis<br>Abnormal | Lexapro                                 |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                  | Lexapro                                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                  | Wellbutrin                              |              |            | S           | Oral         | 150 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                                                                  | Wellbutrin (Bupropion<br>Hydrochloride) |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                                                                  | Wellbutrin (Bupropion<br>Hydrochloride) |              |            | S           | Oral         | 450 Mg Qd Po       |                 | Not Reported |
|                                                                                                                                                                                                  | Armour Thyroid                          |              |            | S           | Oral         | 60 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                  | Risperdal                               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2006              | 6108647       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02981-01     |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Triglycerides<br>Increased | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                  | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                  | Narproxen      |              |            | C           |              |                    |                 | Not Reported |
|                                  | Goodys         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 07-Aug-2006                                         | 6111990                           | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-02980-01       |                      | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Gun Shot Wound; Suicide Attempt   | Lexapro                           |                    |                    | S               | Oral                   | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2006                                         | 6000623                           | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-00552-01       |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertension                                        | Lexapro                           |                    |                    | S               | Oral                   | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Lexapro                           |                    |                    | S               | Oral                   | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Diovan Hct                        |                    |                    | C               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2006                                         | 6101243                           | EXPEDITED (15-DAY) |                    | DE              | FR-AVENTIS-200612714FR |                      | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Ventricular Fibrillation | Lasix                             |                    |                    | S               | Oral                   |                      |                 | Aventis      |                |
|                                                     | Pravastatin Sodium                |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Bisoprolol Fumarate               |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Escitalopram Oxalate              |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Perindopril Erbumine              |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Glucophage                        |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Dafalgan                          |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                     | Aspegic [Acetylsalicylate Lysine] |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                     | Gliclazide                        |                    |                    | C               | Oral                   |                      |                 | Not Reported |                |
|                                                     | Acarbose                          |                    |                    | C               |                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------|-----------------|--------------|----------------|
| 08-Aug-2006                                                                                                   | 6106093                      | EXPEDITED (15-DAY) | Y                  | DE              | S06-NOR-02918-01                         |                        | 53 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                                                                   | Cipralext                    |                    |                    | S               | Oral                                     | 5 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                               | Furadantin                   |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Hiprex                       |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Vagifem                      |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Livial                       |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Stilnoct (Zolpidem Tartrate) |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Sobril (Oxazepam)            |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Diazepam                     |                    |                    | C               |                                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2006                                                                                                   | 6027181                      | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | FR-BRISTOL-MYERS SQUIBB COMPANY-13340856 |                        | 26 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Chills; Malaise; Metrorrhagia; Multiple Organ Dysfunction Syndrome; Respiratory Arrest        | Abilify                      |                    |                    | S               | Oral                                     | Dosage: 10 Mg To 40 Mg |                 | Not Reported |                |
|                                                                                                               | Tiapride                     |                    |                    | S               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate         |                    |                    | S               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Cytotec                      |                    |                    | S               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Zopiclone                    |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Prazepam                     |                    |                    | C               |                                          |                        |                 | Not Reported |                |
|                                                                                                               | Mifegyne                     |                    |                    | C               |                                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2006                                                                                                   | 6111283                      | DIRECT             | N                  | DS, HO, LT      |                                          |                        | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Confusional State; Depressed Level Of Consciousness; Drug Hypersensitivity; Feeling | Lexapro                      |                    |                    | S               | Oral                                     | Twice Daily Po         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Abnormal; Hyperhidrosis;  
Loss Of Consciousness;  
Pain; Seizure; Tinnitus;  
Tongue Biting

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------|-----------------|----------------------|----------------|
| 10-Aug-2006                                                                               | 6081340                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-02472-02                         |                          |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation Neonatal; Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy | Lexapro                 |                    |                    | S               | Transplacental                           | 35 Mg Bid Transplacental |                 | Not Reported         |                |
|                                                                                           | Methadone Hydrochloride |                    |                    | S               |                                          |                          |                 | Not Reported         |                |
|                                                                                           | Prenatabs Fa            |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
|                                                                                           | Synthroid               |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
|                                                                                           | Vitamin B6              |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
|                                                                                           | Propranolol             |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 10-Aug-2006                                                                               | 6093062                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02553-01                         |                          | 20 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Aortic Valve Incompetence; Cardiac Valve Disease; Insomnia                                | Lexapro                 |                    |                    | S               | Oral                                     | 10 Mg Qd Po              |                 | Not Reported         |                |
|                                                                                           | Aspirin                 |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
|                                                                                           | Garlic Pills            |                    |                    | C               |                                          |                          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 10-Aug-2006                                                                               | 6103205                 | EXPEDITED (15-DAY) | N                  | DE, HO          | FR-BRISTOL-MYERS SQUIBB COMPANY-13467808 |                          | 58 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardio-Respiratory Arrest; Multiple Organ Dysfunction Syndrome; Ventricular Fibrillation  | Glucophage              |                    |                    | S               | Oral                                     |                          |                 | Bristol Myers Squibb |                |
|                                                                                           | Pravastatin Sodium      |                    |                    | S               | Oral                                     |                          |                 | Bristol Myers Squibb |                |
|                                                                                           | Lasix                   |                    |                    | S               | Oral                                     |                          |                 | Not Reported         |                |
|                                                                                           | Bisoprolol Fumarate     |                    |                    | S               | Oral                                     |                          |                 | Not Reported         |                |
|                                                                                           | Perindopril Erbumine    |                    |                    | S               | Oral                                     |                          |                 | Not Reported         |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                   |   |      |         |              |
|-----------------------------------|---|------|---------|--------------|
| Escitalopram Oxalate              | S | Oral | 12 WEEK | Not Reported |
| Dafalgan                          | C |      |         | Not Reported |
| Aspegic [Acetylsalicylate Lysine] | C |      |         | Not Reported |
| Gliclazide                        | C | Oral |         | Not Reported |
| Acarbose                          | C |      |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2006              | 6103493       | EXPEDITED (15-DAY) |                    | DE              | FR-SOLVAY-00206002538 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cardio-Respiratory Arrest; Coma; Coronary Artery Disease; Ventricular Fibrillation | Perindopril Erbumine              |              |            | S           | Oral         | Daily Dose: 2 Milligram(S)    |                 | Not Reported |
|                                                                                    | Escitalopram Oxalate              |              |            | S           | Oral         | Daily Dose: 10 Milligram(S)   | 84 DAY          | Not Reported |
|                                                                                    | Bisoprolol Fumarate               |              |            | S           | Oral         | Daily Dose: 1 Dosage Form     |                 | Not Reported |
|                                                                                    | Glucophage                        |              |            | S           | Oral         | Daily Dose: 2550 Milligram(S) |                 | Not Reported |
|                                                                                    | Lasix                             |              |            | S           | Oral         | Daily Dose: 1 Dosage Form     |                 | Not Reported |
|                                                                                    | Pravastatin Sodium                |              |            | S           | Oral         | Daily Dose: 1 Dosage Form     |                 | Not Reported |
|                                                                                    | Aspegic [Acetylsalicylate Lysine] |              |            | C           | Unknown      | Daily Dose: Unknown           |                 | Not Reported |
|                                                                                    | Dafalgan                          |              |            | C           | Unknown      | Daily Dose: Unknown           |                 | Not Reported |
|                                                                                    | Diamicron                         |              |            | C           | Unknown      | Daily Dose: Unknown           |                 | Not Reported |
|                                                                                    | Glucor                            |              |            | C           | Unknown      | Daily Dose: Unknown           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2006              | 6103561       | EXPEDITED (15-DAY) | N                  | OT              | PHEH2006US09800      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cyanosis; Drug Interaction; Heart Rate Decreased; Loss Of | Trileptal      |              |            | S           |              | 150 Mg, Bid        |                 | Novartis     |
|                                                           | Lexapro        |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |                          |                    |                    |                 |                              |                      |                 |                 |                |
|------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Consciousness; Syncope                                     |                          | Strattera          |                    | C               |                              | Not Reported         |                 |                 |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2006                                                | 6103655                  | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0586836A |                      | 37 YR           | Female          | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthralgia; Joint Swelling                                 | Paroxetine Hydrochloride |                    |                    | S               | Oral                         | 40mg Per Day         |                 | Glaxosmithkline |                |
|                                                            | Lexapro                  |                    |                    | S               |                              | 2.5mg Per Day        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2006                                                | 6103903                  | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0593709A |                      | 52 YR           | Male            | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Decreased Appetite; Depression; Insomnia; Weight Decreased | Paxil                    |                    |                    | S               |                              |                      | 22 DAY          | Glaxosmithkline |                |
|                                                            | Lexapro                  |                    |                    | S               | Oral                         |                      |                 | Not Reported    |                |
|                                                            | Ativan                   |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2006                                                | 6113157                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03018-01             |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Procedural Haemorrhage                                     | Lexapro                  |                    |                    | S               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2006                                                | 6113160                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03020-01             |                      | 86 YR           | Female          | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Urinary Retention                                          | Namenda                  |                    |                    | S               |                              |                      |                 | Not Reported    |                |
|                                                            | Lexapro                  |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                            | Norvasc                  |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                                            | Metoprolol               |                    |                    | C               |                              |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Tylenol (Paracetamol)       |                |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
| Exelon                      |                |                    | C                  |                 |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2006                 | 6115046        | EXPEDITED (15-DAY) | Y                  | HO, RI          | S06-USA-03017-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Appendicitis Perforated;    | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Haematoma Infection;        | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Haemoglobin Decreased;      |                |                    |                    |                 |                      |                      |                 |              |                |
| Incisional Hernia;          |                |                    |                    |                 |                      |                      |                 |              |                |
| Procedural Haemorrhage      |                |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                 | 6034042        | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-00959-01     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Multiforme         | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Vitamin B12    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                 | 6057243        | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-01877-01     |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;       | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Anxiety; Bacterial          | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
| Infection; Dehydration;     | Xanax          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Diarrhoea; Gastrointestinal |                |                    |                    |                 |                      |                      |                 |              |                |
| Infection; Hyperacusis;     |                |                    |                    |                 |                      |                      |                 |              |                |
| Mental Impairment;          |                |                    |                    |                 |                      |                      |                 |              |                |
| Nausea; Panic Attack;       |                |                    |                    |                 |                      |                      |                 |              |                |
| Paraesthesia; Pharyngeal    |                |                    |                    |                 |                      |                      |                 |              |                |
| Oedema; Pruritus            |                |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 11-Aug-2006                                                                                                                                              | 6100804                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-USA-02838-01              |                               | 24 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Benign Breast Neoplasm;<br>Breast Cyst; Breast<br>Discharge; Intentional<br>Overdose; Intentional Self-<br>Injury; Suicidal Ideation;<br>Suicide Attempt | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                          | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                          | Depakote                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                          | Depakote                |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                          | Risperdal               |                           |                             | S                        |                               | 2 Mg Qd                       |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Aug-2006                                                                                                                                              | 6113476                 | EXPEDITED (15-DAY)        | N                           | HO                       | S06-USA-03031-01              |                               | 53 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Contusion; Immune<br>Thrombocytopenic<br>Purpura                                                                                                         | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |
|                                                                                                                                                          | Lipitor                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                          | Flonase                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Aug-2006                                                                                                                                              | 6113479                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-03037-01              |                               | 36 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Thrombosis; Vaginal<br>Haemorrhage                                                                  | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                          | Wellbutrin XI           |                           |                             | S                        |                               | 300 Mg Qd                     |                          | Not Reported        |                         |
|                                                                                                                                                          | Prenatal Vitamins       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Aug-2006                                                                                                                                              | 6114164                 | EXPEDITED (15-DAY)        | N                           | RI, OT                   | S06-USA-03023-01              |                               | 28 YR                    | Female              | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                      | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------|---------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cholelithiasis;<br>Electrocardiogram<br>Abnormal; Product Dose<br>Omission | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                                                                | 6167874                         | NON-EXPEDITED    | N                  |                 | S06-USA-02517-01     |                      | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue                                                                    | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                            | Lexapro                         |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                            | Flomax                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                            | Proscar                         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                            | Pill To Increase Appetite (Nos) |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                                                                | 6167897                         | NON-EXPEDITED    | N                  |                 | S06-USA-02544-01     |                      | 87 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                                                                  | Namenda                         |                  |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                                                            | Namenda                         |                  |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                            | Lexapro                         |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                            | Synthroid                       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                            | Plavix                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                            | Norvasc                         |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2006              | 6167902       | NON-EXPEDITED    | N                  |                 | S06-USA-02715-01     |                      | 87 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Dizziness | Namenda            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                 | Namenda            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                 | Namenda            |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                                 | Namenda            |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                 | Namenda            |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                 | Namenda            |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                 | Lexapro            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                 | Aricept            |              |            | C           |              |                    |                 | Not Reported |
|                                 | Flomax             |              |            | C           |              |                    |                 | Not Reported |
|                                 | Singulair          |              |            | C           |              |                    |                 | Not Reported |
|                                 | Toprol XL          |              |            | C           |              |                    |                 | Not Reported |
|                                 | Prilosec           |              |            | C           |              |                    |                 | Not Reported |
|                                 | Zocor              |              |            | C           |              |                    |                 | Not Reported |
|                                 | Aspirin            |              |            | C           |              |                    |                 | Not Reported |
|                                 | Multivitamin (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2006              | 6168195       | NON-EXPEDITED    | N                  |                 | S06-USA-01874-01     |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache              | Namenda        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                       | Namenda        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Namenda        |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Aricept        |              |            | C           |              |                    |                 | Not Reported |
|                       | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                       | Gemfibrozil    |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>               | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Aug-2006                            | 6168738                | NON-EXPEDITED    | N                  |                 | S06-USA-01632-01     |                      | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Food Interaction; Retching | Namenda                |                  |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                        | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Unspecified Ingredient |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                        | Aricept                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Digoxin                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Coumadin               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Fosamax                |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                            | 6173913                | NON-EXPEDITED    | Y                  |                 | S06-USA-02147-01     |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gait Disturbance                       | Namenda                |                  |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                        | Namenda                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                        | Lexapro                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                        | Razadyne               |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2006                            | 6179370                | NON-EXPEDITED    | N                  |                 | S06-USA-01867-01     |                      | 89 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue                                | Namenda                |                  |                    | S               | Oral                 | 5 Mg Qs Po           |                 | Not Reported |                |
|                                        | Namenda                |                  |                    | S               | Oral                 | 5 Mg Bid Po          |                 | Not Reported |                |
|                                        | Lexapro                |                  |                    | S               | Oral                 | 15 Mg Qhs Po         |                 | Not Reported |                |
|                                        | Aricept                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Plavix                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Norvasc                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Premarin               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                        | Ambien                 |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Aug-2006                                                                                                                                                                                                                                      | 6112346                     | DIRECT             | N                  | OT              |                      |                      | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Affect Lability; Aggression; Cold Sweat; Depression; Disturbance In Attention; Drug Withdrawal Syndrome; Inappropriate Schedule Of Product Administration; Loss Of Personal Independence In Daily Activities; Suicidal Ideation | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg Once Day Po    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2006                                                                                                                                                                                                                                      | 6114356                     | EXPEDITED (15-DAY) | Y                  | HO              | S06-UKI-03127-01     |                      | 76 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Intertrigo; Rash Generalised; Rash Pustular; Skin Abrasion                                                                                                                                                                              | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | L-Thyroxine (Levothyroxine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Dipyridamole                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Furosemide                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Atorvastatin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Spiriva                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Symbicort                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2006                                                                                                                                                                                                                                      | 6094664                     | EXPEDITED (15-DAY) | Y                  | OT              | L06-GER-02656-01     |                      | 22 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Myoclonus                                                                                                                                                                                                                      | Escitalopram Oxalate        |                    |                    | S               |                      | 30 Mg Daily          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                  | Lamotrigine                 |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                 |                              | Lamotrigine        |                    | S               |                      | 100 Mg Qd            |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                 |                              | Lamotrigine        |                    | S               |                      | 250 Mg Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2006                                                                                                                                                                     | 6104396                      | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-03073-01     |                      | 55 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Myocardial Ischaemia; Productive Cough                                                                                                                          | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                 | Stagid (Metformin Embonate)  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Trandate                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Zocor                        |                    |                    | S               | Oral                 | 40 Mg 1qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                 | Tareg                        |                    |                    | S               | Oral                 | 80 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                 | Plavix                       |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                 | Aspirin                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Repaglinide                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2006                                                                                                                                                                     | 6108953                      | EXPEDITED (15-DAY) | Y                  | DS              | S06-DEN-03089-01     |                      | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Fatigue; Initial Insomnia; Malaise; Middle Insomnia; Muscle Contractions Involuntary; Nausea; Night Sweats; Nightmare; Poor Quality Sleep; Weight Decreased | Cipralext                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                 | Cipralext                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                 | Mirtazapine                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Stilnoct (Zolpidem Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                 | Alopam (Oxazepam)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2006                                                                                                                                                                     | 6007630                      | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-00810-01     |                      | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                    |                      |   |      |             |  |  |  |  |              |
|--------------------|----------------------|---|------|-------------|--|--|--|--|--------------|
| Rectal Haemorrhage | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po |  |  |  |  | Not Reported |
|                    | Risperdal            | C |      |             |  |  |  |  | Not Reported |
|                    | Lormetazepam         | C |      |             |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2006              | 6069055       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-02007-01     |                      | 49 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Drug Interaction; Haemoglobin Decreased; Rectal Haemorrhage | Escitalopram Oxalate   |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                        | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                        | Previscan (Fluindione) |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                        | Prazepam               |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Innohep                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2006              | 6069057       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-02006-01     |                      | 49 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Drug Interaction; Haemoglobin Decreased; Phlebitis; Rectal Haemorrhage | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                   | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                   | Prazepam             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2006              | 6071599       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02141-01     |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| No Adverse Event      | Lexapro                |              |            | S           | Oral         | 25 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro                |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                       | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
|                       | Diuretics              |              |            | C           |              |                    |                 | Not Reported |
|                       | Potassium              |              |            | C           |              |                    |                 | Not Reported |
|                       | Vitamins               |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 17-Aug-2006                                                                                                            | 6108192                            | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-03076-01     |                      | 69 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Cardiac Valve Vegetation;<br>Drug Eruption; Erythema;<br>Hyperthermia; Rash<br>Macular; Urticaria;<br>Vascular Purpura | Escitalopram Oxalate<br>Vancomycin |                    |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 17-Aug-2006                                                                                                            | 6117933                            | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-03223-01     |                      | 31 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide;<br>Thinking Abnormal                                                                                | Lexapro                            |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Aug-2006                                                                                                            | 6064047                            | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01735-01     |                      | 54 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Blood Pressure Increased;<br>Headache                                                                                  | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                                        | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                                        | Lexapro                            |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported                 |                |
|                                                                                                                        | Ativan                             |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                                                                        | Metoprolol                         |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                                                                        | Diovan Hct                         |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                                                                        | Hydrochlorothiazide                |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Aug-2006                                                                                                            | 6093120                            | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02724-01     |                      | 50 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |            |   |      |              |              |
|-------------------------------------------------|------------|---|------|--------------|--------------|
| Abnormal Behaviour; Loss Of Employment;         | Lexapro    | S | Oral | 20 Mg Bid Po | Not Reported |
| Obsessive-Compulsive Disorder; Trichotillomania | Lexapro    | S | Oral | 20 Mg Qd Po  | Not Reported |
|                                                 | Lexapro    | S | Oral | 10 Mg Qd Po  | Not Reported |
|                                                 | Lexapro    | S | Oral | 10 Mg Qod Po | Not Reported |
|                                                 | Glucophage | C |      |              | Not Reported |
|                                                 | Inderal    | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2006              | 6094367       | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWI-02669-01     |                      | 36 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; Hepatocellular Injury; Serum Ferritin Increased | Cipralext      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                            | Seroquel       |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |
|                                                            | Exjade         |              |            | S           |              | 1500 Mg Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Aug-2006              | 6035749       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-00386-01     |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                    | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acid Base Balance                                                                                                                                                                                                                                                                                                        | Lexapro                     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Pressure Decreased; Blood Sodium Decreased; Blood Urea Increased; Breath Sounds Abnormal; Cardiac Failure; Cardio-Respiratory Arrest; Coagulation Factor V Level Decreased; Coagulation Factor Vii | Coumadin                    |              |            | S           |              | 5 Mg               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Ativan                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Heparin                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Lovenox                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | Norco                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                          | (Hydrocodone/Acetaminophen) |              |            |             |              |                    |                 |              |
|                                                                                                                                                                                                                                                                                                                          | Lasix                       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Level Decreased;  
Coagulation Factor X  
Level Decreased; Drug  
Interaction; Heart Rate  
Increased;  
Hypercalcaemia;  
International Normalised  
Ratio Increased; Lipase  
Increased; Metabolic  
Acidosis; Pericardial  
Effusion; Peripheral  
Coldness; Pleural  
Effusion;  
Postpericardiotomy  
Syndrome; Prothrombin  
Level Decreased; Urine  
Output Decreased;  
Ventricular Extrasystoles;  
Ventricular Fibrillation;  
Vomiting; White Blood Cell  
Count Increased

| <u>FDA Received Date</u>                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 21-Aug-2006                                        | 6117442                       | DIRECT             | N                  | OT              |                      |                       | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen False<br>Positive                      | Lexapro                       |                    |                    | S               | Oral                 | 10 One By Mouth Od Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2006                                        | 6119980                       | EXPEDITED (15-DAY) | Y                  | HO              | 8018352              |                       | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Pressure<br>Increased; Chest Pain; | Methylphenidate Hydrochloride |                    |                    | S               | Oral                 | 10 Mg Twice Po        |                 | Not Reported |                |
| Dizziness; Drug<br>Intolerance; Flushing;          | Venlafaxine                   |                    |                    | S               | Oral                 | 75 Mg /D Po           | 2 DAY           | Not Reported |                |
| Hallucination; Headache;                           | Venlafaxine                   |                    |                    | S               | Oral                 | 150 Mg /D Po          | 1 DAY           | Not Reported |                |
|                                                    | Venlafaxine                   |                    |                    | S               | Oral                 | 225 Mg /D Po          | 4 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                                                                                                        |                            |      |             |                                                                                              |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------|------|-------------|----------------------------------------------------------------------------------------------|
| Hyperventilation; Lethargy;<br>Movement Disorder; Pain;<br>Pallor; Pharyngeal<br>Erythema; Serotonin<br>Syndrome | Escitalopram Oxalate<br>Lithium<br>Lamotrigine<br>Trazodone Hydrochloride<br>Mirtazapine<br>Gabapentin | S<br>C<br>C<br>C<br>C<br>C | Oral | 10 Mg /D Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------|------|-------------|----------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2006              | 6111237       | EXPEDITED (15-DAY) | Y                  | RI              | S06-USA-02961-01     |                      | 76 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Deafness; Ear<br>Congestion; Ear<br>Discomfort; Ear Infection;<br>Insomnia; Middle Ear<br>Effusion; Muscle<br>Tightness; Nasal<br>Congestion; Productive<br>Cough; Rhinorrhoea | Lexapro<br>Zestril<br>Atenolol<br>Lipitor<br>Flomax |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2006              | 6120914       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03230-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcoholism; Legal Problem | Campral        |              |            | S           | Oral         | 666 Mg Tid Po      |                 | Not Reported |
|                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2006              | 6113473       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-03036-01     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                      |
|-------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|-------------------------------------------------|
| Gestational Diabetes;<br>Haemorrhage In<br>Pregnancy; Normal<br>Newborn; Peripartum | Wellbutrin Xi<br>Lexapro<br>Prenatal Vitamins |              |            | S<br>S<br>C | Oral<br>Oral | 300mg Per Day<br>20mg Per Day |                 | Glaxosmithkline<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haemorrhage

| <u>FDA Received Date</u>         | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------|---------------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 23-Aug-2006                      | 6113772             | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0608387A |                      | 52 YR           | Male            | USA            |
| <u>Preferred Term</u>            | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Disorientation;<br>Fall | Malarone            |                  |                    | S               | Oral                                 | 1tab Per Day         | 3 DAY           | Glaxosmithkline |                |
|                                  | Lexapro             |                  |                    | S               | Oral                                 | 10mg Per Day         |                 | Not Reported    |                |
|                                  | Diovan              |                  |                    | C               | Oral                                 | 320mg Twice Per Day  |                 | Not Reported    |                |
|                                  | Hydrochlorothiazide |                  |                    | C               | Oral                                 | 25mg Twice Per Day   |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Aug-2006                                                                                                                                                                                                                                                                      | 6122550           | EXPEDITED (15-DAY) | N                  | OT              | DSA_28575_2006       |                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Blood<br>Pressure Increased; Chest<br>Discomfort; Drug<br>Withdrawal Syndrome; Dry<br>Mouth; Headache;<br>Inappropriate Schedule Of<br>Product Administration;<br>Insomnia; Nausea;<br>Palpitations; Sensation Of<br>Foreign Body; Treatment<br>Noncompliance | Ativan            |                    |                    | S               | Oral                 | 0.5 Mg Qid Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Lexapro           |                    |                    | S               | Oral                 | 5 Mg Once Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Cardizem          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Dyazide           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Tenormin          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Vitamin E         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Calcium Gluconate |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Aspirin           |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Aug-2006                                                           | 5804716        | EXPEDITED (15-DAY) | Y                  | OT              | 8010447              |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During<br>Pregnancy; Placenta<br>Praevia; Pregnancy | Keppra         |                    |                    | S               | Oral                 | 1000 Mg/D Po         |                 | Not Reported |                |
|                                                                       | Keppra         |                    |                    | S               | Oral                 | 1500 Mg/D Po         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                   |   |      |              |              |
|-------------------|---|------|--------------|--------------|
| Lexapro           | S | Oral | 20 Mg /D Po  | Not Reported |
| Seroquel          | S | Oral | 100 Mg /D Po | Not Reported |
| Baby Aspirin      | S | Oral | Po           | Not Reported |
| Prenatal Vitamins | S | Oral | Po           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2006              | 6091155       | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | 2006082942           |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|---------------|-------------------------------------------|-----------------|--------------|
| Fall; Loss Of Consciousness | Geodon         |              |            | S           |               | 160 Mg (160 Mg, 1 In 1 D),                |                 | Not Reported |
|                             | Lexapro        |              |            | S           | Oral          | 20 Mg (20 Mg, 1 In 1 D), Oral             |                 | Not Reported |
|                             | Cogentin       |              |            | S           | Oral          | 2 Mg (2 Mg, 1 In 1 D), Oral               |                 | Not Reported |
|                             | Haldol         |              |            | S           | Intramuscular | 150 Mg (150 Mg, 1 In 4 Wk), Intramuscular |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2006              | 6121170       | DIRECT           | Y                  | HO, RI          |                      |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acne; Infection; Skin Toxicity; Subcutaneous Abscess; Therapy Non-Responder | Iressa         |              |            | S           | Oral         | 250 Mg Daily Po    |                 | Not Reported |
|                                                                             | Prednisone     |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |
|                                                                             | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |
|                                                                             | Levoxyl        |              |            | S           | Oral         | 75 Mg Daily Po     |                 | Not Reported |
|                                                                             | Pepcid         |              |            | S           | Oral         | 20 Mg Daily Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2006              | 6121810       | DIRECT           | Y                  | HO, LT          |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                             |           |   |      |                                     |              |
|---------------------------------------------------------------------------------------------|-----------|---|------|-------------------------------------|--------------|
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Neonatal<br>Seizure; Posturing | Lexapro   | S | Oral | 10 Mg Daily Po At Least 9<br>Months | Not Reported |
|                                                                                             | Ephedrine | C |      |                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2006              | 6013137       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01049-01     |                      | 15 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cough; Haematemesis;<br>Upper Respiratory Tract<br>Infection; Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                        | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                        | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2006              | 6020051       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01155-01     |                      | 86 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Gastrointestinal<br>Angiodysplasia;<br>Haematocrit Decreased;<br>Platelet Count Decreased | Lexapro                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                | Coumadin                |              |            | S           |              | 2 Mg Qd            |                 | Not Reported |
|                                                                                                                | Aspirin                 |              |            | S           |              | 325 Mg Qd          |                 | Not Reported |
|                                                                                                                | Verapamil Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Arsenic                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                | Melphalan               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2006              | 6094983       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-02768-01     |                      | 22 YR      | Male       | USA            |

  

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Body Temperature<br>Increased; Drug<br>Interaction; Vomiting | Lexapro        |              |            | S           |               |                    |                 | Not Reported |
|                                                                                       | Demerol        |              |            | S           | Intramuscular | 50 Mg Im           |                 | Not Reported |
|                                                                                       | Trileptal      |              |            | C           |               |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 25-Aug-2006                                                                                                                                                                         | 6120590                           | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-03346-01     |                                       | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Coma; Coronary Artery<br>Bypass; Multiple Organ<br>Dysfunction Syndrome;<br>Ventricular Fibrillation                                                  | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg Qd Po                           |                 | Not Reported |                |
|                                                                                                                                                                                     | Bisoprolol Fumarate               |                    |                    | S               | Oral                 | 1 Qd Po                               |                 | Not Reported |                |
|                                                                                                                                                                                     | Perindopril Erbumine              |                    |                    | S               | Oral                 | 2 Mg Qd Po                            |                 | Not Reported |                |
|                                                                                                                                                                                     | Glucophage                        |                    |                    | S               | Oral                 | 850 Mg Tid Po                         |                 | Not Reported |                |
|                                                                                                                                                                                     | Lasilix (Furosemide)              |                    |                    | S               | Oral                 | 1 Tablet Qd Po                        |                 | Not Reported |                |
|                                                                                                                                                                                     | Pravastatin                       |                    |                    | S               | Oral                 | 20 Mg Qd Po                           |                 | Not Reported |                |
|                                                                                                                                                                                     | Aspegic [Acetylsalicylate Lysine] |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Dafalgan (Paracetamol)            |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Gliclazide                        |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Acarbose                          |                    |                    | C               |                      |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2006                                                                                                                                                                         | 6064076                           | EXPEDITED (15-DAY) | N                  | OT              | 2006066943           |                                       | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol<br>Increased;<br>Cerebrovascular Accident;<br>Chest Pain; Depression;<br>Dyspnoea; Emotional<br>Disorder; Myocardial<br>Infarction; Transient<br>Ischaemic Attack | Bextra                            |                    |                    | S               |                      | Unknown (1-2 Times A<br>Day); Unknown |                 | Not Reported |                |
|                                                                                                                                                                                     | Vioxx                             |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Lexapro                           |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Lorcet Plus                       |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                                                     | Lipitor                           |                    |                    | C               |                      |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2006                                                                                                                                                                         | 6074948                           | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-02369-01     |                                       | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence;                                                                                                                                                                 | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 15 Mg Qd Po                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Retinal Vein Occlusion

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2006              | 6109298       | EXPEDITED (15-DAY) | Y                  | HO              | T06-CAN-03124-01     |                      | 57 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Renal Cell Carcinoma  | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                       | Norfloxacin            |              |            | C           |              |                    |                 | Not Reported |
|                       | Percocet               |              |            | C           |              |                    |                 | Not Reported |
|                       | Levaquin               |              |            | C           |              |                    |                 | Not Reported |
|                       | Septra Ds              |              |            | C           |              |                    |                 | Not Reported |
|                       | Tylenol Extra Strength |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2006              | 6116920       | NON-EXPEDITED    | Y                  |                 | S06-USA-01834-01     |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Alopecia              | Wellbutrin XI  |              |            | S           | Oral         | 150mg Per Day      |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |
|                       | Hyzaar         |              |            | C           | Oral         | 50mg Per Day       |                 | Not Reported    |
|                       | Klonopin       |              |            | C           | Oral         | .5mg As Required   |                 | Not Reported    |
|                       | Vistaril       |              |            | C           | Oral         | 25mg As Required   |                 | Not Reported    |
|                       |                |              |            |             |              |                    |                 |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2006              | 6119375       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-USA-03204-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coagulopathy;<br>Hypertension; Transient<br>Ischaemic Attack | Lexapro                |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                              | Effexor                |              |            | S           |              |                    |                 | Not Reported |
|                                                              | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Aug-2006              | 6122139       | DIRECT           | N                  | OT              |                      |                      | 30 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Aggression                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 1 Once A Day Po      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2006                                                                                                                                                         | 6076269                 | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-02235-01     |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound; Head Injury; Maternal Exposure During Pregnancy; Product Dose Omission; Refusal Of Treatment By Patient; Treatment Noncompliance | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2006                                                                                                                                                         | 6126342                 | EXPEDITED (15-DAY) | Y                  |                 | S06-USA-03415-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Hyponatraemia                                                                                                                             | Lexapro                 |                    |                    | S               | Oral                 | 60 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Trileptal               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Seroquel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Fentanyl Patch          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                     | Unspecified Ingredient  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2006                                                                                                                                                         | 6177311                 | NON-EXPEDITED      | N                  |                 | S06-USA-02083-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dyspepsia; Flatulence                                                                                                                                    | Campral                 |                    |                    | S               | Oral                 | 666 Mg Tid Po        |                 | Not Reported |                |
|                                                                                                                                                                     | Lexapro                 |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                     | Minocycline\Minocycline |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hydrochloride  
Xanax

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2006              | 6079829       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02444-01     |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Withdrawal Syndrome; Muscle Twitching | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qod Po       |                 | Not Reported |
|                                                       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                       | Lexapro        |              |            | S           | Oral         | 5 Mg Po            |                 | Not Reported |
|                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                       | Benicar        |              |            | C           |              |                    |                 | Not Reported |
|                                                       | Crestor        |              |            | C           |              |                    |                 | Not Reported |
| Zantac                                                |                |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2006              | 6127001       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03411-01     |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Irritability; Mania; Paranoia | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                           | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2006              | 7136013       | DIRECT           | Y                  |                 |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Back Pain; Chest Pain; Pain | Actonel        |              |            | S           | Oral         | 35 Mg 1q Week Po [Only One Dose Taken] |                 | Not Reported |
|                             | Toprol XL      |              |            | S           |              |                                        |                 | Not Reported |
|                             | Lexapro        |              |            | S           |              |                                        |                 | Not Reported |
|                             | Midrin         |              |            | C           |              |                                        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|---------------------------------------|-----------------|--------------|----------------|
| 31-Aug-2006                                                                                                                                                            | 6106253        | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20060800535 |                                       | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Benign Breast Neoplasm;<br>Breast Cyst; Breast<br>Discharge; Intentional<br>Self-Injury; Suicidal<br>Ideation                                                          | Risperdal      |                    |                    | S               |                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                        | Lexapro        |                    |                    | S               | Oral                  |                                       |                 | Not Reported |                |
|                                                                                                                                                                        | Lexapro        |                    |                    | S               | Oral                  |                                       |                 | Not Reported |                |
|                                                                                                                                                                        | Depakote Er    |                    |                    | S               |                       |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2006                                                                                                                                                            | 6123764        | DIRECT             | N                  | HO, LT          |                       |                                       | 13 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Anxiety;<br>Hallucination; Ill-Defined<br>Disorder; Mania;<br>Nervousness;<br>Restlessness; Suicide<br>Attempt; Thinking<br>Abnormal | Lexapro        |                    |                    | S               | Oral                  | 20mg Once A Day Po                    |                 | Not Reported |                |
|                                                                                                                                                                        | Zoloft         |                    |                    | S               | Oral                  | 100mg Once A Day Po                   |                 | Pfizer       |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2006                                                                                                                                                            | 6125078        | DIRECT             | N                  |                 |                       |                                       | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia                                                                                                                                                                | Lexapro        |                    |                    | S               | Oral                  | One 5-Mg Tab Per Day<br>Once Daily Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Aug-2006                                                                                                                                                            | 6126660        | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-03383-01      |                                       | 54 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                      |   |      |              |              |
|--------------------------|----------------------|---|------|--------------|--------------|
| Blood Glucose Increased; | Ciprallex            | S | Oral | 20 Mg Qd Po  | Not Reported |
| Electrocardiogram        | Clozapine            | S | Oral | 700 Mg Qd Po | Not Reported |
| Abnormal;                | Lamotrigine          | C |      |              | Not Reported |
| Electrocardiogram Qt     | Levothyroxine Sodium | C |      |              | Not Reported |
| Prolonged; Orthostatic   | Zopiclone            | C |      |              | Not Reported |
| Hypotension; Respiratory |                      |   |      |              |              |
| Rate Increased           |                      |   |      |              |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2006              | 6108955       | EXPEDITED (15-DAY) | Y                  | HO              | S06-GER-03084-01     |                      | 35 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematochezia         | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2006              | 6125127       | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Akathisia; Depressed    | Lexapro        |              |            | S           | Oral         | Lexapro 10 Mg Po Q 24 H |                 | Not Reported |
| Level Of Consciousness; | Nexium         |              |            | C           |              |                         |                 | Not Reported |
| Dyskinesia; Loss Of     | Synthroid      |              |            | C           |              |                         |                 | Not Reported |
| Consciousness;          | Centrum Mvi    |              |            | C           |              |                         |                 | Not Reported |
| Somnolence              |                |              |            |             |              |                         |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2006              | 6125459       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-03350-01     |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acquired Haemophilia;          | Escitalopram Oxalate             |              |            | S           | Oral         | 1 Units Qd Po      |                 | Not Reported |
| Activated Partial              | Fluidione                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Thromboplastin Time            | Pulmicort Flexhaler              |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Acute Coronary       | Combivent                        |              |            | C           |              |                    |                 | Not Reported |
| Syndrome; Anaemia; Anti        | Flecainide Acetate               |              |            | C           |              |                    |                 | Not Reported |
| Factor Viii Antibody           | Josir (Tamsulosin Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
| Positive; Atrial Fibrillation; |                                  |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                       |                   |        |  |  |  |  |  |  |                              |
|-----------------------------------------------------------------------------------------------------------------------|-------------------|--------|--|--|--|--|--|--|------------------------------|
| Condition Aggravated;<br>Haematoma;<br>Haemorrhage;<br>International Normalised<br>Ratio Increased;<br>Rhabdomyolysis | Aricept<br>Epogen | C<br>C |  |  |  |  |  |  | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------|-------------------|--------|--|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2006              | 6127623       | EXPEDITED (15-DAY) | Y                  | OT              | S06-GER-03394-01     |                      | 36 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|----------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Ciprallex<br>Ciprallex |              |            | S<br>S      | Oral         | 20 Mg Qd Po        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2006              | 6129057       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-03466-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2006              | 6072585       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-02204-01     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------|--------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------------------------|
| Completed Suicide; Gun<br>Shot Wound | Lexapro<br>Lexapro |              |            | S<br>S      | Oral<br>Oral | 20 Mg Qd;Po<br>10 Mg Qd; Po |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2006              | 6108579       | EXPEDITED (15-DAY) | N                  | HO, LT, RI      | S06-USA-02938-01     |                      | 67 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bladder Cancer; Cardiac<br>Murmur; Coronary Arterial | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                           |   |      |             |              |
|------------------------------------------------------------------------------------|---------------------------|---|------|-------------|--------------|
| Stent Insertion; Drug Ineffective; Myocardial Infarction; Ureteral Stent Insertion | Lexapro                   | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                                                    | Lexapro                   | S | Oral | 50 Mg Qd Po | Not Reported |
|                                                                                    | Pilocarpine Hydrochloride | C |      |             | Not Reported |
|                                                                                    | Lipitor                   | C |      |             | Not Reported |
|                                                                                    | Colace                    | C |      |             | Not Reported |
|                                                                                    | Aspirin                   | C |      |             | Not Reported |
|                                                                                    | Sodium Bicarbonate        | C |      |             | Not Reported |
|                                                                                    | Folic Acid                | C |      |             | Not Reported |
|                                                                                    | Calcium Gluconate         | C |      |             | Not Reported |
|                                                                                    | Ferrous Sulfate           | C |      |             | Not Reported |
|                                                                                    | Multi-Vitamin             | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2006              | 6125899       | DIRECT           | Y                  | OT              |                      |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Anembryonic Gestation; Caesarean Section; Foetal Death; Haemoglobin Decreased; Haemorrhage In Pregnancy; Maternal Exposure During Pregnancy | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po          |                 | Not Reported |
|                                                                                                                                             | Wellbutrin XL  |              |            | S           | Oral         | 150 Mg 2 Tabs Qam Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2006              | 6129474       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-03465-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Hypomania; Psychotic Disorder | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                 | Strattera      |              |            | S           |              | 100 Mg Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2006              | 6129477       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-02796-01     |                      | 75 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Abdominal Pain Upper;<br>Anxiety; Confusional<br>State; Constipation;<br>Decreased Appetite;<br>Dementia; Depressed<br>Level Of Consciousness;<br>Drug Ineffective; Memory<br>Impairment; Muscle<br>Spasms | Lexapro                |                    |                    | S               | Oral                                 | 40 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                                            | Lexapro                |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                                            | Razadyne               |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                            | Lunesta                |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 05-Sep-2006                                                                                                                                                                                                | 6131539                | DIRECT             | Y                  | DS              |                                      |                      | 75 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Thrombocytopenia                                                                                                                                                                                           | Escitalopram Oxalate   |                    |                    | S               | Oral                                 | 10mg Daily Po        | 4 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 06-Sep-2006                                                                                                                                                                                                | 7385668                | EXPEDITED (15-DAY) | N                  | HO              | US-JNJFOC-<br>20060900247            |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Anxiety;<br>Confusional State; Drug<br>Interaction; Motor<br>Dysfunction; Seizure                                                                                                                 | Tramadol Hydrochloride |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                            | Lexapro                |                    |                    | S               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 06-Sep-2006                                                                                                                                                                                                | 7385702                | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0609224A |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Drug Interaction;<br>Oral Pain; Teeth Brittle                                                                                                                                                    | Requip                 |                    |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                            | Lexapro                |                    |                    | S               | Oral                                 |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Sep-2006                                                                                                                                                   | 6094669                 | EXPEDITED (15-DAY)        | Y                           | DS, HO                   | S06-FRA-02858-01              |                               | 26 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State;<br>Disorientation; Dyskinesia;<br>Impaired Work Ability;<br>Refusal Of Treatment By<br>Patient; Social Avoidant<br>Behaviour; Tic; Trismus | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                               | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                               | Lansoprazole            |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2006                                                                                                                                                   | 6123324                 | EXPEDITED (15-DAY)        | Y                           | HO                       | CH-JNJFOC-20060900125         |                               | 65 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Somnolence; Toxicity To<br>Various Agents                                                                                                                     | Risperdal               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                               | Lormetazepam            |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                               | Cipralext               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                               | Aspirin                 |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                               | Norvasc                 |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Sep-2006                                                                                                                                                   | 6132295                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-UKI-03567-01              |                               | 42 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Scintillating Scotoma                                                                                                                                         | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Sep-2006                                                                                                                                                   | 6135038                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-SWI-03573-01              |                               | 55 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                                                                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                        |   |      |             |              |
|----------|------------------------|---|------|-------------|--------------|
| Epilepsy | Cipralext              | S | Oral | 10 Mg Qd Po | Not Reported |
|          | Cipralext              | S | Oral | 5 Mg Qd Po  | Not Reported |
|          | Unspecified Ingredient | S |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2006              | 6105695       | EXPEDITED (15-DAY) | N                  | HO              | US-ABBOTT-06P-163-0339293-00 |                      |            | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Benign Breast Neoplasm;      | Depakote Er    |              |            | S           |              |                    |                 | Not Reported |
| Breast Cyst; Breast Cyst     | Depakote Er    |              |            | S           |              |                    |                 | Not Reported |
| Drainage; Intentional        | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
| Overdose; Intentional Self-  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Injury; Self-Injurious       | Risperidone    |              |            | S           |              |                    | 4 YR            | Not Reported |
| Ideation; Suicidal Ideation; |                |              |            |             |              |                    |                 | Not Reported |
| Suicide Attempt              |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2006              | 6115950       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ABBOTT-06P-163-0341064-00 |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Benign Breast Neoplasm;      | Depakote Er    |              |            | S           |              |                    |                 | Not Reported |
| Breast Cyst; Breast          | Depakote Er    |              |            | S           |              |                    |                 | Not Reported |
| Discharge; Intentional       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Intentional Self-  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Injury; Self-Injurious       | Risperidone    |              |            | S           |              |                    | 4 YR            | Not Reported |
| Ideation; Suicidal Ideation; |                |              |            |             |              |                    |                 | Not Reported |
| Suicide Attempt              |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2006              | 6068773       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-02078-01     |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Increased; Aspartate     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Aminotransferase         |                |              |            |             |              |                    |                 |              |
| Increased; Blood Lactate |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |                          |        |      |             |              |
|--------------------------------------------------------------------------|--------------------------|--------|------|-------------|--------------|
| Dehydrogenase Increased; Dizziness; Headache; Nausea; Neck Pain; Pyrexia | Lexapro<br>Inhaler (Nos) | S<br>C | Oral | 10 Mg Qd Po | Not Reported |
|                                                                          |                          |        |      |             | Not Reported |

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Sep-2006                                                                                               | 6077035        | EXPEDITED (15-DAY) | Y                  | HO              | T06-SWI-02397-01     |                      | 22 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Abnormal; Epilepsy; Generalised Tonic-Clonic Seizure; Schizophrenia; Treatment Noncompliance | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Seroquel       |                    |                    | S               | Oral                 | 600 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                           | Tegretol       |                    |                    | S               | Oral                 | 400 Mg Qd Po         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Sep-2006                                                                                                                                                                                                                                                                                                          | 6137792               | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-00440-01     |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alpha Globulin Increased; Haematocrit Decreased; Haemoglobin Decreased; Hypergammaglobulinaemia; Hypoalbuminaemia; Laboratory Test Abnormal; Mean Cell Volume Increased; Myelocyte Percentage Increased; Protein Total Increased; Red Blood Cell Count Decreased; Thrombocytopenia; White Blood Cell Count Decreased | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Insulatard Nph Human  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Glcophage (Metformin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Zolpidem Tartrate     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Noctran 10            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Ferrous Sulfate       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                      | Elevit Vitamine B9    |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 13-Sep-2006              | 6126553       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20060902269 |                      | 57 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------|-----------------|--------------|----------------|
| Brain Oedema; Death;<br>Pulmonary Oedema;<br>Toxicity To Various Agents | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Oxycodone                     |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Phentermine                   |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate          |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Unspecified Ingredient        |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2006                                                             | 6126840                       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20060902039 |                         | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                              | Topiramate                    |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Quetiapine                    |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate          |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Hctz                          |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Iron                          |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
|                                                                         | Glucophage                    |                    |                    | S               | Oral                  |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2006                                                             | 6076366                       | EXPEDITED (15-DAY) | N                  | HO, LT          | S06-USA-02306-02      |                         |                 | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During<br>Pregnancy; Premature<br>Baby                | Lexapro                       |                    |                    | S               | Transplacental        | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                         | Methadone Hydrochloride       |                    |                    | C               |                       |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2006                                                             | 6112430                       | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2006US10511       |                         | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                              |          |   |      |           |          |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|------|-----------|----------|--------------|
| Chest Pain; Depressed Level Of Consciousness; Fear; Feeling Abnormal; Headache; Hyperhidrosis; Hypotension; Loss Of Consciousness; Tremor; Visual Impairment | Diovan   | S | Oral | 80 Mg, Qd | 4320 MIN | Novartis     |
|                                                                                                                                                              | Prilosec | C |      | Unk, Prn  |          | Not Reported |
|                                                                                                                                                              | Tagamet  | C |      | Unk, Prn  |          | Not Reported |
|                                                                                                                                                              | Lexapro  | S | Oral | 10 Mg, Qd |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2006              | 6127078       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-CAN-03104-01     |                      | 54 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaphylactic Reaction; Drug Hypersensitivity; Drug Ineffective | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Clonazepam     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 14-Sep-2006              | 6127580       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-13380589 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Agitation; Dyskinesia; Fatigue | Buspar               |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                                | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2006              | 6129475       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03464-01     |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Supraventricular Tachycardia | Lexapro                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                              | Lexapro                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                              | Multiple Medications (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2006              | 6137392       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-03606-01     |                      | 24 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hypertension; Pharyngitis<br>Streptococcal | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                            | Ortho Cyclen         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2006                                | 6137398              | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03548-01     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Atrophy; Mental<br>Status Changes | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                            | Multiple (Nos)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Sep-2006                                | 6138630              | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-03756-01     |                      | 72 YR           | Male         | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound       | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                            | Urbanyl              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2006                                | 6191952              | NON-EXPEDITED      | Y                  | HO              | S06-USA-01446-01     |                      | 77 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged          | Celexa               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                            | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2006                                | 6091045              | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02547-01     |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                              | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                            | Monopril             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                            | Synthroid            |                    |                    | C               |                      |                      |                 | Not Reported |                |



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|                                   |   |              |
|-----------------------------------|---|--------------|
| Prevacid                          | C | Not Reported |
| Fosamax                           | C | Not Reported |
| Dyazide                           | C | Not Reported |
| (Triamterene/Hydrochlorothiazide) |   |              |
| Coumadin                          | C | Not Reported |
| Amaryl                            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2006              | 6124204       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CHWYE731318AUG06     |                      | 43 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Intentional Overdose;<br>Pneumonia Aspiration | Enbrel                 |              |            | S           | Subcutaneous | Unknown            |                 | Not Reported |
|                                                                        | Enbrel                 |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                                        | Cipralext              |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                        | Voltaren               |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                        | Unspecified Ingredient |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                        | Tramadol Hydrochloride |              |            | S           |              | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2006              | 6207163       | NON-EXPEDITED    | Y                  | OT              | US-JNJFOC-20050805935 |                      | 43 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Therapeutic Response<br>Unexpected; Weight<br>Decreased | Topamax                              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                   | Lexapro                              |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                                                                   | Morphine Sulfate                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Clonidine                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Xanax                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Cannabis                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Nexium (Esomeprazole)                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Chemotherapy (Antineoplastic Agents) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------------------------|----------------|
| 19-Sep-2006                                    | 6130302                 | EXPEDITED (15-DAY) | N                  | HO, OT          | CA-ABBOTT-06P-028-0343572-00 |                      | 54 YR           | Male                         | CAN            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anaphylactic Reaction                          | Ciprallex<br>Clonazepam |                    |                    | S<br>C          |                              |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Sep-2006                                    | 6140028                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03687-01             |                      | 30 YR           | Female                       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Impaired Driving Ability                       | Lexapro                 |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Sep-2006                                    | 6140056                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03683-01             |                      | 30 YR           | Female                       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Akathisia; Headache;<br>Restless Legs Syndrome | Lexapro                 |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                | Lexapro                 |                    |                    | S               | Oral                         | 30 Mg Qd Po          |                 | Not Reported                 |                |
|                                                | Lexapro                 |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported                 |                |
|                                                | Lexapro                 |                    |                    | S               | Oral                         | 15 Mg Qd Po          |                 | Not Reported                 |                |
|                                                | Lexapro                 |                    |                    | S               | Oral                         | 14 Mg Qd Po          |                 | Not Reported                 |                |
|                                                | Clonazepam              |                    |                    | C               |                              |                      |                 | Not Reported                 |                |
|                                                | Birth Control Pills     |                    |                    | C               |                              |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-Sep-2006                                    | 6138466                 | DIRECT             | N                  | HO, LT, RI      |                              |                      | 26 YR           | Female                       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Suicide Attempt                                | Lexapro                 |                    |                    | S               | Oral                         | One A Day Po         |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------|-----------------|--------------|----------------|
| 20-Sep-2006                                                    | 6140151                  | EXPEDITED (15-DAY) | Y                  | OT              | FR-2006-027140                        |                           | 93 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura Non-Thrombocytopenic; Skin Discolouration; Skin Lesion | Sotalol Hydrochloride    |                    |                    | S               | Oral                                  | Oral                      |                 | Not Reported |                |
|                                                                | Calciparine              |                    |                    | S               | Subcutaneous                          | 0.2, 2x/Day, Subcutaneous |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate     |                    |                    | S               | Intravenous (not otherwise specified) | Intravenous               |                 | Not Reported |                |
|                                                                | Atarax                   |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                                                | Eupantol                 |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                                                | Oliclimonel              |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                                                | Inexium                  |                    |                    | C               |                                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2006                                                    | 6141276                  | EXPEDITED (15-DAY) |                    | HO              | 2006-147869-NL                        |                           | 69 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis; Drug Interaction                         | Mirtazapine              |                    |                    | S               |                                       | 60 Mg                     |                 | Not Reported |                |
|                                                                | Olanzapine               |                    |                    | S               |                                       | 5 Mg                      |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate     |                    |                    | S               |                                       | 5 Mg                      | 6 DAY           | Not Reported |                |
|                                                                | Tamsulosin Hydrochloride |                    |                    | C               |                                       |                           |                 | Not Reported |                |
|                                                                | Levothyroxine Sodium     |                    |                    | C               |                                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2006                                                    | 6093707                  | EXPEDITED (15-DAY) | Y                  | DE              | S06-DEN-02855-01                      |                           | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                   | Cipraxel                 |                    |                    | S               | Oral                                  | 15 Mg Qd Po               |                 | Not Reported |                |
|                                                                | Orlistat                 |                    |                    | S               | Oral                                  | 140 Mg Qd Po              |                 | Not Reported |                |
|                                                                | Ibuprofen                |                    |                    | C               |                                       |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------------|--------------------------|---------------------|-------------------------|
| 21-Sep-2006                                                                        | 6132348                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-ITA-03570-01              |                                      |                          | Male                | ITA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chronic Lymphocytic Leukaemia                                                      | Cipralext               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Sep-2006                                                                        | 6132388                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-GER-03562-01              |                                      | 60 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Urinary Retention                                                                  | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                          |                          | Not Reported        |                         |
|                                                                                    | Mirtazapine             |                           |                             | C                        |                               |                                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Sep-2006                                                                        | 6389951                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-SWI-03799-01              |                                      | 66 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alcoholism; Coordination Abnormal; Drug Abuser; Overdose; Sluggishness; Somnolence | Cipralext               |                           |                             | S                        | Oral                          | 20 Mg Qd Po                          |                          | Not Reported        |                         |
|                                                                                    | Lormetazepam            |                           |                             | S                        |                               |                                      |                          | Not Reported        |                         |
|                                                                                    | Risperdal               |                           |                             | S                        | Oral                          | 4 Mg Qd Po                           |                          | Not Reported        |                         |
|                                                                                    | Aspirin                 |                           |                             | C                        |                               |                                      |                          | Not Reported        |                         |
|                                                                                    | Norvasc                 |                           |                             | C                        |                               |                                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>        | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Sep-2006                                                                        | 6119691                 | EXPEDITED (15-DAY)        | N                           | HO                       | US-ROCHE-460948               |                                      | 44 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cerebrovascular Accident                                                           | Pegasys                 |                           |                             | S                        | Subcutaneous                  | Form Reported As Prefilled Syringes. | 40 DAY                   | Roche               |                         |
|                                                                                    | Copegus                 |                           |                             | S                        | Oral                          |                                      | 40 DAY                   | Roche               |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                       |                                           |                    |                    |                 |                      |                         |                 |                                              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|----------------------------------------------|----------------|
| Lexapro                                                                                                                                                                                                                                                                                                                                                                                               |                                           |                    | S                  |                 | Oral                 |                         |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 25-Sep-2006                                                                                                                                                                                                                                                                                                                                                                                           | 5941886                                   | EXPEDITED (15-DAY) | Y                  | OT              | S05-GER-05519-01     |                         | 44 YR           | Female                                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Diarrhoea Haemorrhagic                                                                                                                                                                                                                                                                                                                                                                                | Ciprallex                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 25-Sep-2006                                                                                                                                                                                                                                                                                                                                                                                           | 5953133                                   | EXPEDITED (15-DAY) | Y                  | LT, RI, OT      | S05 USA-05179-01     |                         | 18 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Caesarean Section;<br>Cervical Incompetence;<br>Dysmenorrhoea; Infection;<br>Lymphocyte Percentage<br>Decreased; Maternal<br>Exposure During<br>Pregnancy;<br>Nasopharyngitis;<br>Neutrophil Percentage<br>Increased; Placental<br>Disorder; Premature<br>Labour; Premature<br>Separation Of Placenta;<br>Rhesus Antibodies<br>Positive; Therapy Non-<br>Responder; Tocolysis;<br>Vaginal Haemorrhage | Lexapro<br>Prenatabs Fa<br>Epidural (Nos) |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po             |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 25-Sep-2006                                                                                                                                                                                                                                                                                                                                                                                           | 5954526                                   | EXPEDITED (15-DAY) | Y                  | DE              | S05-USA-05179-02     |                         | < 1 DAY         | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Foetal Heart Rate<br>Deceleration Abnormality;                                                                                                                                                                                                                                                                                                                                                        | Lexapro                                   |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                       |                   |   |              |
|-----------------------------------------------------------------------------------------------------------------------|-------------------|---|--------------|
| Infection; Maternal Exposure During Pregnancy; Placental Disorder; Premature Labour; Premature Separation Of Placenta | Prenatal Vitamins | C | Not Reported |
|-----------------------------------------------------------------------------------------------------------------------|-------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2006              | 6108954       | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-03072-01     |                      | 50 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Convulsive Threshold Lowered; Generalised Tonic-Clonic Seizure | Ciprallex                     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                      | Topamax                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Risperdal                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Clonazepam                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Detrol                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Ibuprofen                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Lithium                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Monistat (Miconazole Nitrate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2006              | 6142514       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-UKI-03790-01     |                      | 39 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Spontaneous; Ectopic Pregnancy; Maternal Exposure During Pregnancy | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2006              | 6142619       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-03690-01     |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cough; Crying; Decreased Appetite; Depressed Mood; Diarrhoea; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                               | Lexapro        |              |            | S           | Oral         | 7.5 Mg Qd Po       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |           |   |      |             |              |
|---------------------------|-----------|---|------|-------------|--------------|
| Disturbance In Attention; | Lexapro   | S | Oral | 5 Mg Qd Po  | Not Reported |
| Drug Dependence; Dry      | Lexapro   | S | Oral | 10 Mg Qd Po | Not Reported |
| Mouth; Headache; Hot      | Paxil     | C |      |             | Not Reported |
| Flush; Insomnia; Memory   | Synthroid | C |      |             | Not Reported |
| Impairment; Nausea;       |           |   |      |             |              |
| Paraesthesia; Self-       |           |   |      |             |              |
| Injurious Ideation;       |           |   |      |             |              |
| Thinking Abnormal;        |           |   |      |             |              |
| Uterine Leiomyoma;        |           |   |      |             |              |
| Vision Blurred; Weight    |           |   |      |             |              |
| Increased                 |           |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2006              | 6142687       | EXPEDITED (15-DAY) | Y                  | DS              | S06-UKI-03791-01     |                      | 39 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accident; Agitation;  | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Myoclonus; Nausea;    | Escitalopram Oxalate        |              |            | S           | Oral         | 7.5 Mg Qd Po       |                 | Not Reported |
| Tremor                | Escitalopram Oxalate        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Citalopram Hydrobromide     |              |            | C           |              |                    |                 | Not Reported |
|                       | Beclomethasone Dipropionate |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2006              | 6143913       | EXPEDITED (15-DAY) | N                  | OT              | HQWYE934320SEP06     |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Feeling Abnormal;          | Effexor Xr        |              |            | S           | Oral         | 150 Mg 3x Per 1 Day, Oral |                 | Not Reported |
| Impaired Work Ability;     | Depakote          |              |            | S           | Oral         | 500 Mg 3x Per 1 Day, Oral |                 | Not Reported |
| Morbid Thoughts;           | Lexapro           |              |            | S           | Oral         | 10 Mg 3x Per 1 Day, Oral  |                 | Not Reported |
| Therapeutic Product Effect | Vistaril          |              |            | S           | Oral         | 50 Mg X 3-4 Hs, Oral      |                 | Not Reported |
| Decreased                  | Alcohol (Ethanol) |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2006              | 6141860       | DIRECT           | N                  | LT              |                      |                      | 42 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Psychotic Disorder; Suicidal Ideation | Celexa         |              |            | S           |              | 20 Mg. 1 X Day     |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           |              | 20 Mg 1 X Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2006              | 6144052       | EXPEDITED (15-DAY) | Y                  | DE              | 2006111647           |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Apnoea; Aspartate                                                                                                 | Pseudoephedrine Hydrochloride               |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Aminotransferase Increased; Blood Creatine Increased; Blood Creatine Phosphokinase Increased;                                                         | Ibuprofen (Ibuprofen)                       |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Blood Methaemoglobin Present; Blood Ph Decreased; Blood Potassium Increased; Body Temperature Increased;                                              | Acetylsalicylic Acid (Acetylsalicylic Acid) |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Carboxyhaemoglobin Increased; Cardio-Respiratory Arrest; Completed Suicide; Hypotension; Hypotonia; Loss Of Consciousness; Myoglobin Blood Increased; | Paracetamol+Codeine                         |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Ophthalmological Examination Abnormal; Overdose; Pco2 Increased; Po2 Increased; Subarachnoid Haemorrhage; Tachycardia; Urinary Retention              | Naproxen (Naproxen)                         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                       | Escitalopram Oxalate                        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                       | Cyclobenzaprine Hydrochloride               |              |            | S           | Oral         | Oral               |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Sep-2006                                                         | 6120972              | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-03239-01             |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide; Parent-Child Problem                   | Lexapro              |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                     | Seroquel             |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2006                                                         | 6138799              | EXPEDITED (15-DAY) | N                  | HO              | US-ABBOTT-06P-163-0344469-00 |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hypomania; Psychotic Disorder                     | Biaxin               |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                         |                      | 1 YR            | Not Reported |                |
|                                                                     | Strattera            |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2006                                                         | 6140794              | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-06P-163-0344438-00 |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Irritability; Suicidal Ideation                   | Lexapro              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                     | Alavert Allergy      |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2006                                                         | 6144779              | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-03829-01             |                      | 39 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy | Escitalopram Oxalate |                    |                    | S               | Oral                         | 15 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Sep-2006                       | 6145009           | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03739-01     |                      | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide                          | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                   | Aricept           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2006                       | 6145018           | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03860-01     |                      | 73 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                          | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                   | Lunesta           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Imdur             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2006                       | 6145021           | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03862-01     |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysuria; Urinary Retention        | Lexapro           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                   | Lisinopril        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2006                       | 6108952           | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-ESP-03094-01     |                      | 70 YR           | Female       | ESP            |
| <u>Preferred Term</u>             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cytomegalovirus Infection; Immune | Cipralext         |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Thrombocytopenic                  | Zolpidem Tartrate |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Purpura; Iron Deficiency          | Paracetamol       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Anaemia; Viral Infection          | Lansoprazole      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Lactulose         |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------|-----------------|------------|-----------------|
| 02-Oct-2006                                                                                                                                                                            | 6139787             | EXPEDITED (15-DAY) | Y                  | OT              | US-GLAXOSMITHKLINE-A0621483A |                           |                 | Male       | USA             |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                 |
| Agitation; Dry Mouth; Hallucination; Serotonin Syndrome                                                                                                                                | Wellbutrin XI       |                    |                    | S               | Oral                         | 300mg Per Day             |                 |            | Glaxosmithkline |
|                                                                                                                                                                                        | Lexapro             |                    |                    | S               |                              |                           |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 02-Oct-2006                                                                                                                                                                            | 6145045             | DIRECT             | Y                  |                 |                              |                           | 56 YR           | Female     | USA             |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                 |
| Medication Error; Product Dispensing Error                                                                                                                                             | Synthroid           |                    |                    | S               |                              | Tablet                    |                 |            | Boots           |
|                                                                                                                                                                                        | Lexapro             |                    |                    | S               |                              | Tablet                    |                 |            | Forest          |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 02-Oct-2006                                                                                                                                                                            | 6146398             | EXPEDITED (15-DAY) | N                  | OT              | 2006114136                   |                           |                 | Female     | USA             |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                 |
| Abnormal Behaviour; Alcohol Use; Amnesia; Feeling Abnormal; Hallucination; Ill-Defined Disorder; Malaise; Nightmare; Psychotic Disorder; Reading Disorder; Thinking Abnormal; Vomiting | Zoloft              |                    |                    | S               |                              | 100 Mg (100 Mg, 1 In 1 D) |                 |            | Not Reported    |
|                                                                                                                                                                                        | Seroquel            |                    |                    | S               |                              | 300 Mg (300 Mg, 1 In 1 D) |                 |            | Not Reported    |
|                                                                                                                                                                                        | Lexapro             |                    |                    | S               |                              |                           |                 |            | Not Reported    |
|                                                                                                                                                                                        | Atenolol (Atenolol) |                    |                    | C               |                              |                           |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                                                                                                               | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 04-Oct-2006                                                                                                                                                                            | 6112315             | EXPEDITED (15-DAY) | Y                  | OT              | S06-SWI-03122-01             |                           | 56 YR           | Female     | CHE             |
| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                 |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |                      |   |      |             |              |
|-----------------------------------------|----------------------|---|------|-------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Ciprallex            | S | Oral | 20 Mg Qd Po | Not Reported |
|                                         | Ciprallex            | S | Oral | 10 Mg Qd Po | Not Reported |
|                                         | Remeron              | S |      | 45 Mg Qd    | Not Reported |
|                                         | Remeron              | S |      | 22.5 Mg Qd  | Not Reported |
|                                         | Lorazepam            | C |      |             | Not Reported |
|                                         | Trittico (Trazodone) | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2006              | 6135468       | EXPEDITED (15-DAY) | Y                  | OT              | S06-SWI-03758-01     |                      | 44 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Diarrhoea; Haematemesis;<br>Nausea; Tachypnoea;<br>Tremor; Visual<br>Impairment; Vomiting | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2006              | 6147618       | EXPEDITED (15-DAY) | Y                  | HO              | 060926-0000826       |                      |            | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Coma; Intentional<br>Overdose; Suicide Attempt | Tranxene T-Tab        |              |            | S           | Oral         | Several Tablets; Po |                 | Not Reported |
|                                                | Escitalopram Oxalate  |              |            | S           | Oral         | 28 Tab; Po          |                 | Not Reported |
|                                                | Trimeprazine Tartrate |              |            | S           | Oral         | 2 Bot; Po           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2006              | 5995702       | EXPEDITED (15-DAY) | Y                  | HO              | S06-ITA-00438-01     |                      | 70 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood<br>Potassium Decreased;<br>Blood Sodium Decreased;<br>Contusion; Electrolyte | Ciprallex                 |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                              | Felodipine                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Irbesartan                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                              | Propafenone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imbalance; Fall; Injury; Karvea Hct C Not Reported  
Poverty Of Speech;  
Somnolence

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2006              | 6018999       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01074-01     |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Attention                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Deficit/Hyperactivity    | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Disorder; Diabetes       | Depakote       |              |            | C           |              |                    |                 | Not Reported |
| Mellitus; Hyperreflexia; |                |              |            |             |              |                    |                 |              |
| Hypoaesthesia;           |                |              |            |             |              |                    |                 |              |
| Intervertebral Disc      |                |              |            |             |              |                    |                 |              |
| Protrusion               |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2006              | 6146524       | EXPEDITED (15-DAY) | Y                  | HO              | S06-CZE-03806-01     |                      | 17 YR      | Female     | CZE            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Prolactin Increased; | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Dehydration; Depression;   | Ciprallex      |              |            | S           | Oral         | 7.5 Mg Qd Po       |                 | Not Reported |
| Disease Recurrence;        | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Galactorrhoea; Insomnia;   |                |              |            |             |              |                    |                 |              |
| Nausea                     |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2006              | 6149021       | EXPEDITED (15-DAY) | Y                  | DE, HO, LT, OT  | 29643                |                      | 24 YR      | Female     | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Arrhythmia;              | Flecainide Acetate   |              |            | S           | Oral         | 6 Gm (6 Gm, Once) Oral |                 | Not Reported |
| Atrioventricular Block   | Escitalopram Oxalate |              |            | S           | Oral         | 1 In 1 Day(S) Oral     |                 | Not Reported |
| Complete; Blood Creatine |                      |              |            |             |              |                        |                 |              |
| Phosphokinase Increased; |                      |              |            |             |              |                        |                 |              |
| Blood Potassium          |                      |              |            |             |              |                        |                 |              |
| Decreased; Blood         |                      |              |            |             |              |                        |                 |              |
| Pressure Decreased;      |                      |              |            |             |              |                        |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Sodium Increased;  
Body Temperature  
Increased; Bundle Branch  
Block Right; C-Reactive  
Protein Increased;  
Cardiogenic Shock; Drug  
Level Above Therapeutic;  
Electrocardiogram Qrs  
Complex Prolonged;  
Extrasystoles; Genital  
Discharge; Incorrect Dose  
Administered; Intentional  
Product Misuse; Loss Of  
Consciousness; Malaise;  
Nausea; Phlebectomy;  
Suicide Attempt; Tendon  
Rupture; Ventricular  
Tachycardia; Vertigo;  
White Blood Cell Count  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2006              | 6089036       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-02612-01     |                      | 47 YR      | Male       | FRA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Emphysema; Gas              | Escitalopram Oxalate |              |            | S           | Oral         | 25 Tablet Once Po  |                 | Not Reported |
| Poisoning; Intentional      | Escitalopram Oxalate |              |            | S           | Oral         | 1.5 Units Qd Po    |                 | Not Reported |
| Overdose; Intentional Self- | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Injury; Interstitial Lung   | Mopral (Omeprazole)  |              |            | C           |              |                    |                 | Not Reported |
| Disease; Pleural Effusion;  |                      |              |            |             |              |                    |                 |              |
| Suicide Attempt             |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2006              | 6148180       | DIRECT           | N                  | HO, RI          |                      |                      | 14 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Colitis Ulcerative;   |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Mental  
Disorder; Rectal  
Haemorrhage; Weight  
Decreased

| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Oct-2006                                                     | 6149020                 | DIRECT                    | N                           | OT                       |                               |                               | 28 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Nausea; Paraesthesia                                            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg 1x Daily Po             | 3 DAY                    | Forest              |                         |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Oct-2006                                                     | 6151587                 | DIRECT                    | Y                           | DE                       |                               |                               | 15 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Apnoea; Asphyxia; Cardio-<br>Respiratory Arrest;                | Lexapro                 |                           |                             | S                        | Unknown                       |                               |                          | Not Reported        |                         |
| Petechiae; Pulse Absent;<br>Pupil Fixed; Skin<br>Discolouration | Seroquel                |                           |                             | S                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Oct-2006                                                     | 6045946                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-SWI-01568-01              |                               | 44 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cholelithiasis;<br>Hepatocellular Injury                        | Ciprallex               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                 | Remeron                 |                           |                             | S                        | Oral                          | 30 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                 | Zolpidem Tartrate       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                 | Codipront               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Oct-2006                                                     | 6126345                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S06-USA-03298-01              |                               | 41 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |               |   |      |             |  |  |  |  |  |
|-----------------------------------|---------------|---|------|-------------|--|--|--|--|--|
| Drug Level Increased;<br>Overdose | Lexapro       | S | Oral | 60 Mg Qd Po |  |  |  |  |  |
|                                   | Kadian        | S |      |             |  |  |  |  |  |
|                                   | Valium        | S |      |             |  |  |  |  |  |
|                                   | Amitriptyline | S |      |             |  |  |  |  |  |
|                                   | Oxycontin     | C |      |             |  |  |  |  |  |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Oct-2006                       | 6150507                | DIRECT                    | N                           | DS, HO, LT, OT           |                               |                               | 10 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Attention-Seeking<br>Behaviour; Coma; Post-<br>Traumatic Stress Disorder;<br>Suicidal Ideation; Suicide<br>Attempt | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                                                                                    | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Oct-2006                       | 6150516                | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-04017-01              |                               | 21 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Aggression; Anger; Legal<br>Problem | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                     | Xanax                   |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Oct-2006                       | 6151360                | EXPEDITED (15-DAY)        | Y                           | DE                       | S06-CZE-04218-01              |                               | 63 YR               | Male                | CZE                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Myocardial Infarction          | Ciprallex               |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
|                                | Unspecified Ingredient  |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Oct-2006                       | 6151685                | EXPEDITED (15-DAY)        | Y                           | HO                       | S06-FRA-04153-01              |                               | 72 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                         |   |      |             |              |
|-------------------------|-------------------------|---|------|-------------|--------------|
| Asthenia; Hyponatraemia | Escitalopram Oxalate    | S | Oral | 15 Mg Qd Po | Not Reported |
|                         | Tenstaten (Cicletanine) | C |      |             |              |
|                         | Vastarel                | C |      |             |              |
|                         | Propranolol             | C |      |             |              |
|                         | Noctran                 | C |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2006              | 6152592       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04122-01     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mitral Valve Incompetence; Mitral Valve Prolapse; Ventricular Extrasystoles; Ventricular Hypertrophy | Lexapro                                 |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                      | Lexapro                                 |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                      | Unspecified Ingredient                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Celebrex                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Non-Steroidal Anti-Inflammatories (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2006              | 6152615       | EXPEDITED (15-DAY) | N                  | HO, RI          | S06-USA-03903-01     |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension; Aggression; Disorientation; Irritability; Nightmare; Ovarian Cancer | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                                                                           | Lipitor                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2006              | 6152642       | EXPEDITED (15-DAY) | Y                  | DS              | 2006-148501-NL       |                      | 38 YR      | Male       | FIN            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erectile Dysfunction; Libido Decreased | Mirtazapine          |              |            | S           | Oral         | 7.5 Mg Oral        | 24 DAY          | Not Reported |
|                                        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Oral         | 24 DAY          | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Oct-2006                           | 6057724                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-01969-01     |                      | 44 YR           | Female       | GBR            |
| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Raynaud'S Phenomenon                  | Ciprallex               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2006                           | 6142672                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-03794-01     |                      | 93 YR           | Male         | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura Non-Thrombocytopenic          | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                       | Sotalol Hydrochloride   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                       | Calciparine             |                    |                    | S               | Subcutaneous         | 1 Unk Bid Sc         |                 | Not Reported |                |
|                                       | Atarax                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Eupantol                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Inexium (Esomeprazole)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Clinomel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Sucralfate              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                       | Tianeptine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2006                           | 6152855                 | EXPEDITED (15-DAY) | Y                  | DE              | 2006000584           |                      | 29 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Respiratory Arrest | Methadone Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                       | Alprazolam              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                           | 6032139                 | EXPEDITED (15-DAY) | Y                  | DS, OT          | S06-FRA-01327-01     |                      | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |                                                    |                           |                             |                          |                               |                               |                          |                     |                              |
|--------------------------------------------------------------|----------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|------------------------------|
| Epidermal Necrosis;<br>Photosensitivity Reaction;<br>Sunburn |                                                    | Escitalopram Oxalate      |                             | S                        | Oral                          |                               | 10 Mg Qd Po              |                     | Not Reported                 |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a>      |
| 13-Oct-2006                                                  | 6148816                                            | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-FRA-03944-01              |                               | 70 YR                    | Female              | DNK                          |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a>                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                              |
| Cough; Extrasystoles;<br>Nervous System Disorder             | Escitalopram Oxalate                               |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          |                     | Not Reported                 |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a>      |
| 13-Oct-2006                                                  | 6220431                                            | NON-EXPEDITED             | N                           | OT                       | S05-USA-04328-01              |                               | 38 YR                    | Male                | USA                          |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a>                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                              |
| Agitation; Depression;<br>Suicidal Ideation                  | Lexapro<br>Wellbutrin (Bupropion<br>Hydrochloride) |                           |                             | S<br>C                   |                               |                               |                          |                     | Not Reported<br>Not Reported |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a>      |
| 13-Oct-2006                                                  | 6220434                                            | NON-EXPEDITED             | Y                           | OT                       | S05-USA-04305-01              |                               | 44 YR                    | Male                | USA                          |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a>                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                              |
| Suicidal Ideation                                            | Lexapro                                            |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          |                     | Not Reported                 |
|                                                              | Lexapro                                            |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported                 |
|                                                              | Toprol XL                                          |                           |                             | C                        |                               |                               |                          |                     | Not Reported                 |
|                                                              | Avalide                                            |                           |                             | C                        |                               |                               |                          |                     | Not Reported                 |
|                                                              | Lipitor                                            |                           |                             | C                        |                               |                               |                          |                     | Not Reported                 |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>                             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a>      |
| 13-Oct-2006                                                  | 6220435                                            | NON-EXPEDITED             | N                           | OT                       | S05-USA-04306-01              |                               | 58 YR                    | Male                | USA                          |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a>                            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                              |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |                       |                  |                    |                 |                      |                      |                    |                 |                |
|------------------------------------------------------|-----------------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Hypertension                                         | Lexapro               |                  | S                  | Oral            | 10 Mg Qd Po          |                      | Not Reported       |                 |                |
|                                                      | Lexapro               |                  | S                  | Oral            | 5 Mg Qd Po           |                      | Not Reported       |                 |                |
|                                                      | Effexor               |                  | C                  |                 |                      |                      | Not Reported       |                 |                |
|                                                      | Altace                |                  | C                  |                 |                      |                      | Not Reported       |                 |                |
|                                                      | Klonopin              |                  | C                  |                 |                      |                      | Not Reported       |                 |                |
|                                                      | Hydrochlorothiazide   |                  | C                  |                 |                      |                      | Not Reported       |                 |                |
|                                                      | Zyprexa               |                  | C                  |                 |                      |                      | Not Reported       |                 |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Oct-2006                                          | 6220437               | NON-EXPEDITED    | Y                  | OT              | S05-USA-04253-01     |                      | 17 YR              | Female          | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hypersensitivity                                     | Lexapro               |                  |                    |                 | S                    | Oral                 | 10 Mg Once Po      |                 | Not Reported   |
|                                                      | Bactrim               |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>                             | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Oct-2006                                          | 6220471               | NON-EXPEDITED    | Y                  | OT              | S05-USA-04254-01     |                      | 50 YR              | Female          | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Dystonia                                             | Lexapro               |                  |                    |                 | S                    | Oral                 | 20 Mg Qd Po        |                 | Not Reported   |
|                                                      | Lexapro               |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
| <u>FDA Received Date</u>                             | <u>Case #</u>         | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 13-Oct-2006                                          | 6220473               | NON-EXPEDITED    | Y                  | LT              | S05-USA-04213-01     |                      | 38 YR              | Female          | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>        |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Anaphylactic Reaction;<br>Dyspepsia; Rash; Urticaria | Lexapro               |                  |                    |                 | S                    | Oral                 | 40 Mg Qd Po        |                 | Not Reported   |
|                                                      | Pepcid                |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
|                                                      | Tylenol (Paracetamol) |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
|                                                      | Motrin                |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
|                                                      | Klonopin              |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2006                                                                                                        | 6220498                              | NON-EXPEDITED    | Y                  | OT              | S05-USA-04192-01     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy; Tachycardia                                                                                             | Lexapro                              |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                    | Wellbutrin (Bupropion Hydrochloride) |                  |                    | S               | Oral                 | 150 Mg Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                                                                                                        | 6220499                              | NON-EXPEDITED    | Y                  | OT              | S05-USA-04087-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness                                                                                              | Lexapro                              |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                                                                                                        | 6220519                              | NON-EXPEDITED    | N                  | OT              | S05-USA-04043-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Drug Ineffective; Hostility; Hot Flush; Hyperhidrosis; Nightmare; Somnolence; Suicidal Ideation; Tremor | Lexapro                              |                  |                    | S               | Oral                 | 40 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 30 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 30 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 10 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg Qhs Po         |                 | Not Reported |                |
|                                                                                                                    | Cymbalta                             |                  |                    | S               |                      | 30 Mg Qd             |                 | Not Reported |                |
|                                                                                                                    | Cymbalta                             |                  |                    | S               |                      | 60 Mg Qd             |                 | Not Reported |                |
|                                                                                                                    | Cymbalta                             |                  |                    | S               |                      | 60 Mg Qd             |                 | Not Reported |                |
|                                                                                                                    | Lorazepam                            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Synthroid                            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                    | Benadryl                             |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                     |                        |                  |                    |                 |                      |                         |                 |              |                |
|---------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Flonase                                                             |                        | C                |                    | Not Reported    |                      |                         |                 |              |                |
| Acyclovir                                                           |                        | C                |                    | Not Reported    |                      |                         |                 |              |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                                                         | 6220557                | NON-EXPEDITED    | Y                  | OT              | S05-USA-04022-01     |                         | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Irritability; Mania                                      | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                     | Lexapro                |                  |                    | S               | Oral                 | 2.5 Mg Qd Po            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                                                         | 6220566                | NON-EXPEDITED    | N                  | OT              | S05-USA-04014-01     |                         | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Dizziness; Fatigue;<br>Melaena; Paranoia      | Lexapro                |                  |                    | S               | Oral                 | 20 Mg Bid Po            |                 | Not Reported |                |
|                                                                     | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                     | Aciphex                |                  |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                     | Elavil                 |                  |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                     | Tramadol Hydrochloride |                  |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                     | Unspecified Ingredient |                  |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2006                                                         | 6220570                | NON-EXPEDITED    | Y                  | HO              | S05-USA-01297-02     |                         | 1 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokinesia Neonatal;<br>Hypotonia Neonatal;<br>Somnolence Neonatal | Lexapro                |                  |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                     | Magnesium Sulfate      |                  |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2006                                                         | 6223941                | NON-EXPEDITED    |                    |                 | 2006SP003156         |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                   |   |      |      |              |
|---------------------------------|-------------------|---|------|------|--------------|
| Drug Interaction;<br>Somnolence | Lunesta           | S | Oral | Oral | Not Reported |
|                                 | Provigil          | S | Oral | Oral | Not Reported |
|                                 | Lexapro           | S | Oral | Oral | Not Reported |
|                                 | Vitamin B Complex | S | Oral | Oral | Not Reported |
|                                 | Mobic             | S | Oral | Oral | Not Reported |
|                                 | Estradiol         | S | Oral | Oral | Not Reported |
|                                 | Clonazepam        | S | Oral | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2006              | 6234974       | NON-EXPEDITED    |                    |                 | 2006SP003217         |                      |            | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Somnolence | Lunesta                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                 | Provigil               |              |            | S           |              |                    |                 | Not Reported |
|                                 | Oxycontin              |              |            | S           |              |                    |                 | Not Reported |
|                                 | Percocet               |              |            | S           |              |                    |                 | Not Reported |
|                                 | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                 | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                 | Ginkgo                 |              |            | S           |              |                    |                 | Not Reported |
|                                 | Vitamin C              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2006              | 6113471       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-03022-01     |                      | 80 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Chloride<br>Decreased; Blood<br>Creatine Phosphokinase<br>Increased; Blood Creatine<br>Phosphokinase Mb<br>Increased; Blood Glucose<br>Increased; Bradycardia;<br>Chest Pain; Epigastric<br>Discomfort; Hiccups;<br>Hyponatraemia; Muscle | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                 | Diovan         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                 | Cardura        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                 | Lopresor       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasms; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2006              | 6130227       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03504-01     |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Bipolar Disorder; Dizziness; Drug Dependence; Euphoric Mood; Feeling Abnormal; Hot Flush; Influenza Like Illness; Intentional Product Misuse; Intentional Self-Injury; Irritability; Night Sweats; Pain In Extremity; Self-Medication; Skin Laceration; Suicidal Ideation; Victim Of Sexual Abuse | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Klonopin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Neurontin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Valium         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Percocet       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2006              | 6131996       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-USA-03509-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anticonvulsant Drug Level Below Therapeutic; Chronic Obstructive Pulmonary Disease; Decreased Appetite; Enuresis; Ischaemic Cerebral Infarction; Seizure; Somnolence; Status Epilepticus; Toxicity To Various Agents | Lexapro                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                      | Dilantin                |              |            | S           |              | 300 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                      | Dilantin                |              |            | S           |              | 200 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                      | Verapamil Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      | Zocor                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      | Zantac                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      | Tricor                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      | Topamax                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                      |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2006              | 6138347       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03607-01     |                      | 64 YR      | Female     | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dermatomyositis; Ovarian Cancer; Recurrent Cancer                                                       | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                         | Lexapro                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                         | Estrogens                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2006                                                                                             | 6140333                     | EXPEDITED (15-DAY) | N                  | RI              |                      | S06-USA-03493-01     | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hunger; Retinal Tear; Weight Increased                                                                  | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                         | Wellbutrin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2006                                                                                             | 6148518                     | EXPEDITED (15-DAY) | Y                  | OT              |                      | S06-FRA-03792-01     | 48 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anterograde Amnesia; Hallucination, Auditory; Mental Disorder; Nervous System Disorder; Suicide Attempt | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                         | Zopiclone                   |                    |                    | S               | Oral                 | 7.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                         | Inexum                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Stagid (Metformin Embonate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Forzaar                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Amlodipine Besylate         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Bisoprolol                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2006                                                                                             | 6157578                     | EXPEDITED (15-DAY) |                    | RI              |                      | S06-USA-04252-01     | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Disorder; Pain                                                                                     | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                         | Remicade                    |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 17-Oct-2006                                                                       | 6158868                  | EXPEDITED (15-DAY) | Y                  | LT              | S06-UKI-04215-01     |                               | 37 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling Abnormal; Overdose; Parosmia                                     | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg Qd Po                   |                 | Not Reported |                |
|                                                                                   | Paracetamol              |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                   | Paroxetine Hydrochloride |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2006                                                                       | 6159348                  | EXPEDITED (15-DAY) | N                  | OT              | CHPA2006US09880      |                               | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Abuser                                                            | Excedrin Extra Strength  |                    | Y                  | S               | Oral                 | 1 Df, Qd, Oral                |                 | Not Reported |                |
|                                                                                   | Lexapro                  |                    |                    | S               | Oral                 | 5 Mg, Qd, Oral                |                 | Not Reported |                |
|                                                                                   | Pravachol                |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2006                                                                       | 6152222                  | DIRECT             |                    | OT              |                      |                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Disturbance In Attention; Dizziness; Prostatic Disorder           | Lexapro                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2006                                                                       | 6152772                  | DIRECT             | Y                  | HO, LT          |                      |                               | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Contraindication To Medical Treatment; Depression; Diarrhoea; | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Daily Po                |                 | Not Reported |                |
|                                                                                   | Maxalt                   |                    |                    | S               | Oral                 | 10 Mg 1 Tab Onset + 1 Prn2 Po |                 | Merck        |                |

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|                                                                    |           |   |              |
|--------------------------------------------------------------------|-----------|---|--------------|
| Headache; Mental Disorder; Nausea; Palpitations; Suicidal Ideation | Synthroid | C | Not Reported |
|--------------------------------------------------------------------|-----------|---|--------------|

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 18-Oct-2006                      | 6153456        | DIRECT           | N                  | HO              |                      |                        | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure | Ativan         |                  |                    | S               | Oral                 | .5mg Once Daily Orally |                 | Not Reported |                |
|                                  | Lexapro        |                  |                    | S               | Oral                 | 20mg Once Daily Orally |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 19-Oct-2006                                                              | 6106066        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-04816-02     |                         | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Jaundice Neonatal; Maternal Exposure During Pregnancy; Neonatal Disorder | Lexapro        |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                          | Lexapro        |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                          | Lamictal       |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                          | Magnesium      |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                          | Epidural (Nos) |                    |                    | C               |                      |                         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2006                                                                                                               | 6161510        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04266-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Completed Suicide; Condition Aggravated; Depressed Mood; Gun Shot Wound; Hostility; Suicidal Ideation | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Po             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2006              | 5885527       | EXPEDITED (15-DAY) | Y                  | HO              | T05-CAN-03319-01     |                      | 26 YR      | Female     | CAN            |

| <u>Preferred Term</u>     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Alkaline            | Cipralext                      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Phosphatase Increased;    | Cipralext                      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Blood Pressure            | Aspirin (Acetylsalicylic Acid) |              |            | S           | Oral         | 81 Mg Qd Po        |                 | Not Reported |
| Decreased; Cerebral Cyst; |                                |              |            |             |              |                    |                 |              |
| Electroencephalogram      |                                |              |            |             |              |                    |                 |              |
| Abnormal; Encephalitis    |                                |              |            |             |              |                    |                 |              |
| Japanese B; Hepato-       |                                |              |            |             |              |                    |                 |              |
| Lenticular Degeneration;  |                                |              |            |             |              |                    |                 |              |
| Mitochondrial             |                                |              |            |             |              |                    |                 |              |
| Encephalomyopathy;        |                                |              |            |             |              |                    |                 |              |
| Pineal Neoplasm; Seizure; |                                |              |            |             |              |                    |                 |              |
| Serum Ferritin Decreased; |                                |              |            |             |              |                    |                 |              |
| Somnolence; Speech        |                                |              |            |             |              |                    |                 |              |
| Disorder                  |                                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2006              | 6001830       | EXPEDITED (15-DAY) | Y                  | OT              | S06-BEL-00800-01     |                      | 78 YR      | Female     | BEL            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Transient Ischaemic   | Escitalopram Oxalate    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Attack                | Cloxacolam              |              |            | C           |              |                    |                 | Not Reported |
|                       | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Lisinopril              |              |            | C           |              |                    |                 | Not Reported |
|                       | Lorazepam               |              |            | C           |              |                    |                 | Not Reported |
|                       | Metoclopramide          |              |            | C           |              |                    |                 | Not Reported |
|                       | Bisoprolol              |              |            | C           |              |                    |                 | Not Reported |
|                       | Paracetamol             |              |            | C           |              |                    |                 | Not Reported |
|                       | Lactulose               |              |            | C           |              |                    |                 | Not Reported |
|                       | Mirtazapine             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2006              | 6022076       | EXPEDITED (15-DAY) | Y                  | DE              | S06-BEL-01236-01     |                      | 78 YR      | Female     | BEL            |

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| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cardiac Failure; Lung Infection                                                                                            | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Remeron                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2006                                                                                                                | 6025333                         | EXPEDITED (15-DAY) | Y                  | OT              | S06-BEL-01260-01     |                      | 16 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Nausea; Scratch; Skin Lesion                                                                      | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Paroxetine Hydrochloride        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Sedanxio (Passiflora Incarnata) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2006                                                                                                                | 6123989                         | EXPEDITED (15-DAY) | Y                  | OT              | S06-DEN-03367-01     |                      | 44 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity Vasculitis                                                                                                | Ciprallex                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Zyprexa                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Zolpidem Tartrate               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2006                                                                                                                | 6138636                         | EXPEDITED (15-DAY) | Y                  | DS, LT          | S06-GER-03759-01     |                      | 53 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Antidepressant Drug Level Decreased; Fall; Paranoia; Paraplegia; Psychotic Disorder; Suicide Attempt | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                            | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                            | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                            | Ximovan (Zopiclone)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                            | Zyprexa                         |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 20-Oct-2006                                                                                                     | 6139087                                 | EXPEDITED (15-DAY) | N                  |                 | S06-USA-03637-01                                            |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Confusional State;<br>Maternal Exposure During<br>Pregnancy; Panic Attack;<br>Pregnancy; Stress                 | Lexapro                                 |                    |                    | S               |                                                             |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Oct-2006                                                                                                     | 6150817                                 | EXPEDITED (15-DAY) | N                  | OT              | US-BOEHRINGER<br>INGELHEIM<br>PHARMACEUTICALS,<br>INC.-2006 |                      | 82 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Colon Cancer; Drug<br>Interaction; Dysuria; Loss<br>Of Libido; Somnolence;<br>Urinary Retention                 | Flomax                                  |                    |                    | S               | Oral                                                        |                      |                 | Boehringer Ingelheim |                |
|                                                                                                                 | Lexapro                                 |                    |                    | S               | Oral                                                        |                      |                 | Not Reported         |                |
|                                                                                                                 | Lexapro                                 |                    |                    | S               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Glucophage                              |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Benicar                                 |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Lipitor                                 |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Oct-2006                                                                                                     | 6161843                                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWI-04326-01                                            |                      | 67 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cerebellar Syndrome;<br>Cognitive Disorder;<br>Condition Aggravated;<br>Drug Interaction;<br>Serotonin Syndrome | Cipraxel                                |                    |                    | S               | Oral                                                        | 10 Mg Qd Po          |                 | Not Reported         |                |
|                                                                                                                 | Tramadol Hydrochloride                  |                    |                    | S               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Depakin (Valproate Sodium)              |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Clonazepam                              |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Norvasc                                 |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Sintrom                                 |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Xatral Uno (Alfuzosin<br>Hydrochloride) |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 | Minirim (Desmopressin Acetate)          |                    |                    | C               |                                                             |                      |                 | Not Reported         |                |
|                                                                                                                 |                                         |                    |                    |                 |                                                             |                      |                 |                      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Oct-2006               | 6161850                       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04303-01     |                      | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Asthenia;      | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Completed Suicide;        | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Disturbance In Attention; | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Fatigue; Flat Affect; Gun | Lorazepam                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Shot Wound; Indifference; | Remeron                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Intentional Self-Injury;  |                               |                    |                    |                 |                      |                      |                 |              |                |
| Irritability; Pain;       |                               |                    |                    |                 |                      |                      |                 |              |                |
| Psychomotor               |                               |                    |                    |                 |                      |                      |                 |              |                |
| Hyperactivity; Weight     |                               |                    |                    |                 |                      |                      |                 |              |                |
| Decreased                 |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2006               | 6162148                       | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWE-04335-01     |                      | 35 YR           | Male         | SWE            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use;              | Cipralext                     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Antidepressant Drug Level | Mirtazapine                   |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
| Decreased; Seizure        | Betnoderm (Betamethasone)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Atarax                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Emovat (Clobetasone Butyrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Imovane (Zopiclone)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Canoderm (Urea)               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2006               | 6162314                       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04294-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Completed     | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Suicide; Gun Shot Wound;  |                               |                    |                    |                 |                      |                      |                 |              |                |
| Head Injury; Intentional  |                               |                    |                    |                 |                      |                      |                 |              |                |
| Self-Injury; Physical     |                               |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Assault

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2006              | 6162376       | EXPEDITED (15-DAY) | Y                  | HO              | L06-USA-04237-01     |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Fall; Fanconi Syndrome; Inappropriate Antidiuretic Hormone Secretion; Renal Tubular Disorder | Escitalopram Oxalate    |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                        | Mirtazapine             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                        | Hydrochlorothiazide     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                        | Ramipril                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                        | Donepezil Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                        | Alendronic Acid         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2006              | 6162380       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04281-01     |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Clonus                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2006              | 6124988       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-05038-02     |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Cyanosis Neonatal; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Postmature Baby; Respiratory Disorder Neonatal; Selective Eating Disorder | Lexapro        |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
|                                                                                                                                                                           | Lexapro        |              |            | S           | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported |
|                                                                                                                                                                           | Lexapro        |              |            | S           |                | 10 Mg Qd Bf             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2006              | 6158006       | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |



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| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|------------|
| Mydriasis             | Lexapro        |              |            | S           | Oral         | 10 Mg Tablet Once Daily Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2006              | 6163035       | EXPEDITED (15-DAY) | N                  | HO, OT          | 2006124396           |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Bacterial Infection; Dizziness; Dry Throat; Ear Congestion; Malaise; Middle Ear Effusion; Nausea; Panic Attack; Somnolence; Throat Irritation; Toxicity To Various Agents; Vision Blurred | Xanax                  |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                                                                                                                                    | Zyrtec                 |              |            | S           |              | Unknown (10 Mg)    |                 | Not Reported |
|                                                                                                                                                                                                    | Unspecified Ingredient |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                                                                                                                                    | Lexapro                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2006              | 6163220       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04282-01     |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Gastrointestinal Haemorrhage | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                | Aspirin               |              |            | S           | Oral         | 81 Mg Qd Po        |                 | Not Reported |
|                                                | Other Medicaton (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2006              | 6163802       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-0875-01      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tuberculosis          | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                       | Strattera      |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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|                              |                       |                    |                    |                 |                      |                      |                 |            |                |
|------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
|                              | Ritalin               |                    |                    | C               |                      |                      |                 |            | Not Reported   |
|                              | Imitrex (Sumatriptan) |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2006                  | 6131993               | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03510-01     |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Seizure                      | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2006                  | 6164398               | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04381-01     |                      | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Anxiety;          | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Po             |                 |            | Not Reported   |
| Completed Suicide;           | Lexapro               |                    |                    | S               | Oral                 | 5 Mg Po              |                 |            | Not Reported   |
| Dysphagia; Gun Shot          | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Po             |                 |            | Not Reported   |
| Wound; Insomnia;             | Lorazepam             |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| Irritability; Rash; Self-    |                       |                    |                    |                 |                      |                      |                 |            |                |
| Injurious Ideation; Suicidal |                       |                    |                    |                 |                      |                      |                 |            |                |
| Ideation                     |                       |                    |                    |                 |                      |                      |                 |            |                |
| <u>FDA Received Date</u>     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2006                  | 6164407               | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04321-01     |                      | 44 YR           | Male       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide;           | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| Crying; Dizziness;           | Xanax                 |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| Emotional Disorder;          | Wellbutrin (Bupropion |                    |                    | C               |                      |                      |                 |            | Not Reported   |
| Negative Thoughts; Sleep     | Hydrochloride)        |                    |                    |                 |                      |                      |                 |            |                |
| Disorder; Toxicologic Test   |                       |                    |                    |                 |                      |                      |                 |            |                |
| Abnormal                     |                       |                    |                    |                 |                      |                      |                 |            |                |
| <u>FDA Received Date</u>     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2006                  | 6165817               | EXPEDITED (15-DAY) | Y                  | OT              | S06-AUT-04384-01     |                      | 35 YR           | Female     | AUT            |

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| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Muscular Weakness;<br>Parkinsonism                                                                                                                            | Cipralext                      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Cipralext                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Amisulpride                    |                    |                    | S               | Oral                 | 200 Mg Daily Po      |                 | Not Reported |                |
|                                                                                                                                                               | Amisulpride                    |                    |                    | S               | Oral                 | 400 Mg Daily Po      |                 | Not Reported |                |
|                                                                                                                                                               | Amisulpride                    |                    |                    | S               | Oral                 | 800 Mg Daily Po      |                 | Not Reported |                |
|                                                                                                                                                               | Oxazepam                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Mirtaron 30                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Zyrtec                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Effectin (Bitolterol Mesilate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Zyprexa                                                                                                                                                       |                                |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2006                                                                                                                                                   | 6169173                        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04377-01     |                      | 13 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide; Conjunctival<br>Haemorrhage; Drug Level<br>Increased; Mouth<br>Haemorrhage; Petechiae;<br>Skin Abrasion;<br>Unevaluable Event | Lexapro                        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Lexapro                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Risperdal                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2006                                                                                                                                                   | 6146532                        | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-03801-01     |                      | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema                                                                                                                                                    | Escitalopram Oxalate           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2006                                                                                                                                                   | 6150282                        | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-03987-01     |                      | 41 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                        |                      |   |      |             |              |
|------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|-------------|--------------|
| Completed Suicide;<br>Delirium; Euphoric Mood;<br>Gun Shot Wound;<br>Homicide; Major<br>Depression; Marital<br>Problem | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                                        | Prazepam             | S | Oral | 40 Mg Qd Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2006              | 6153983       | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2006US16131      |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>                                                                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------------------------|
| Asthenia; Blood Calcium<br>Decreased; Blood<br>Chloride Decreased;<br>Blood Creatinine<br>Decreased; Blood<br>Osmolarity Decreased;<br>Blood Phosphorus<br>Decreased; Blood Sodium<br>Decreased; Blood Urea<br>Decreased; Blood Uric<br>Acid Decreased;<br>Confusional State;<br>Creatinine Urine<br>Increased; Drug<br>Interaction; Fall;<br>Glycosuria; Ph Urine<br>Increased; Renal Tubular<br>Disorder | Hydrochlorothiazide<br>Ramipril<br>Donepezil Hydrochloride<br>Mirtazapine<br>Escitalopram Oxalate<br>Citalopram<br>Alendronic Acid |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S |              | 10 Mg/Day          |                 | Novartis<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2006              | 6159286       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-04253-01     |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u>                            | <u>Product</u>                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>                                   |
|--------------------------------------------------|---------------------------------------------------------------|--------------|------------|-------------|----------------------|--------------------------------------------|-----------------|----------------------------------------------|
| Hypoglycaemia;<br>Hypokalaemia;<br>Hyponatraemia | Escitalopram Oxalate<br>Gliclazide<br>Metformin Hydrochloride |              |            | S<br>S<br>S | Oral<br>Oral<br>Oral | 10 Mg Qd Po<br>80 Mg Qd Po<br>850 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 26-Oct-2006                                                                                                                                   | 6224735                  | NON-EXPEDITED      | N                  | OT              | 2006117858           |                        | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Complex Regional Pain Syndrome; Drug Ineffective; Dry Eye; Eye Pain; Fatigue; Hand Fracture; Headache; Muscle Spasms; Myalgia; Vision Blurred | Lyrica                   |                    |                    | S               |                      | 50 Mg (50 Mg 1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                               | Lexapro                  |                    |                    | S               |                      | 5 Mg (5 Mg, 1 In 1 D)  |                 | Not Reported |                |
|                                                                                                                                               | Vicodin                  |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                               | Armour Thyroid           |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2006                                                                                                                                   | 6042922                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01505-01     |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract                                                                                                                                      | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                               | Valtrex                  |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2006                                                                                                                                   | 6167926                  | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04405-01     |                        | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Foot Fracture; Gait Inability; Mobility Decreased; Pulmonary Embolism                                                                         | Lexapro                  |                    |                    | S               | Oral                 | 15 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                               | Lexapro                  |                    |                    | S               | Oral                 | 20 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                               | Lexapro                  |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                               | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                               | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                               | Yasmin                   |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                               | Abilify                  |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                                                                                                                                               | Cabatrol (Carbamazepine) |                    |                    | C               |                      |                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 30-Oct-2006                            | 6148521                           | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-03986-01                         |                      | 50 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Chest Pain; Coronary Artery Thrombosis | Escitalopram Oxalate              |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported         |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Oct-2006                            | 6155847                           | EXPEDITED (15-DAY) | Y                  | OT              | AU-BRISTOL-MYERS SQUIBB COMPANY-13556451 |                      | 99 YR           | Male                 | AUS            |
| <u>Preferred Term</u>                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Angioedema; Peripheral Ischaemia       | Irbesartan                        |                    |                    | S               |                                          |                      |                 | Bristol Myers Squibb |                |
|                                        | Coumadin                          |                    |                    | S               |                                          |                      |                 | Bristol Myers Squibb |                |
|                                        | Benadryl                          |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                        | Lexapro                           |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                        | Unspecified Ingredient            |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                        | Lucrin                            |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Norvasc                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Rocaltrol                         |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Xalatan                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Azopt                             |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Pred Forte                        |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Aratac                            |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Oct-2006                            | 6158393                           | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04170-01                         |                      | 90 YR           | Female               | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Dysarthria                             | Lexapro                           |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported         |                |
|                                        | Dyazide                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | (Triamterene/Hydrochlorothiazide) |                    |                    |                 |                                          |                      |                 |                      |                |
|                                        | Inderal                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                        | Lipitor                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |   |              |
|--|----------------|---|--------------|
|  | Plavix         | C | Not Reported |
|  | Clarinet       | C | Not Reported |
|  | Atenolol       | C | Not Reported |
|  | Lidoderm Patch | C | Not Reported |
|  | Sonata         | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2006              | 6165059       | DIRECT           | Y                  | RI              |                      |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Cerebellar        | Axert          |              |            | S           | Oral         | 12.5 Bid Po        |                 | Not Reported |
| Ataxia; Confusional State; | Lexapro        |              |            | S           | Oral         | 15 Mg Q Day Po     |                 | Not Reported |
| Coordination Abnormal;     | Climara        |              |            | C           |              |                    |                 | Not Reported |
| Depressed Level Of         | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
| Consciousness; Migraine;   | Vicoprofen     |              |            | C           |              |                    |                 | Not Reported |
| Somnolence; Tremor         |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2006              | 6094877       | EXPEDITED (15-DAY) | Y                  | DE              | S06-IRL-02685-01     |                      | 63 YR      | Male       | IRL            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arteriosclerosis; Asphyxia; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Completed Suicide; Ear      |                |              |            |             |              |                    |                 |              |
| Haemorrhage; Hepatic        |                |              |            |             |              |                    |                 |              |
| Steatosis; Hepatomegaly;    |                |              |            |             |              |                    |                 |              |
| Hyperhidrosis; Mediastinal  |                |              |            |             |              |                    |                 |              |
| Haemorrhage; Nightmare;     |                |              |            |             |              |                    |                 |              |
| Petechiae; Pulmonary        |                |              |            |             |              |                    |                 |              |
| Congestion; Pulmonary       |                |              |            |             |              |                    |                 |              |
| Oedema; Renal               |                |              |            |             |              |                    |                 |              |
| Haemorrhage; Self-          |                |              |            |             |              |                    |                 |              |
| Medication; Sleep           |                |              |            |             |              |                    |                 |              |
| Disorder; Staring           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2006              | 6131999       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03509-02     |                      | 29 YR      | Female     | USA            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Bronchitis; Carbon Dioxide Decreased; Condition Aggravated; Depression; Disease Recurrence; Drug Level Above Therapeutic; Mood Swings; Nausea; Pharyngitis; Seizure; Vomiting | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                               | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                               | Ms Contin               |                    |                    | S               | Oral                 | 15 Mg Bid Po         |                 | Not Reported    |                |
|                                                                                                                                                                               | Zanaflex                |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                               | Duragesic               |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Oct-2006                                                                                                                                                                   | 6148515                 | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-03951-01     |                      |                 | Male            | FRA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dementia; Overdose; Parkinsonism                                                                                                                                              | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                               | Zyprexa                 |                    |                    | S               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 31-Oct-2006                                                                                                                                                                   | 6158794                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-01943-01     |                      | 66 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hepatic Enzyme Increased                                                                                                                                                      | Bupropion Hydrochloride |                    |                    | S               | Oral                 | 200mg Twice Per Day  |                 | Glaxosmithkline |                |
|                                                                                                                                                                               | Lexapro                 |                    |                    | S               | Oral                 | 20mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                                               | Lunesta                 |                    |                    | S               | Unknown              | 3mg Unknown          |                 | Not Reported    |                |
|                                                                                                                                                                               | Adderall Xr             |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
|                                                                                                                                                                               | Uroxatral               |                    |                    | S               | Unknown              | 10mg Unknown         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Nov-2006                                                                                                                                                                   | 6081516                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-FRA-02575-01     |                      | 27 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Hepatitis; Intentional Overdose; Suicide Attempt                                                                                                                              | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |



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|                                                                                                   |                        | Escitalopram Oxalate |                    | S               |                      |                         |                 |              | Not Reported   |
|---------------------------------------------------------------------------------------------------|------------------------|----------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
|                                                                                                   |                        | Fludrocortisone      |                    | C               |                      |                         |                 |              | Not Reported   |
|                                                                                                   |                        | Hydrocortisone       |                    | C               |                      |                         |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>          | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2006                                                                                       | 6099730                | EXPEDITED (15-DAY)   | Y                  | OT              | S06-FRA-02890-01     |                         | 57 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>         | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                                                                                      | Escitalopram Oxalate   |                      |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                   | Unspecified Ingredient |                      |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>          | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2006                                                                                       | 6170311                | EXPEDITED (15-DAY)   | Y                  | HO              | S06-FRA-04407-03     |                         |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>         | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Premature Baby            | Escitalopram Oxalate   |                      |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                   | Escitalopram Oxalate   |                      |                    | S               | Transplacental       | 5 Mg Qd Transplacental  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>          | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2006                                                                                       | 6170312                | EXPEDITED (15-DAY)   | Y                  | HO              | S06-FRA-04407-01     |                         |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>         | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pregnancy; Premature Baby | Escitalopram Oxalate   |                      |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                   | Escitalopram Oxalate   |                      |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>          | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2006                                                                                       | 6168803                | DIRECT               | N                  | OT              |                      |                         | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>         | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                    |         |   |                        |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------------------------|--------------|
| Amnesia; Anger; Condition Aggravated; Depression; Dissociation; Drug Dependence; Drug Withdrawal Syndrome; Emotional Disorder; Memory Impairment; Mental Disorder; Mental Status Changes; Muscle Spasms; Pain; Panic Reaction; Paranoia; Social Avoidant Behaviour; Social Problem | Lexapro | S | 1 Tablet Every Morning | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2006              | 6093598       | EXPEDITED (15-DAY) | Y                  | DS              | S06-DEN-02851-01     |                      | 32 YR      | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Decreased; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Diabetes Mellitus        | Citalopram           |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Inadequate Control;      | Insulin Nos          |              |            | C           |              |                    |                 | Not Reported |
| Feeling Abnormal         | Isophane Insulin     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2006              | 6144777       | EXPEDITED (15-DAY) | Y                  | OT              | S06-HRV-03932-01     |                      | 43 YR      | Female     | HRV            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Obesity               | Ciprallex       |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Zyprexa Velotab |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2006              | 6161522       | EXPEDITED (15-DAY) | N                  | HO              | USA-04330-01         |                      | 14 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |          |   |      |                 |
|----------------------------------------------------------------------|----------|---|------|-----------------|
| Blepharospasm; Legal Problem; Loss Of Consciousness; Seizure; Tremor | Lamictal | S | Oral | Glaxosmithkline |
|                                                                      | Lexapro  | S |      | Not Reported    |

| <u>FDA Received Date</u>                  | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2006                               | 6163628          | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-04360-01     |                      | 40 YR           | Male         | IRL            |
| <u>Preferred Term</u>                     | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Muscle Spasms; Seizure; Tremor | Lexapro          |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                           | Lexapro          |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                           | Omega 3 Fish Oil |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Alprazolam       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                           | Flurazepam       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2006                                  | 6171526        | EXPEDITED (15-DAY) | Y                  | LT              | S06-SAF-04581-01     |                      |                 | Male         | ZAF            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness; Road Traffic Accident | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Nov-2006              | 6171530              | EXPEDITED (15-DAY) | Y                  | OT              | S06-AUS-04520-01     |                      | 24 YR           | Female       | AUS            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Psychosis          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Nov-2006              | 6170076              | EXPEDITED (15-DAY) | Y                  | OT              | T06-USA-03771-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning;       | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                               |   |      |                |              |
|---------------------------------|-------------------------------|---|------|----------------|--------------|
| Amnesia; Victim Of Sexual Abuse | Escitalopram Oxalate          | S | Oral | 20 Mg Qd Po    | Not Reported |
|                                 | Escitalopram Oxalate          | S | Oral | 10 Mg Qd Po    | Not Reported |
|                                 | Placebo                       | S | Oral | 1 Tablet Qd Po | Not Reported |
|                                 | Yaz                           | C |      |                | Not Reported |
|                                 | Iron Supplement (Iron)        | C |      |                | Not Reported |
|                                 | Pseudoephedrine Hydrochloride | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Nov-2006              | 6171956       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2006129875           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Anticonvulsant Drug Level Above Therapeutic; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Decreased Appetite; Enuresis; Platelet Count Increased; Seizure; Somnolence; Status Epilepticus; Toxicity To Various Agents | Dilantin                |              |            | S           |              | 300mg Alternating With 200mg (1 D) |                 | Not Reported |
|                                                                                                                                                                                                                                       | Lexapro                 |              |            | S           | Oral         | 20 Mg (1 D), Oral                  |                 | Not Reported |
|                                                                                                                                                                                                                                       | Verapamil Hydrochloride |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                       | Zocor                   |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                       | Trazodone Hydrochloride |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                       | Zantac                  |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                       | Tricor                  |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                       | Topamax                 |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2006              | 6170581       | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-0611USA01366 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Insomnia; Language Disorder | Zocor          |              |            | S           | Oral         |                    |                 | Merck        |
|                                               | Pepcid Ac      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Nexium         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                               | Toprol XL      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                               | Ambien         |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                               | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                               | Dyazide        |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                            | Iron           |                    | S                  | Unknown         |                              |                                    |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------|-----------------|--------------|----------------|
|                                                                                                                            | Calcium        |                    | S                  | Unknown         |                              |                                    |                 | Not Reported |                |
|                                                                                                                            | Vitamins       |                    | S                  | Unknown         |                              |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2006                                                                                                                | 6171587        | DIRECT             | N                  | LT              |                              |                                    | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Self-Injurious Ideation; Suicidal Ideation                                                             | Lexapro        |                    |                    | S               |                              | 1/2 Tab. X 6 Days Then 1 Tab After |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2006                                                                                                                | 6083811        | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-USA-02448-01             |                                    | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Contusion; Epistaxis; Fall; Generalised Tonic-Clonic Seizure; Head Injury; Loss Of Consciousness; Postictal State | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po                        |                 | Not Reported |                |
|                                                                                                                            | Klonopin       |                    |                    | C               |                              |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2006                                                                                                                | 6093113        | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-02095-01             |                                    | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypothyroidism                                                                                                             | Lexapro        |                    |                    | S               | Oral                         | 20 Mg Qd Po                        |                 | Not Reported |                |
|                                                                                                                            | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po                        |                 | Not Reported |                |
|                                                                                                                            | Wellbutrin XL  |                    |                    | C               |                              |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2006                                                                                                                | 6164701        | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-06P-163-0348893-00 |                                    | 75 YR           | Unknown      | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Completed Suicide                                          | Levothyroxine             |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                            | Escitalopram Oxalate      |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                            | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                            | Unspecified Ingredient    |                    |                    | S               |                      | Not Reported             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2006                                                | 6174897                   | EXPEDITED (15-DAY) | Y                  | OT              | HQWYE560206NOV06     |                          | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Hypertension; Suicidal Ideation  | Effexor Xr                |                    |                    | S               |                      | 150 Mg 1x Per 1 Day      |                 | Not Reported |                |
|                                                            | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg 1x Per 1 Day, Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2006                                                | 6175169                   | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-04594-01     |                          | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Dizziness; Loss Of Consciousness | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qhs Po             |                 | Not Reported |                |
|                                                            | Inderal La                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2006                                                | 6165599                   | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-ROCHE-466256      |                          | 57 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Shock                                | Loxen Lp                  |                    |                    | S               | Oral                 |                          | 1 DAY           | Roche        |                |
|                                                            | Loxen Lp                  |                    |                    | S               | Oral                 |                          |                 | Roche        |                |
|                                                            | Quinapril                 |                    |                    | S               | Oral                 |                          | 1 DAY           | Not Reported |                |
|                                                            | Quinapril                 |                    |                    | S               | Oral                 |                          |                 | Not Reported |                |
|                                                            | Levothyrox                |                    |                    | S               | Oral                 |                          | 1 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |       |  |  |              |
|----------------------|---|------|-------|--|--|--------------|
| Levothyrox           | S | Oral |       |  |  | Not Reported |
| Atarax               | S | Oral | 1 DAY |  |  | Not Reported |
| Atarax               | S | Oral |       |  |  | Not Reported |
| Escitalopram Oxalate | S | Oral | 1 DAY |  |  | Not Reported |
| Escitalopram Oxalate | S | Oral |       |  |  | Not Reported |
| Calcifediol          | C |      |       |  |  | Not Reported |
| Vitamin D3           | C |      |       |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2006              | 6086176       | EXPEDITED (15-DAY) | Y                  | DE              | S06-FRA-02605-01     |                      | 53 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Acute     | Escitalopram Oxalate |              |            | S           | Oral         | 20 Tablet Once Po  |                 | Not Reported |
| Kidney Injury; Acute      | Escitalopram Oxalate |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |
| Respiratory Distress      | Oxazepam             |              |            | S           | Oral         | 60 Tablet Once Po  |                 | Not Reported |
| Syndrome; Cholestasis;    | Oxazepam             |              |            | S           |              |                    |                 | Not Reported |
| Coagulopathy;             |                      |              |            |             |              |                    |                 |              |
| Haemodynamic Instability; |                      |              |            |             |              |                    |                 |              |
| Hepatic Failure; Hepatic  |                      |              |            |             |              |                    |                 |              |
| Pain; Hepatic Steatosis;  |                      |              |            |             |              |                    |                 |              |
| Hepatitis; Hepatomegaly;  |                      |              |            |             |              |                    |                 |              |
| Hypoxia; Intentional      |                      |              |            |             |              |                    |                 |              |
| Overdose; Jaundice;       |                      |              |            |             |              |                    |                 |              |
| Jaundice Cholestatic;     |                      |              |            |             |              |                    |                 |              |
| Lung Disorder; Septic     |                      |              |            |             |              |                    |                 |              |
| Shock; Somnolence;        |                      |              |            |             |              |                    |                 |              |
| Speech Disorder;          |                      |              |            |             |              |                    |                 |              |
| Thrombocytopenia;         |                      |              |            |             |              |                    |                 |              |
| Vomiting                  |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2006              | 6143375       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03691-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| White Blood Cell Count Decreased | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 13-Nov-2006                                                                                    | 6173405                 | DIRECT                    |                             | DS, HO, LT, RI,<br>OT    |                               |                               | 39 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Back Pain; Glaucoma;<br>Pruritus; Rash; Swelling<br>Face                                       | Lamictal                |                           |                             | S                        |                               | 100 Mg                        |                          | Glaxo Wellcome      |                         |
|                                                                                                | Geodon                  |                           |                             | S                        |                               | 40 Mg                         |                          | Pfizer              |                         |
|                                                                                                | Lexapro                 |                           |                             | S                        |                               | 20 Mg                         |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Nov-2006                                                                                    | 6176529                 | DIRECT                    | N                           | HO                       |                               |                               | 45 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Behaviour;<br>Aggression; Amnesia;<br>Hallucination, Visual; Loss<br>Of Consciousness | Lexapro                 |                           |                             | S                        |                               | 10 Mg Bid                     |                          | Not Reported        |                         |
|                                                                                                | Geodon                  |                           |                             | S                        |                               | 40 Mg Bid                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Nov-2006                                                                                    | 6176722                 | EXPEDITED (15-DAY)        | Y                           | OT                       | L06-MEX-04556-01              |                               | 13 YR                    | Female              | MEX                     |
| <a href="#">Preferred Term</a>                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cutaneous Vasculitis;<br>Drug Hypersensitivity                                                 | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Nov-2006                                                                                    | 5886074                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S05-GER-03316-01              |                               | 22 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Maternal Exposure During<br>Pregnancy; Pregnancy On<br>Oral Contraceptive                      | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                | Ethinyl Estradiol       |                           |                             | S                        | Oral                          | Po                            |                          | Not Reported        |                         |
|                                                                                                | Levonorgestrel          |                           |                             | S                        | Oral                          | Po                            |                          | Not Reported        |                         |



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| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|--------------------------|-----------------|-----------------|----------------|
| 14-Nov-2006                  | 6161471        | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04279-01             |                          | 11 YR           | Female          | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Asphyxia;         | Lexapro        |                    |                    | S               | Oral                         | 5 Mg Qd Po               |                 | Not Reported    |                |
| Completed Suicide;           | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po              |                 | Not Reported    |                |
| Condition Aggravated;        | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Qd Po              |                 | Not Reported    |                |
| Depression; Irritability;    | Clonidine      |                    |                    | C               |                              |                          |                 | Not Reported    |                |
| Skin Abrasion; Suicidal      | Singular       |                    |                    | C               |                              |                          |                 | Not Reported    |                |
| Ideation; Vomiting           |                |                    |                    |                 |                              |                          |                 |                 |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Nov-2006                  | 6167516        | EXPEDITED (15-DAY) | Y                  | OT              | US-GLAXOSMITHKLINE-A0627043A |                          |                 | Unknown         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Drug Interaction; | Requip         |                    |                    | S               | Oral                         | 2mg Per Day              |                 | Glaxosmithkline |                |
| Serotonin Syndrome           | Lexapro        |                    |                    | S               |                              |                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Nov-2006                  | 6176187        | DIRECT             | Y                  |                 |                              |                          |                 | Unknown         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Intercepted Medication       | Lexapro        |                    |                    | S               |                              | Tablet Vial, Multi-Dose  |                 | Forest          |                |
| Error; Medication Error;     | Nexium         |                    |                    | S               |                              | Capsule Vial, Multi-Dose |                 | Astrazeneca     |                |
| Product Dispensing Error     |                |                    |                    |                 |                              |                          |                 |                 |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Nov-2006                  | 6176314        | EXPEDITED (15-DAY) | Y                  | DS              | S06-UKI-04634-01             |                          | 37 YR           | Female          | GBR            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Ageusia; Confusional         | Cipraxex       |                    |                    | S               | Oral                         | 20 Mg Daily Po           |                 | Not Reported    |                |
| State; Muscle Twitching;     | Propranolol    |                    |                    | C               |                              |                          |                 | Not Reported    |                |
| Tremor                       |                |                    |                    |                 |                              |                          |                 |                 |                |

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| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Nov-2006                                  | 6177927                           | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04730-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Hypoaesthesia                    | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Azmacort                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Restoril                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Vicodin                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Valium                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2006                                  | 6177984                           | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04682-01     |                      | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                         | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2006                                  | 6177988                           | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-04680-01     |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Serotonin Syndrome | Lexapro                           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                              | Lexapro                           |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Elavil                            |                    |                    | S               | C                    |                      |                 | Not Reported |                |
|                                              | Orthonovum                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | (Norethindrone/Ethinyl Estradiol) |                    |                    |                 |                      |                      |                 |              |                |
|                                              | Xanax                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Skelaxin                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2006                                  | 6235872                           | NON-EXPEDITED      | Y                  |                 | S06-USA-03527-01     |                      | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                           |                         |   |      |               |              |
|---------------------------|-------------------------|---|------|---------------|--------------|
| Disturbance In Attention; | Namenda                 | S | Oral | 10 Mg Bid; Po | Not Reported |
| Dizziness; Nail           | Namenda                 | S | Oral | 5 Mg Bid; Po  | Not Reported |
| Discolouration; Nail      | Namenda                 | S | Oral | 5 Mg, Bid; Po | Not Reported |
| Disorder; Nail Growth     | Namenda                 | S | Oral | 15 Mg Qd; Po  | Not Reported |
| Abnormal                  | Namenda                 | S | Oral | 5 Mg, Qd; Po  | Not Reported |
|                           | Lexapro                 | S | Oral | 20 Mg Qd; Po  | Not Reported |
|                           | Trazodone Hydrochloride | C |      |               | Not Reported |
|                           | Alprazolam              | C |      |               | Not Reported |
|                           | Prilosec                | C |      |               | Not Reported |
|                           | Singulair               | C |      |               | Not Reported |
|                           | Furosemide              | C |      |               | Not Reported |
|                           | Potassium               | C |      |               | Not Reported |
|                           | Albuterol               | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2006              | 6151369       | EXPEDITED (15-DAY) | Y                  | DS, HO          | S06-FRA-04185-01     |                      | 81 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;    | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Incorrect Dose        | Hemidigoxine (Digoxin) |              |            | C           |              |                    |                 | Not Reported |
| Administered; Speech  | Previscan (Fluindione) |              |            | C           |              |                    |                 | Not Reported |
| Disorder              | Rabeprazole Sodium     |              |            | C           |              |                    |                 | Not Reported |
|                       | Motilium               |              |            | C           |              |                    |                 | Not Reported |
|                       | Zolpidem Tartrate      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2006              | 6162149       | EXPEDITED (15-DAY) | Y                  | HO              | S06-PRT-04356-01     |                      | 50 YR      | Female     | PRT            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis A           | Cipraxel                |              |            | S           |              |                    |                 | Not Reported |
|                       | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                       | Cipraxel                |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6000729       | EXPEDITED (15-DAY) | Y                  | HO, LT          | US016832             |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u>             | <u>Dosage Text</u>                                                                                                              | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Alcohol Use; Anterograde<br>Amnesia; Burning<br>Sensation; Cognitive<br>Disorder; Condition<br>Aggravated; Conversion<br>Disorder; Delirium;<br>Delusion; Drug<br>Dependence; Drug<br>Ineffective; Drug<br>Interaction; Epilepsy; Fall;<br>Fear; Hallucination;<br>Incorrect Dose<br>Administered; Injury;<br>Insomnia; Irritability; Loss<br>Of Consciousness; Major<br>Depression; Nightmare;<br>Overdose; Pain; Paranoia;<br>Post-Traumatic Stress<br>Disorder; Psychotic<br>Disorder; Refusal Of<br>Treatment By Patient;<br>Retrograde Amnesia;<br>Scar; Seizure; Self-<br>Medication; Status<br>Epilepticus; Suicidal<br>Behaviour; Suicidal<br>Ideation | Gabitril<br>Adderall<br>Xanax<br>Neurontin<br>Lexapro<br>Synthroid<br>Keppra<br>Remeron |              |            | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Oral<br>Oral<br><br>Oral | 16 Mg Up To 120-130 Mg<br>Daily Oral<br>30 Mg Bid Oral<br>1 Q 1-2 Hours; A Few<br>Years<br>Up To 2400mg Daily<br>30 Mg Bid Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6168906       | EXPEDITED (15-DAY) | N                  | HO              | AU-JNJFOC-<br>20061101818 |                      |            | Female     | AUS            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|                                                                                              |           |   |      |              |
|----------------------------------------------------------------------------------------------|-----------|---|------|--------------|
| Circulatory Collapse;<br>Drooling; Dysphagia; Fall;<br>Musculoskeletal Stiffness;<br>Staring | Risperdal | S | Oral | Not Reported |
|                                                                                              | Lexapro   | S | Oral | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2006                       | 6178240                | DIRECT                    | N                           | LT, OT                   |                               |                               | 44 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Confusional State; Heart Rate Increased; Nervous System Disorder; Nervousness; Panic Attack; Paraesthesia; Paranoia; Suicidal Ideation | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Daily Po              |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2006                       | 6178264                | DIRECT                    | Y                           | LT                       |                               |                               | 36 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Megacolon                      | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Every Night Po        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2006                       | 6178268                | DIRECT                    | N                           | RI                       |                               |                               | 55 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Libido Decreased; Loss Of Libido | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Daily Po              |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2006                       | 6179425                | EXPEDITED (15-DAY)        | Y                           | DE                       | L06-USA-04699-10              |                               | 28 YR               | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

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|                              |                      |   |              |
|------------------------------|----------------------|---|--------------|
| Cardiac Arrest; Completed    | Escitalopram Oxalate | S | Not Reported |
| Suicide; Intentional         | Amitriptyline        | S | Not Reported |
| Overdose; Respiratory Arrest | Olanzapine           | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6179432       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-08     |                      | 35 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Overdose | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                         | Topiramate           |              |            | S           |              |                    |                 | Not Reported |
|                                         | Quetiapine           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6180090       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-15     |                      | 18 YR      | Unknown    | USA            |

| <u>Preferred Term</u>        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed    | Escitalopram Oxalate      |              |            | S           |              |                    |                 | Not Reported |
| Suicide; Intentional         | Venlafaxine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Respiratory Arrest | Bupropion Hydrochloride   |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6180092       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-14     |                      | 34 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Overdose | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                         | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                         | Alprazolam             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2006              | 6180095       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-13     |                      | 75 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;    | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                               |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Intentional Overdose      | Levothyroxine                 |                    |                    | S               |                      |                      |                 |              | Not Reported   |
|                           | Venlafaxine Hydrochloride     |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2006               | 6180098                       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-12     |                      | 45 YR           | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;        | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Intentional Overdose      | Gabapentin                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2006               | 6180100                       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-18     |                      | 35 YR           | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;        | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Intentional Overdose      | Clonazepam                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Venlafaxine                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2006               | 6180102                       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-17     |                      | 28 YR           | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Suicide; Intentional      | Atropine                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Overdose; Respiratory     | Clozapine                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Arrest                    |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2006               | 6180106                       | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-16     |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Suicide; Intentional      | Pseudoephedrine Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Overdose; Respiratory     | Acetaminophen And Codeine     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Arrest                    | Phosphate                     |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 16-Nov-2006                  | 6180690              | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-09     |                          | 36 YR           | Unknown      | USA            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed    | Escitalopram Oxalate |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Suicide; Intentional         | Amitriptyline        |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Overdose; Respiratory Arrest | Phenobarbital        |                    |                    | S               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2006                  | 6180692              | EXPEDITED (15-DAY) | Y                  | DE              | L06-USA-04699-11     |                          | 39 YR           | Unknown      | USA            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed    | Escitalopram Oxalate |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Suicide; Intentional         | Chlorpheniramine     |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Overdose; Respiratory Arrest | Alprazolam           |                    |                    | S               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2006                  | 6179319              | DIRECT             | N                  | DS, LT          |                      |                          | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome           | Zoloft               |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                              | Lexapro              |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                              | Zoloft               |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Lexapro              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Bispirone            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Zomig                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2006                  | 6179409              | DIRECT             | Y                  | LT              |                      |                          | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Dizziness;       | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Every Night Po One |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Megacolon

Dose Only

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Nov-2006                                                                                                                                                      | 6180888                   | EXPEDITED (15-DAY) | Y                  | LT              | S06-NOR-04853-01     |                      | 36 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Asphyxia;<br>Disturbance In Attention;<br>Ill-Defined Disorder;<br>Intentional Self-Injury;<br>Paraesthesia; Sensory<br>Disturbance; Suicide<br>Attempt | Cipraxel                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2006                                                                                                                                                      | 6181522                   | EXPEDITED (15-DAY) | Y                  | DE              | PAR_0949_2006        |                      | 35 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning                                                                                                                                  | Clonazepam                |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                                                                                                                                  | Escitalopram Oxalate      |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
|                                                                                                                                                                  | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 | Df Po                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2006                                                                                                                                                      | 6182657                   | EXPEDITED (15-DAY) | N                  | DE              | 28027                |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose                                                                                                                                                         | Pseudoephedrine           |                    | Y                  | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                  | Escitalopram Oxalate      |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2006                                                                                                                                                      | 8086640                   | DIRECT             | Y                  | HO              |                      |                      | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |               |   |      |                  |              |
|--------------------|---------------|---|------|------------------|--------------|
| Serotonin Syndrome | Lexapro       | S | Oral | 10 Mg Daily Po   | Not Reported |
|                    | Ultracet      | S | Oral | 2 Tabs Q4 Prn Po | Not Reported |
|                    | Darvocet      | C |      |                  | Not Reported |
|                    | Zetia         | C |      |                  | Not Reported |
|                    | Benicar       | C |      |                  | Not Reported |
|                    | Amitriptyline | C |      |                  | Not Reported |
|                    | Synthroid     | C |      |                  | Not Reported |
|                    | Combivent     | C |      |                  | Not Reported |
|                    | Flovent       | C |      |                  | Not Reported |
|                    | Clonazepam    | C |      |                  | Not Reported |
|                    | Nexium        | C |      |                  | Not Reported |
|                    | Sucralfate    | C |      |                  | Not Reported |
|                    | Hctz          | C |      |                  | Not Reported |
|                    | Topamax       | C |      |                  | Not Reported |
|                    | Liquid Iron   | C |      |                  | Not Reported |
|                    | Glucosamine   | C |      |                  | Not Reported |
|                    | Chondroitin   | C |      |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 21-Nov-2006              | 6171456       | EXPEDITED (15-DAY) | Y                  | DE              | US-KINGPHARMUSA00001-K200601462 |                      | 75 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Levoxyl                   |              |            | S           | Oral         |                    |                 | King         |
|                       | Escitalopram Oxalate      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2006              | 6265174       | NON-EXPEDITED    | N                  |                 | TPA2006A01676        |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Drug Ineffective; Initial Insomnia; Libido Decreased | Rozerem        |              |            | S           | Oral         | 8 Mg, Qhs, Per Oral |                 | Not Reported |
|                                                      | Lexapro        |              |            | S           |              |                     |                 | Not Reported |
|                                                      | Klonopin       |              |            | C           |              |                     |                 | Not Reported |
|                                                      | Amoxicillin    |              |            | C           |              |                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 24-Nov-2006                 | 6183677                 | EXPEDITED (15-DAY) | Y                  | DE              | 2006138308           |                         | 29 YR           | Unknown      | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;             | Alprazolam (Alprazolam) |                    |                    | S               |                      |                         |                 | Not Reported |                |
| Respiratory Arrest          | Methadone Hydrochloride |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                             | Escitalopram Oxalate    |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2006                 | 6183960                 | EXPEDITED (15-DAY) | Y                  | DE              | 2006138633           |                         | 34 YR           | Unknown      | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide           | Alprazolam              |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                             | Unspecified Ingredient  |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                             | Escitalopram Oxalate    |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                             | Unspecified Ingredient  |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2006                 | 6184177                 | EXPEDITED (15-DAY) | Y                  | DE              | 2006138570           |                         | 39 YR           | Unknown      | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed   | Alprazolam (Alprazolam) |                    |                    | S               |                      |                         |                 | Not Reported |                |
| Suicide; Respiratory        | Escitalopram Oxalate    |                    |                    | S               |                      |                         |                 | Not Reported |                |
| Arrest; Toxicity To Various | Chlorpheniramine        |                    |                    | S               |                      |                         |                 | Not Reported |                |
| Agents                      |                         |                    |                    |                 |                      |                         |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2006                 | 6186761                 | EXPEDITED (15-DAY) | Y                  | OT              | 2006141077           |                         |                 | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;           | Geodon                  |                    |                    | S               |                      |                         |                 | Not Reported |                |
| Serotonin Syndrome          | Lexapro                 |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 24-Nov-2006                                                                                                                                                               | 6187209                   | EXPEDITED (15-DAY) | Y                  | DE              | IMP_2540_2006                        |                      | 18 YR           | Unknown         | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest                                                                                                    | Bupropion                 |                    |                    | S               | Oral                                 | Df Po                |                 | Not Reported    |                |
|                                                                                                                                                                           | Venlafaxine Hydrochloride |                    |                    | S               | Oral                                 | Df Po                |                 | Not Reported    |                |
|                                                                                                                                                                           | Escitalopram Oxalate      |                    |                    | S               | Oral                                 | Df Po                |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Nov-2006                                                                                                                                                               | 6173652                   | EXPEDITED (15-DAY) | Y                  | OT              | DE-<br>GLAXOSMITHKLINE-<br>D0051554A |                      | 64 YR           | Female          | DEU            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Intentional Overdose;<br>Sopor; Suicide Attempt                                                                                                                           | Lithium Carbonate         |                    |                    | S               | Oral                                 | 6750mg Single Dose   | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                                                                           | Amitriptyline             |                    |                    | S               | Oral                                 | 1350mg Single Dose   | 1 DAY           | Not Reported    |                |
|                                                                                                                                                                           | Cipralext                 |                    |                    | S               | Oral                                 | 140mg Single Dose    | 1 DAY           | Not Reported    |                |
|                                                                                                                                                                           | Euthyrox                  |                    |                    | S               | Oral                                 | 2.4mg Single Dose    | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                                                                           | Flupentixol               |                    |                    | S               | Oral                                 | 100mg Single Dose    | 1 DAY           | Not Reported    |                |
|                                                                                                                                                                           | Glimepiride               |                    |                    | S               | Oral                                 |                      | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                                                                           | Glucophage                |                    |                    | S               | Oral                                 | 10g Single Dose      | 1 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Nov-2006                                                                                                                                                               | 6181456                   | DIRECT             | Y                  | HO              |                                      |                      | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Apgar Score Low;<br>Caesarean Section;<br>Hypoglycaemia Neonatal;<br>Maternal Exposure During<br>Pregnancy; Metabolic<br>Acidosis; Muscle Disorder;<br>Neonatal Disorder; | Lexapro                   |                    |                    | S               | Oral                                 | 30 Mg Daily Po       |                 | Forest          |                |
|                                                                                                                                                                           | Lexapro                   |                    |                    | S               |                                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Prolonged Labour;  
Respiratory Disorder  
Neonatal

| <u>FDA Received Date</u>                              | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Nov-2006                                           | 6185374                             | EXPEDITED (15-DAY) | Y                  | DE              | AND_AAPCC_2006_0959  |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Acetaminophen And Codeine Phosphate |                    |                    | S               |                      | Df Unk 047           |                 | Not Reported |                |
|                                                       | Pseudoephedrine Hydrochloride       |                    |                    | S               |                      | Df Unk 047           |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate                |                    |                    | S               |                      | Df Unk 047           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Nov-2006              | 6188274        | DIRECT           | N                  | RI              |                      |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction       | Lexapro        |                  |                    | S               |                      | 10mg                 | 1 YR            | Not Reported |                |
|                          | Lexapro        |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Nov-2006                                                                                                                                                                                                                      | 6142689              | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-03796-01     |                      | 33 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Asthenia; Basophil Count Increased; Hepatitis; Hyperhidrosis; Lymphocyte Count Increased; Monocyte Count Increased; Platelet Count Decreased; Pyrexia; Splenomegaly; Treatment Noncompliance; White Blood Cell Count | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                  | Atarax               |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6163233       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04250-01     |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure Decreased; Chest Discomfort; Impulsive Behaviour; Insomnia; Muscle Twitching; Musculoskeletal Pain; Myalgia; Restlessness; Supraventricular Extrasystoles; Supraventricular Tachycardia; Ventricular Extrasystoles | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                            | Toprol XL      |              |            | S           | Oral         | 50 Mg Unk Po       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Toprol XL      |              |            | S           | Oral         | 25 Mg Unk Po       |                 | Not Reported |
|                                                                                                                                                                                                                                            | Flexeril       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                            | Xanax          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6169032       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-04495-01     |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Prostatic Specific Antigen Increased; Urinary Retention | Escitalopram Oxalate      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                         | Escitalopram Oxalate      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                         | Escitalopram Oxalate      |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                         | Moclobemide (Moclobemide) |              |            | C           |              |                    |                 | Not Reported |
|                                                         | Colchicine                |              |            | C           |              |                    |                 | Not Reported |
|                                                         | Tranxene T-Tab            |              |            | C           |              |                    |                 | Not Reported |
|                                                         | Zyprexa                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6189660       | EXPEDITED (15-DAY) | Y                  | DE              | 6027523              |                      | 75 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                      |   |      |      |              |
|----------------------|----------------------|---|------|------|--------------|
| Intentional Overdose | Levothyroxine Sodium | S | Oral | Oral | Not Reported |
|                      | Escitalopram Oxalate | S |      |      | Not Reported |
|                      | Venlafaxine          | S |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6189673       | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-04863-01     |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Contusion; Fall;<br>Generalised Tonic-Clonic<br>Seizure; Head Injury; Loss<br>Of Consciousness;<br>Migraine; Myoclonus;<br>Swelling; Vomiting | Lexapro                     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                        | Lamictal                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                        | Keppra                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                        | Yasmin (Estrogen/Progestin) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6190116       | EXPEDITED (15-DAY) | N                  | DE              | 2006P1000493         |                      | 57 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Acute<br>Respiratory Distress<br>Syndrome; Injury;<br>Intentional Overdose;<br>Lung Infiltration;<br>Myocarditis;<br>Pneumothorax; Shock;<br>Somnolence | Nicardipine Hydrochloride |              |            | S           | Oral         | 900 Mg, Unk; Po    |                 | Not Reported |
|                                                                                                                                                                              | Levothyroxine Sodium      |              |            | S           | Oral         | 675 Ug, Unk; Po    |                 | Not Reported |
|                                                                                                                                                                              | Quinapril Hydrochloride   |              |            | S           | Oral         | 180 Mg; Unk; Po    |                 | Not Reported |
|                                                                                                                                                                              | Hydroxyzine               |              |            | S           | Oral         | 225 Mg, Unk; Po    |                 | Not Reported |
|                                                                                                                                                                              | Escitalopram Oxalate      |              |            | S           | Oral         | 180 Mg; Unk; Po    |                 | Not Reported |
|                                                                                                                                                                              | Calcifediol               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                              | Vitamin D3                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2006              | 6191914       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04932-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Drug Interaction;<br>Serotonin Syndrome | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                                |                    |                    |                 |                                |                      |                 |              |                |
|------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Requip                       |                                |                    | S                  |                 | 2 Mg Qd                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2006                  | 6191951                        | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-046862-01              |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;        | Lexapro                        |                    |                    | S               | Oral                           | 10 Mg Qd Po          |                 | Not Reported |                |
| Anxiety; Decreased           | Ambien                         |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Appetite; Depression;        | Tenormin                       |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Diarrhoea; Dysuria;          | Tenex                          |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Feeling Abnormal; Hot        | Benadryl                       |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Flush; Hyperhidrosis;        | Vitamins Nos                   |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Libido Decreased; Self-      |                                |                    |                    |                 |                                |                      |                 |              |                |
| Injurious Ideation; Suicidal |                                |                    |                    |                 |                                |                      |                 |              |                |
| Ideation; Tunnel Vision;     |                                |                    |                    |                 |                                |                      |                 |              |                |
| Weight Decreased             |                                |                    |                    |                 |                                |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2006                  | 6004309                        | EXPEDITED (15-DAY) | Y                  | DS, HO          | S06-FRA-00803-01               |                      | 65 YR           | Male         | FRA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; General           | Escitalopram Oxalate           |                    |                    | S               | Oral                           | 10 Mg Qd Po          |                 | Not Reported |                |
| Physical Health              | Seropram (Citalopram           |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Deterioration;               | Hydrobromide)                  |                    |                    |                 |                                |                      |                 |              |                |
| Leukoencephalopathy;         | Depakote                       |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Motor Dysfunction;           | Tropatepine Hydrochloride      |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Speech Disorder;             | Sulfarlem (Anethole Trithione) |                    |                    | C               |                                |                      |                 | Not Reported |                |
| Syncope; Viral Infection     |                                |                    |                    |                 |                                |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2006                  | 6144098                        | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PURDUE-<br>USA_2006_0025313 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death;            | Oxycontin                      |                    |                    | S               |                                | Unk, Unk             |                 | Not Reported |                |
| Accidental Overdose;         | Cardizem                       |                    |                    | S               |                                |                      |                 | Not Reported |                |
| Akathisia; Blood Gases       | Doxepin                        |                    |                    | S               |                                |                      |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |             |   |              |
|-----------------------------|-------------|---|--------------|
| Abnormal; Cardio-           | Seroquel    | S | Not Reported |
| Respiratory Arrest;         | Lexapro     | S | Not Reported |
| Confusional State;          | Lidocaine   | S | Not Reported |
| Depressed Level Of          | Caffeine    | S | Not Reported |
| Consciousness;              | Insulin Nos | C | Not Reported |
| Dyskinesia;                 | Lyrica      | C | Not Reported |
| Hypoglycaemia; Muscle       | Ambien      | C | Not Reported |
| Twitching; Respiratory      | Cortef      | C | Not Reported |
| Distress; Snoring; Suicidal | Allopurinol | C | Not Reported |
| Ideation; Tremor;           | Protonix    | C | Not Reported |
| Unresponsive To Stimuli     | Coumadin    | C | Not Reported |
|                             | Lipitor     | C | Not Reported |
|                             | Depakote    | C | Not Reported |
|                             | Clonidine   | C | Not Reported |
|                             | Lasix       | C | Not Reported |
|                             | Diovan      | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|------------------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 29-Nov-2006              | 6175372                | NON-EXPEDITED    | N                  | OT              | US-<br>GLAXOSMITHKLINE-<br>A0586456A |                      | 38 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Event;           | Wellbutrin             |                  |                    | S               | Oral                                 | 200mg Twice Per Day  | 38 DAY          | Glaxosmithkline |                |
| Generalised Tonic-Clonic | Lexapro                |                  |                    | S               | Oral                                 |                      |                 | Not Reported    |                |
| Seizure                  | Unspecified Ingredient |                  |                    | C               | Respiratory<br>(inhalation)          |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2006              | 6175911              | EXPEDITED (15-DAY) |                    | HO              | US-ROXANE<br>LABORATORIES, INC-<br>2006-DE-06211GD |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Confusional    | Hydrochlorothiazide  |                    |                    | S               |                                                    | Maintenance Dose     |                 | Roxane       |                |
| State; Drug Interaction; | Escitalopram Oxalate |                    |                    | S               |                                                    |                      | 3 WEEK          | Not Reported |                |
| Fall; Fanconi Syndrome   | Mirtazapine          |                    |                    | S               |                                                    | Maintenance Dose     |                 | Roxane       |                |
| Acquired; Glycosuria;    | Ramipril             |                    |                    | S               |                                                    | Maintenance Dose     |                 | Not Reported |                |
| Hyperphosphaturia;       |                      |                    |                    |                 |                                                    |                      |                 |              |                |
| Hypouricaemia;           |                      |                    |                    |                 |                                                    |                      |                 |              |                |

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|                                                                                                    |                         |   |                  |              |
|----------------------------------------------------------------------------------------------------|-------------------------|---|------------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion; Renal Tubular Disorder; Urine Electrolytes Increased | Donepezil Hydrochloride | S | Maintenance Dose | Not Reported |
|                                                                                                    | Alendronic Acid         | S | Maintenance Dose | Not Reported |

| <u>FDA Received Date</u>                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2006                                       | 6181412                     | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-04758-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Haemorrhage; Toxicity To Various Agents | Lexapro                     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Hydromorphone Hydrochloride |                    |                    | S               | Oral                 | 8 Mg Prn Po          |                 | Not Reported |                |
|                                                   | Diphenhydramine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Alcohol                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Promethazine                |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Nov-2006                                                                                         | 6192025                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04889-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cushingoid; Hemianopia Homonymous; Ischaemic Stroke; Ocular Vascular Disorder; Optic Nerve Disorder | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                     | Lipitor                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Thyroid Medication (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Lisinopril               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Estrogen Nos             |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------|---------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 30-Nov-2006                       | 6176794                   | NON-EXPEDITED    | Y                  |                 | S06-USA-02815-01     |                      | 62 YR           | Male            | USA            |
| <u>Preferred Term</u>             | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Breast Enlargement; Gynaecomastia | Wellbutrin XI             |                  |                    | S               | Oral                 | 300mg Per Day        | 2 YR            | Glaxosmithkline |                |
|                                   | Lexapro                   |                  |                    | S               | Oral                 | 20mg Per Day         | 2 YR            | Not Reported    |                |
|                                   | No Concurrent Medications |                  |                    | C               |                      |                      |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|---------------------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 30-Nov-2006                                                                                             | 6176895                   | NON-EXPEDITED    | N                  |                 | BPC-XL-06-054                        |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Drug Reaction;<br>Agitation; Anxiety; Crying;<br>Hypersensitivity; Pruritus;<br>Rash; Urticaria | Wellbutrin XI             |                  |                    | S               | Unknown                              | 300mg Unknown        |                 | Glaxosmithkline |                |
|                                                                                                         | Lexapro                   |                  |                    | S               | Unknown                              | 10ml Unknown         | 5 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Nov-2006                                                                                             | 6176900                   | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0619907A |                      | 48 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety                                                                                                 | Wellbutrin XI             |                  |                    | S               | Oral                                 |                      | 2 WEEK          | Glaxosmithkline |                |
|                                                                                                         | Lexapro                   |                  |                    | S               |                                      |                      | 2 WEEK          | Not Reported    |                |
|                                                                                                         | Unspecified Ingredient    |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Dec-2006                                                                                             | 6177831                   | NON-EXPEDITED    | N                  |                 | 805-USA-01707-01                     |                      | 10 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Drug Ineffective;<br>Drug Interaction                                                          | Amoxicillin & Clavulanate |                  |                    | S               | Oral                                 | 600mg Twice Per Day  |                 | Glaxosmithkline |                |
|                                                                                                         | Potassium<br>Lexapro      |                  |                    | S               | Oral                                 | 10mg Per Day         |                 | Not Reported    |                |
|                                                                                                         | Biaxin                    |                  |                    | C               |                                      |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Dec-2006                                                                                             | 6177844                   | NON-EXPEDITED    | N                  |                 | S06-USA-03614-01                     |                      | 14 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain;<br>Headache                                                                             | Augmentin                 |                  |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |

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|                            | Lexapro                 |                    | S                  | Oral            | 10mg Per Day         |                      |                 | Not Reported |                |
|----------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                            | Ativan                  |                    | C                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2006                | 6198329                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-BEL-04780-01     |                      | 74 YR           | Male         | BEL            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure     | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Olmesartan              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Barnidipine             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2006                | 5766522                 | EXPEDITED (15-DAY) | Y                  | HO              | T05-USA-00114-01     |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Lower;      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Adnexa Uteri Mass; Back    | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Pain; Blood Pressure       | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Diastolic Increased; Blood | Multi-Vitamin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Urea Increased;            | Calcium                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Bronchitis; Gingival Pain; | Peginterferon Alfa-2a   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Headache; Heart Rate       | Ribavirin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Increased; Neutropenia;    | Doxycycline             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Normochromic Normocytic    | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Anaemia; Ovarian           | Nexium (Esomeprazole)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Neoplasm; Pancytopenia;    | Tylenol (Paracetamol)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Pelvic Pain; Pruritus;     | Generic Sleep Aid       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Rectal Haemorrhage;        | Ibuprofen               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Therapy Non-Responder;     | Pepto-Bismol            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Uterine Enlargement        | Tylenol Pm              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Otc Anti-Nausea Liquid  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Otc Antacid             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Advil                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Lortab                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Ultram                  |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2006              | 5766548       | EXPEDITED (15-DAY) | Y                  |                 | T05-USA-00911-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Adnexa     | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Uteri Pain; Anaemia; Anal  | Lexapro                |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Fissure; Back Injury; Back | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Pain; Feeling Abnormal;    | Phenergan              |              |            | C           |              |                    |                 | Not Reported |
| Fungal Infection; Genital  | Multivitamins          |              |            | C           |              |                    |                 | Not Reported |
| Rash; Intervertebral Disc  | Calcium                |              |            | C           |              |                    |                 | Not Reported |
| Degeneration;              | Peginterferon Alfa-2a  |              |            | C           |              |                    |                 | Not Reported |
| Lymphocyte Count           | Ribavirin              |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Muscle          | Ibuprofen              |              |            | C           |              |                    |                 | Not Reported |
| Spasms; Neutrophil Count   | Pepto-Bismol (Bismuth  |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Platelet Count  | Subsalicylate)         |              |            |             |              |                    |                 | Not Reported |
| Decreased; Rectal          | Advil                  |              |            | C           |              |                    |                 | Not Reported |
| Haemorrhage; Thrombosis    | Lortab                 |              |            | C           |              |                    |                 | Not Reported |
|                            | Otc Antacid            |              |            | C           |              |                    |                 | Not Reported |
|                            | Doxycycline            |              |            | C           |              |                    |                 | Not Reported |
|                            | Celebrex               |              |            | C           |              |                    |                 | Not Reported |
|                            | Nexium (Esomeprazole)  |              |            | C           |              |                    |                 | Not Reported |
|                            | Naproxen (Naproxen)    |              |            | C           |              |                    |                 | Not Reported |
|                            | Tylenol (Paracetamol)  |              |            | C           |              |                    |                 | Not Reported |
|                            | Prevacid               |              |            | C           |              |                    |                 | Not Reported |
|                            | Generic Sleep Aid      |              |            | C           |              |                    |                 | Not Reported |
|                            | Otc Anti-Nausea Liquid |              |            | C           |              |                    |                 | Not Reported |
|                            | Diclofenac             |              |            | C           |              |                    |                 | Not Reported |
|                            | Ultram                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2006              | 6094989       | EXPEDITED (15-DAY) | Y                  | DE, HO          | S06-USA-02769-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose; Suicidal<br>Ideation | Lexapro        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 04-Dec-2006                       | 6118468                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | S06-GER-03150-01              |                               | 84 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Seizure                           | Ciprallex               |                           |                             | S                        | Oral                          | 3 Drops Qd Po                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2006                       | 6151362                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S06-CZE-04182-01              |                               | 46 YR                    | Male                | CZE                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depression                        | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2006                       | 6159901                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-SWI-04297-01              |                               | 34 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Angioedema; Type Ii               | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| Hypersensitivity; Urticaria       | Lamictal                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Lorazepam               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Dec-2006                       | 6199729                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-04931-01              |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sperm Concentration Decreased     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Dec-2006                       | 6093587                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-GER-02854-01              |                               | 62 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                                  |   |      |             |              |
|-----------------------------------|----------------------------------|---|------|-------------|--------------|
| Lipomatosis; Oedema<br>Peripheral | Escitalopram Oxalate             | S | Oral | 5 Mg Qd Po  | Not Reported |
|                                   | Escitalopram Oxalate             | S | Oral | 5 Mg Qd Po  | Not Reported |
|                                   | Citalopram                       | S | Oral | 10 Mg Qd Po | Not Reported |
|                                   | Blopress (Candesartan Cilexetil) | C |      |             | Not Reported |
|                                   | Nebivolol Hydrochloride          | C |      |             | Not Reported |
|                                   | Ovestin (Estril)                 | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2006              | 6168089       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-04394-01     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Amnesia; Hallucination,<br>Visual | Paxil          |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |
|                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported    |
|                                   | Neurontin      |              |            | C           |              |                    |                 | Not Reported    |
|                                   | Amitriptyline  |              |            | C           |              | 10mg Per Day       |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2006              | 6203042       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-UKI-03755-01     |                      | 52 YR      | Female     | GBR            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psychotic Disorder;<br>Suicidal Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                          | Atenolol             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2006              | 6203070       | EXPEDITED (15-DAY) | Y                  | OT              | S06-DEN-04949-01     |                      | 54 YR      | Unknown    | DNK            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dry Mouth; Gingival<br>Disorder; Hypoaesthesia;<br>Movement Disorder;<br>Seizure | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                  | Cipralext      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 06-Dec-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 6192192        | DIRECT             | Y                  | HO, LT          |                      |                             | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Eating Disorder; Feeling Abnormal; Hallucinations, Mixed; Incorrect Dose Administered; Memory Impairment; Suicide Attempt; Weight Decreased                                                                                                                                                                                                                                                                                                                                                                            | Lexapro        |                    |                    | S               | Oral                 | 10 Daily Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 6202858        | EXPEDITED (15-DAY) | Y                  | HO, LT          | SPV1-2006-01902      |                             | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation; Anterograde Amnesia; Cognitive Disorder; Compulsions; Confusional State; Delirium; Depression Suicidal; Drug Dependence; Drug Ineffective; Drug Interaction; Drug Screen Positive; Fall; Incorrect Dose Administered; Injury; Intentional Overdose; Loss Of Consciousness; Major Depression; Nightmare; Pain; Post-Traumatic Stress Disorder; Psychotic Disorder; Refusal Of Treatment By Patient; Retrograde Amnesia; Scar; Status Epilepticus; Suicidal Behaviour; Suicidal Ideation; Suicide | Adderall       |                    |                    | S               | Oral                 | 30 Mg, 2x/Day: Bid, Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Gabitril       |                    |                    | S               | Oral                 | 16 Mg Up To 120 30 Mg, Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Xanax          |                    |                    | S               |                      | 1                           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Neurontin      |                    |                    | S               |                      | 2400 Mg, 1x/Day: Qd,        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Lexapro        |                    |                    | S               | Oral                 | 30 Mg, 2x/Day: Bid, Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Synthroid      |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Keppra         |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Remeron        |                    |                    | C               |                      |                             |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Attempt; Thinking  
Abnormal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2006              | 6203293       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-05028-01     |                      | 43 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Behcet'S Syndrome;       | Escitalopram Oxalate       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Blindness; Condition     | Mirtazapine                |              |            | C           |              |                    |                 | Not Reported |
| Aggravated; Dilatation   | Valproate Sodium           |              |            | C           |              |                    |                 | Not Reported |
| Atrial; Dilatation       | Aredia                     |              |            | C           |              |                    |                 | Not Reported |
| Ventricular; Haemoglobin | Zocor                      |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Hepatitis;    | Lorazepam                  |              |            | C           |              |                    |                 | Not Reported |
| International Normalised | Noctran 10                 |              |            | C           |              |                    |                 | Not Reported |
| Ratio Increased;         | Cyclophosphamide           |              |            | C           |              |                    |                 | Not Reported |
| Neutrophil Count         | Uromitexan (Mesna)         |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Prothrombin   | Bisoprolol Fumarate        |              |            | C           |              |                    |                 | Not Reported |
| Time Shortened           | Ramipril                   |              |            | C           |              |                    |                 | Not Reported |
|                          | Plavix                     |              |            | C           |              |                    |                 | Not Reported |
|                          | Colchicine                 |              |            | C           |              |                    |                 | Not Reported |
|                          | Prednisone                 |              |            | C           |              |                    |                 | Not Reported |
|                          | Coumadin                   |              |            | C           |              |                    |                 | Not Reported |
|                          | Actonel                    |              |            | C           |              |                    |                 | Not Reported |
|                          | Sulfamethoxazole &         |              |            | C           |              |                    |                 | Not Reported |
|                          | Trimethoprim               |              |            |             |              |                    |                 |              |
|                          | Speciafoldine (Folic Acid) |              |            | C           |              |                    |                 | Not Reported |
|                          | Diamox Sequels             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2006              | 6228167       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2006145694           |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Aggression; Agitation;   | Xanax          |              |            | S           |              |                         |                 | Not Reported |
| Alcohol Use; Anterograde | Neurontin      |              |            | S           |              | 2400 Mg                 |                 | Not Reported |
| Amnesia; Anxiety;        | Gabitril       |              |            | S           | Oral         | Oral                    |                 | Not Reported |
| Blepharospasm; Burning   | Adderall       |              |            | S           | Oral         | 60 Mg (30mg, 2 In 1 D), |                 | Not Reported |
| Sensation; Cognitive     |                |              |            |             |              | Oral                    |                 |              |
| Disorder; Compulsions;   |                |              |            |             |              |                         |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |           |   |                         |              |
|----------------------------|-----------|---|-------------------------|--------------|
| Confusional State;         | Lexapro   | S | 60 Mg (30 Mg, 2 In 1 D) | Not Reported |
| Delusion; Disturbance In   | Synthroid | C |                         | Not Reported |
| Attention; Dizziness; Drug | Keppra    | C |                         | Not Reported |
| Dependence; Drug           | Remeron   | C |                         | Not Reported |
| Ineffective; Drug          |           |   |                         |              |

Interaction; Drug Screen  
Positive; Dysarthria;  
Electroencephalogram  
Abnormal; Excessive Eye  
Blinking; Fall; Fear;  
Flashback; Hallucination;  
Incorrect Dose  
Administered; Insomnia;  
Irritability; Loss Of  
Consciousness; Loss Of  
Personal Independence In  
Daily Activities; Major  
Depression; Nightmare;  
Overdose; Paranoia; Post-  
Traumatic Stress Disorder;  
Psychotic Disorder;  
Refusal Of Treatment By  
Patient; Retrograde  
Amnesia; Scar; Seizure;  
Self-Medication; Sensory  
Disturbance; Speech  
Disorder; Suicidal  
Ideation; Thinking  
Abnormal; Toxicity To  
Various Agents

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2006              | 5860893       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2005075333           |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Anaphylactic Shock;        | Geodon         |              |            | S           | Oral         | 60 Mg (20 Mg, 3 In 1 D), |                 | Not Reported |
| Cardio-Respiratory Arrest; |                |              |            |             |              | Oral                     |                 |              |
| Dyskinesia;                | Lexapro        |              |            | S           |              |                          |                 | Not Reported |
| Extrapyramidal Disorder;   |                |              |            |             |              |                          |                 |              |
| Fall; Obstructive Airways  |                |              |            |             |              |                          |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Swollen Tongue

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2006              | 6093591       | EXPEDITED (15-DAY) | Y                  |                 | S06-USA-02720-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Septal Defect; Caesarean Section; Cardiac Failure Congestive; Maternal Exposure During Pregnancy; Neonatal Disorder; Pregnancy; Trisomy 21 | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                             | Prenatal Vitamin (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2006              | 6182768       | EXPEDITED (15-DAY) | Y                  | DE              | 2006UW27263          |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Depression | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2006              | 6205084       | EXPEDITED (15-DAY) | Y                  | OT              | S06-BEL-05062-01     |                      | 75 YR      | Male       | BEL            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Depression; Diabetes Mellitus; Disease Recurrence; Weight Increased | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                           | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                           | Depakene               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Lambipol (Lamotrigine) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Amarylle (Glimepiride) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Sertraline             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Dec-2006              | 6205086       | EXPEDITED (15-DAY) | Y                  | DS, OT          | S06-CAN-05056-01     |                      | 60 YR      | Female     | ALB            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Confusional State;<br>Diarrhoea; Dizziness;<br>Dysphagia; Headache;<br>Nausea; Pharyngeal<br>Oedema; Pruritus                    | Ciprallex                           |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                  | Ciprallex                           |                    |                    | S               | Oral                 | 5 Mg Bid Po             |                 | Not Reported |                |
|                                                                                                                                  | Ciprallex                           |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                  | Flovent                             |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                  | Spiriva                             |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                  | Breba (Salbutamol<br>W/Ipratropium) |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                  | Altace                              |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2006                                                                                                                      | 6205128                             | EXPEDITED (15-DAY) | N                  | CA, HO          | S06-USA-02720-02     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Septal<br>Defect; Caesarean<br>Section; Cardiac Failure<br>Congestive; Maternal<br>Exposure During<br>Pregnancy | Lexapro                             |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                  | Prenatal Vitamin (Nos)              |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2006                                                                                                                      | 6202419                             | DIRECT             |                    |                 |                      |                         | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Intercepted Product<br>Administration Error;<br>Medication Error; Product<br>Dispensing Error                                    | Lexapro                             |                    |                    | S               |                      | Tablet                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2006                                                                                                                      | 6203067                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-ESP-04950-01     |                         | 70 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                             |   |      |               |              |
|---------------------------|-----------------------------|---|------|---------------|--------------|
| Drug Interaction; Seizure | Ciprallex                   | S | Oral | 15 Mg Qd Po   | Not Reported |
|                           | Depakine (Valproate Sodium) | S | Oral | 1000 Mg Qd Po | Not Reported |
|                           | Omeprazole                  | C |      |               | Not Reported |
|                           | Aldactone                   | C |      |               | Not Reported |
|                           | Digoxin                     | C |      |               | Not Reported |
|                           | Enalapril                   | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6203068       | DIRECT           | N                  | HO, LT          |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Overdose; Suicidal Behaviour; Suicidal Ideation; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 40mg 1 X Per Day Orally |                 | Forest       |
|                                                                  | Lorazepam      |              |            | C           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6203346       | DIRECT           | N                  |                 |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intercepted Product                | Lipitor        |              |            | S           |              | Tablet             |                 | Pfizer       |
| Dispensing Error; Medication Error | Lexapro        |              |            | S           |              | Tablet             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6205032       | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-05119-01     |                      |            | Unknown    | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation; Anhidrosis; Anuria; Arthralgia; Decreased Appetite; Depersonalisation/Derealisation Disorder; Diarrhoea; Dizziness; Dry Mouth; Electric Shock; Hypertension; Insomnia; | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Mydriasis; Nausea;  
Nightmare; Palpitations;  
Suicidal Ideation; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6206375       | EXPEDITED (15-DAY) | Y                  | HO              | 2006S1011034         |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;                                                                                | Levothyroxine Sodium          |              |            | S           | Oral         | 50 Ug; Qd; Po      |                 | Not Reported |
| Atrioventricular Block First Degree; Chest Pain;                                               | Lexapro                       |              |            | S           | Oral         | 10 Mg; Qd; Po      |                 | Not Reported |
| Diarrhoea; Disorientation;                                                                     | Lithium                       |              |            | S           | Oral         | 1200 Mg; Bid; Po   |                 | Not Reported |
| Dizziness; Drug Interaction; Hyperhidrosis;                                                    | Clonidine                     |              |            | S           | Oral         | 0.4 Mg; Bid; Po    |                 | Not Reported |
| Hypophagia; Hypotension;                                                                       | Methylphenidate Hydrochloride |              |            | S           | Oral         | 36 Mg; Qd; Po      |                 | Not Reported |
| Hypothyroidism; Pallor;                                                                        | Oxcarbazepine                 |              |            | S           | Oral         | 600 Mg; Qd; Po     |                 | Not Reported |
| Palpitations; Rhythm Idioventricular; Toxicity To Various Agents;                              | Depakote                      |              |            | S           |              |                    |                 | Not Reported |
| Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting; White Blood Cell Count Increased |                               |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6206610       | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-05120-01     |                      | 39 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depersonalisation/Derealisation Disorder; Euphoric Mood; Panic Reaction | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                         | Celexa         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 6276770       | NON-EXPEDITED    | Y                  | RI              | E3810-00075-SPO-US   |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                                              |   |      |           |              |
|------------------------------|----------------------------------------------|---|------|-----------|--------------|
| Tubulointerstitial Nephritis | Aciphex                                      | S | Oral | Oral      | Not Reported |
|                              |                                              |   | Oral | Oral      |              |
|                              | Lotrel                                       | S |      |           |              |
|                              | Lexapro                                      | S | Oral | See Image |              |
|                              |                                              |   | Oral | See Image | Not Reported |
|                              |                                              |   | Oral | See Image |              |
|                              |                                              |   | Oral | See Image |              |
|                              | Hydrochlorothiazide<br>(Hydrochlorothiazide) | C |      |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2006              | 7466173       | EXPEDITED (15-DAY) | N                  | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0449038A |                      | 48 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|-----------------|
| Atrial Septal Defect; Blood Lactic Acid Increased; Cardiac Aneurysm; Coordination Abnormal; Extrapramidal Disorder; Facial Paralysis; Gait Inability; Hypertriglyceridaemia; Hypotension; Loss Of Consciousness; Malaise; Neurogenic Bladder; Sensory Loss | Telzir               |              |            | S           | Oral         | 700mg Twice Per Day      |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                            | Kivexa               |              |            | S           | Oral         | 1unit Per Day            |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                            | Norvir               |              |            | S           | Oral         | 100mg Twice Per Day      |                 | Unknown         |
|                                                                                                                                                                                                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 15mg Per Day             |                 | Unknown         |
|                                                                                                                                                                                                                                                            | Cyamemazine          |              |            | S           | Oral         | 10mg Three Times Per Day |                 | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2006              | 6139061       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-03634-01     |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose; Lethargy; Medication Error; Nausea; Renal Failure | Lexapro             |              |            | S           | Oral         | 140 Mg Once Po     |                 | Not Reported |
|                                                                        | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                        | Lexapro             |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                        | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Atenolol            |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |              |
|-----------------------------|---|--------------|
| Accupril                    | C | Not Reported |
| Amitriptyline               | C | Not Reported |
| Lisinopril                  | C | Not Reported |
| Prilosec                    | C | Not Reported |
| Norco                       | C | Not Reported |
| (Hydrocodone/Acetaminophen) |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2006              | 6173538       | EXPEDITED (15-DAY) | Y                  | HO              | AU-ROCHE-450410      |                      | 64 YR      | Female     | AUS            |

| <u>Preferred Term</u>             | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|-----------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Lower Respiratory Tract Infection | Peginterferon Alfa-2a |              |            | S           | Subcutaneous |                              |                 | Roche        |
|                                   | Ribavirin             |              |            | S           | Oral         |                              |                 | Roche        |
|                                   | Rabeprazole Sodium    |              |            | S           | Unknown      | Drug Taken For Eleven Years. |                 | Not Reported |
|                                   | Lexapro               |              |            | S           | Unknown      |                              |                 | Not Reported |
|                                   | Indapamide            |              |            | S           | Unknown      |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2006              | 6206916       | EXPEDITED (15-DAY) | Y                  | DE              | S06-USA-05105-01     |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2006              | 6207815       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 231633K06USA         |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Condition Aggravated; Depression; Focal Dyscognitive Seizures; Generalised Tonic-Clonic | Rebif          |              |            | S           | Subcutaneous | 44 Mcg, 3 In 1 Weeks, Subcutaneous |                 | Not Reported |
|                                                                                         | Doxepin        |              |            | S           |              | 2 Dosage Forms, Once, Not Reported |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                                                      |                       |      |                          |              |
|------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------|------|--------------------------|--------------|
| Seizure; Incorrect Dose Administered; Insomnia; Memory Impairment; Viral Infection | Lexapro<br>Ambien<br>Dilantin<br>Depakote<br>Dalmane | S<br>C<br>C<br>C<br>C | Oral | 10 Mg, 1 In 1 Days, Oral | Not Reported |
|------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------|------|--------------------------|--------------|

| <u>FDA Received Date</u>       | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------|-------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 13-Dec-2006                    | 6281013                       | NON-EXPEDITED    | Y                  | HO, RI          | 2004UW22593          |                      | 43 YR           | Male                                         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Erectile Dysfunction; Priapism | Seroquel<br>Lexapro<br>Ambien |                  |                    | S<br>S<br>C     | Oral                 | 400 Mg Daily Po      |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 13-Dec-2006              | 6281281             | NON-EXPEDITED    | Y                  | HO              | 2004UW20277          |                      |                 | Male                         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Priapism                 | Seroquel<br>Lexapro |                  |                    | S<br>S          | Oral                 | 900 Mg Po            |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|------------------|--------------------|-----------------------|----------------------|-----------------------------------------------|-----------------|------------------------------------------------------------------------------|----------------|
| 13-Dec-2006                                                                                                                   | 6282247                                                 | NON-EXPEDITED    | Y                  | HO                    | 2004UW12190          |                                               | 30 YR           | Female                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Rhabdomyolysis | Seroquel<br>Seroquel<br>Lexapro<br>Neurontin<br>Lithium |                  |                    | S<br>S<br>S<br>C<br>C | Oral<br>Oral<br>Oral | 100 Mg Bid Po<br>100 Mg Bid Po<br>10 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Dec-2006                                       | 6178146                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | ES-ABBOTT-06P-144-0351571-00 |                      | 70 YR           | Male         | ESP            |
| <u>Preferred Term</u>                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure                         | Depakene                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Omeprazole                  |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Spironolactone              |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Digoxin                     |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Enalapril                   |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Cipralex                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2006                                       | 6181252                     | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-06P-163-0351715-00 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Haemorrhage; Toxicity To Various Agents | Hydromorphone Hydrochloride |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Lexapro                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Lexapro                     |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                   | Diphenhydramine             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                   | Alcohol                     |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                   | Promethazine                |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                   | Promethazine                |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2006                                       | 6206536                     | DIRECT             | Y                  | LT              |                              |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Seizure                     | Lexapro                     |                    |                    | S               | Oral                         | 5 Mg Daily Po        |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Dec-2006                                            | 6206600                    | EXPEDITED (15-DAY) | Y                  | HO              | S06-UKI-05127-01     |                      | 86 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                          | Escitalopram Oxalate       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                        | Ventolin                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Symbicort                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Cozaar (Lostarn Potassium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Spironolactone             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2006                                            | 6276740                    | NON-EXPEDITED      | N                  |                 | IND-AE-06-SAN-047    |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea                                              | Sanctura                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                        | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Oral        |                 | Not Reported |                |
|                                                        | Metamucil (Psullium)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Levoxyl                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Diovan                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Tylenol (Paracetamol)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Motrin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2006                                            | 6175122                    | EXPEDITED (15-DAY) | Y                  | DS, LT          | S06-FRA-04599-01     |                      | 19 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Parasomnia;<br>Skin Injury;<br>Somnambulism | Escitalopram Oxalate       |                    |                    | S               |                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Trileptal                  |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Dec-2006                | 6178979                                | EXPEDITED (15-DAY) | Y                  | OT              | S06-HRV-04767-01     |                      | 55 YR           | Female       | HRV            |
| <u>Preferred Term</u>      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Obesity                    | Cipralext                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Lorazepam                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Non Steroid Antirheumatic Agents (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2006                | 6208773                                | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-05134-01     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coronary Artery Occlusion  | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                            | Lexapro                                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                            | Caduet                                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Aspirin                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2006                | 6143373                                | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03737-01     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Anxiety;      | Lexapro                                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Bipolar Disorder;          | Seroquel                               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Decreased Appetite;        | Zoloft                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Diarrhoea; Dyskinesia;     | Atenolol                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hallucination;             | Inderal                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hallucinations, Mixed;     |                                        |                    |                    |                 |                      |                      |                 |              |                |
| Headache; Hyperhidrosis;   |                                        |                    |                    |                 |                      |                      |                 |              |                |
| Imprisonment; Insomnia;    |                                        |                    |                    |                 |                      |                      |                 |              |                |
| Panic Attack; Psychotic    |                                        |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Suicide Attempt; |                                        |                    |                    |                 |                      |                      |                 |              |                |
| Vomiting                   |                                        |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Dec-2006                                                                                                                                                     | 6150524                     | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-04039-01     |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Attention<br>Deficit/Hyperactivity<br>Disorder; Blindness; Loss<br>Of Consciousness;<br>Nervousness;<br>Restlessness; Seizure;<br>Tremor | Lexapro                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                 | Lexapro                     |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Dec-2006                                                                                                                                                     | 6211402                     | DIRECT             | Y                  | HO              |                      |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Muscle Spasms;<br>Serotonin Syndrome;<br>Tremor                                                                                                      | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 20mg Daily Po        |                 | Not Reported |                |
|                                                                                                                                                                 | Nortriptyline Hydrochloride |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                                                 | Fentanyl                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Albuterol                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Flovent                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Birth Control Pills         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Xanax                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2006                                                                                                                                                     | 6210561                     | DIRECT             | Y                  | LT, RI          |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Crying; Personality<br>Change; Social Problem;<br>Suicidal Ideation; Suicide<br>Attempt                                                                  | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2006                                      | 6212939                              | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-05312-01             |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hypertension;<br>Overdose; Suicide Attempt | Lexapro                              |                    |                    | S               | Oral                         | 54 Mg Once Po        |                 | Not Reported |                |
|                                                  | Lunesta                              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                  | Wellbutrin (Bupropion Hydrochloride) |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2006                                      | 6213295                              | EXPEDITED (15-DAY) | Y                  | HO              | S06-ISR-05260-01             |                      | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Menometrorrhagia                                 | Escitalopram Oxalate                 |                    |                    | S               |                              | 10 Mg Qd             |                 | Not Reported |                |
|                                                  | Cinnarizine                          |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                  | Propoxyphene (Propoxyphene)          |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2006                                      | 5925014                              | EXPEDITED (15-DAY) | Y                  | LT, OT          | DE-ABBOTT-05P-062-0316195-00 |                      | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia               | Ciprallex                            |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                  | Ciprallex                            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                  | Valproate Sodium                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                  | Olanzapine                           |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                  | Amitriptyline Hydrochloride          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2006                                      | 6201568                              | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20061205114        |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                           |           |   |              |
|---------------------------|-----------|---|--------------|
| Blood Pressure Increased; | Risperdal | S | Not Reported |
| Depression; Dizziness;    | Risperdal | S | Not Reported |
| Drug Interaction; Feeling | Tegretol  | C | Not Reported |
| Of Despair; Feelings Of   | Lexapro   | S | Not Reported |
| Worthlessness;            | Lexapro   | S | Not Reported |

Hallucination, Visual;  
Headache; Insomnia;  
Mental Impairment;  
Nightmare; Tinnitus

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2006              | 6212898       | DIRECT           | Y                  |                 |                      |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lip Oedema; Pruritus;<br>Rash | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Dec-2006              | 6046615       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-01617-01     |                      | 72 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypothyroidism        | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Evista         |              |            | C           |              |                    |                 | Not Reported |
|                       | Actonel        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Dec-2006              | 6055707       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-IRL-01956-01     |                      | 56 DAY     | Male       | IRL            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome; Maternal<br>Exposure During<br>Pregnancy; Platelet Count<br>Decreased | Lexapro        |              |            | S           | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Dec-2006                                                                                                                                                                                                                          | 6181405                      | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-04772-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Intentional<br>Overdose; Intentional Self-<br>Injury; Suicidal Ideation;<br>Suicide Attempt                                                                                                     | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                      |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro                      |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Abilify                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Focalin (Dexmethylphenidate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Effexor                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2006                                                                                                                                                                                                                          | 6209797                      | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-05236-01     |                      | 52 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                                                                              | Ciprallex                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lorazepam                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Unspecified Ingredient       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2006                                                                                                                                                                                                                          | 6209809                      | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-05153-01     |                      | 48 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aneurysm; Atrial Septal<br>Defect; Coordination<br>Abnormal; Csf Lactate<br>Increased; Facial<br>Paralysis; Gait<br>Disturbance;<br>Hypertriglyceridaemia;<br>Hypotension; Loss Of<br>Consciousness; Malaise;<br>Neurogenic Bladder; | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Cyamemazine                  |                    |                    | S               | Oral                 | 10 Mg Tid Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Norvir                       |                    |                    | S               | Oral                 | 100 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Telzir                       |                    |                    | S               | Oral                 | 700 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Kivexa                       |                    |                    | S               | Oral                 | 1 Qd Po              |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Nuclear Magnetic  
Resonance Imaging Brain  
Abnormal; Pyramidal Tract  
Syndrome

| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Dec-2006                | 6213668                  | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-04862-01     |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anxiety;   | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Condition Aggravated;      | Ambien                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased Appetite;        | Tenormin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Depression; Diarrhoea;     | Tenex                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Dysuria; Feeling           | Unspecified Ingredient   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Abnormal; Hot Flush;       | Guanfacine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyperhidrosis; Loss Of     | Benadryl                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Libido; Suicidal Ideation; | Vitamins Nos             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Tunnel Vision; Weight      |                          |                    |                    |                 |                      |                      |                 |              |                |
| Decreased                  |                          |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2006                | 6213719                  | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-05307-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;      | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Seizure                    | Dilantin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2006                | 6213721                  | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-05371-01     |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;      | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Depression; Intentional    |                          |                    |                    |                 |                      |                      |                 |              |                |
| Self-Injury; Suicidal      |                          |                    |                    |                 |                      |                      |                 |              |                |
| Ideation; Suicide Attempt  |                          |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 26-Dec-2006                                                                                                                                                      | 6214473               | DIRECT             | N                  | HO, OT          |                              |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Muscle Injury; Musculoskeletal Disorder                                                                                        | Lexapro               |                    |                    | S               | Oral                         | 10 Mg Daily Po       | 6 MTH           | Not Reported |                |
|                                                                                                                                                                  | Lexapro               |                    |                    | S               | Oral                         | 5 Mg Daily Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2006                                                                                                                                                      | 6171532               | EXPEDITED (15-DAY) | Y                  | DE              | S06-CZE-04576-01             |                      | 65 YR           | Male         | CZE            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident                                                                                                                                         | Cipralext             |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2006                                                                                                                                                      | 6182220               | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-06P-056-0351864-00 |                      | 48 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal; Facial Paralysis; Gait Inability; Hypotension; Loss Of Consciousness; Malaise; Neurogenic Bladder; Paraesthesia; Pyramidal Tract Syndrome | Ritonavir             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                  | Cyamemazine           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                  | Escitalopram Oxalate  |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                  | Fosamprenavir Calcium |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                  | Abacavir\Lamivudine   |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2006                                                                                                                                                      | 6188068               | EXPEDITED (15-DAY) | Y                  | OT              | S06-NOR-04910-01             |                      | 33 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Fatigue; Headache; Nocturia                                                                                                                            | Cipralext             |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                  | Flutide               |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                  | Ventolin              |                    |                    | C               |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Dec-2006                                                   | 6211685                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-05272-01              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Disorientation; Fatigue;<br>Loss Of Consciousness;<br>Seizure | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Dec-2006                                                   | 6213649                 | DIRECT                    | N                           | HO, LT                   |                               |                               | 51 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Suicide Attempt                                     | Lexapro                 |                           |                             | S                        | Oral                          | 40 Mg 1 X Per Day Orally      |                          | Not Reported        |                         |
|                                                               | Lorazepam Tabs          |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Dec-2006                                                   | 6213880                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-USA-05324-01              |                               | 89 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                                                 | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Dec-2006                                                   | 7466174                 | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-ABBOTT-06P-056-0352740-00  |                               | 48 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Atrial Septal Defect; Brain                                   | Norvir                  |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| Stem Syndrome; Cardiac                                        | Escitalopram Oxalate    |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| Aneurysm; Coordination                                        | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| Abnormal; Csf Lactate                                         | Fosamprenavir Calcium   |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| Increased; Facial                                             | Kivexa                  |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| Paralysis; Gait                                               | Cyamemazine             |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| Disturbance;                                                  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Hypertriglyceridaemia;                                        |                         |                           |                             |                          |                               |                               |                          |                     |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                               |             |   |  |  |  |  |  |  |              |
|---------------------------------------------------------------------------------------------------------------|-------------|---|--|--|--|--|--|--|--------------|
| Hypotension; Loss Of Consciousness; Malaise; Mass; Neurogenic Bladder; Pyramidal Tract Syndrome; Sensory Loss | Cyamemazine | S |  |  |  |  |  |  | Not Reported |
|---------------------------------------------------------------------------------------------------------------|-------------|---|--|--|--|--|--|--|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 28-Dec-2006              | 6204478       | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0632596A |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure | Lamictal                |              |            | S           | Oral         | 100mg Twice Per Day |                 | Glaxosmithkline |
|                                                                                          | Lovenox                 |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Folic Acid              |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Synthroid               |              |            | S           |              |                     |                 | Glaxosmithkline |
|                                                                                          | Pentoxifylline          |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Fosamax                 |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Lexapro                 |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Nexium                  |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Gabapentin              |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Furosemide              |              |            | S           |              |                     |                 | Glaxosmithkline |
|                                                                                          | Trazodone Hydrochloride |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Calcium                 |              |            | S           |              |                     |                 | Not Reported    |
|                                                                                          | Aspirin                 |              |            | S           |              |                     |                 | Glaxosmithkline |
| Vitamin D Nos                                                                            |                         |              | S          |             |              |                     | Not Reported    |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2006              | 6214930       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Dyspnoea; Erythema; Treatment Noncompliance | Lexapro        |              |            | S           | Oral         | 10 Mg Tab Daily Oral | 3 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2006              | 6215610       | EXPEDITED (15-DAY) | Y                  | LT              | 2006-152044-NL       |                      | 46 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                       |   |                                          |                   |       |              |
|-------------------------|-----------------------|---|------------------------------------------|-------------------|-------|--------------|
| Abdominal Distension;   | Vecuronium Bromide    | S |                                          |                   | 1 DAY | Not Reported |
| Acute Hepatic Failure;  | Amoxicillin           | S |                                          |                   |       | Not Reported |
| Coagulopathy;           | Diclofenac            | S | Intravenous (not<br>otherwise specified) | Intravenous (Nos) |       | Not Reported |
| Hepatomegaly;           |                       |   |                                          |                   |       |              |
| Hypotension; Oxygen     | Escitalopram Oxalate  | S |                                          |                   |       | Not Reported |
| Saturation Decreased;   | Fentanyl              | S |                                          |                   |       | Not Reported |
| Post Procedural         | Glycopyrrolate        | S |                                          |                   |       | Not Reported |
| Complication;           | Isoflurane            | S |                                          |                   |       | Not Reported |
| Somnolence; Stridor;    | Morphine              | S |                                          |                   |       | Not Reported |
| Tachycardia; Tachypnoea | Neostigmine           | S |                                          |                   |       | Not Reported |
|                         | Nitrous Oxide         | S |                                          |                   |       | Not Reported |
|                         | Ondansetron           | S |                                          |                   |       | Not Reported |
|                         | Oxygen                | S |                                          |                   |       | Not Reported |
|                         | Propofol              | S |                                          |                   |       | Not Reported |
|                         | Co-Dydramol           | C |                                          |                   |       | Not Reported |
|                         | Diazepam              | C |                                          |                   |       | Not Reported |
|                         | Escitalopram Oxalate  | C |                                          |                   |       | Not Reported |
|                         | Norethindrone Acetate | C |                                          |                   |       | Not Reported |
|                         | Zolpidem              | C |                                          |                   |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2006              | 6049302       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2006S1003754         |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;     | Rebif                      |              |            | S           |              | 44 Ug; Tiw;        |                 | Not Reported |
| Depression; Drug          | Doxepin Hydrochloride      |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Ineffective; Focal        | Lexapro                    |              |            | S           | Oral         | 10 Mg; Qd; Po      |                 | Not Reported |
| Dyscognitive Seizures;    | Ambien (Con.)              |              |            | C           |              |                    |                 | Not Reported |
| Generalised Tonic-Clonic  | Dilantin /00017401/ (Con.) |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Incoherent;      | Depakote (Con.)            |              |            | C           |              |                    |                 | Not Reported |
| Incorrect Dose            | Dalmane (Con.)             |              |            | C           |              |                    |                 | Not Reported |
| Administered; Insomnia;   |                            |              |            |             |              |                    |                 |              |
| Memory Impairment;        |                            |              |            |             |              |                    |                 |              |
| Mobility Decreased;       |                            |              |            |             |              |                    |                 |              |
| Speech Disorder; Suicidal |                            |              |            |             |              |                    |                 |              |
| Ideation; Viral Infection |                            |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2006                                                                                       | 6086854           | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-AUT-02641-01     |                      | 46 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug Withdrawal Syndrome; Hallucination; Illusion; Major Depression; Restlessness | Cipralelex        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                   | Bromazepam        |                    |                    | S               |                      | 6 Mg Unk             |                 | Not Reported |                |
|                                                                                                   | Bromazepam        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2006                                                                                       | 6168088           | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04370-01     |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Confusional State; Disorientation; Loss Of Consciousness; Seizure             | Lexapro           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                   | Effexor           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2007                                                                                       | 6213280           | EXPEDITED (15-DAY) | Y                  | HO              | T06-GER-05238-01     |                      |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Suicide Attempt                                                                 | Cipralelex        |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                   | Cipralelex        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                   | Tavor (Lorazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Doxepin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Seroquel          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Carbamazepine     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Insulin Human     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2007                                                                                       | 6215004           | DIRECT             | N                  | DE              |                      |                      | 32 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|------------------------------------|--------------------------|---------------------|-------------------------|
| Completed Suicide;<br>Intentional Overdose                                                                                                          | Lexapro                 |                           |                             | S                        | Oral                          | 20/ Then 40 Mg Per Day<br>Daily Po |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2007                                                                                                                                         | 6215534                 | EXPEDITED (15-DAY)        | Y                           | DE, HO                   | 2006-151988-NL                |                                    | 65 YR                    | Male                | ESP                     |
| <a href="#">Preferred Term</a>                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Delirium Tremens; Drug<br>Ineffective; Neuroleptic<br>Malignant Syndrome;<br>Nosocomial Infection;<br>Pseudomonas Infection;<br>Respiratory Failure | Mirtazapine             |                           |                             | S                        | Oral                          | 15 Mg/30 Mg Oral                   | 19 DAY                   | Not Reported        |                         |
|                                                                                                                                                     |                         |                           |                             |                          | Oral                          | 15 Mg/30 Mg Oral                   | 11 DAY                   |                     |                         |
|                                                                                                                                                     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg/20 Mg Oral                   | 19 DAY                   | Not Reported        |                         |
|                                                                                                                                                     |                         |                           |                             |                          | Oral                          | 10 Mg/20 Mg Oral                   | 11 DAY                   |                     |                         |
|                                                                                                                                                     | Unspecified Ingredient  |                           |                             | C                        |                               |                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2007                                                                                                                                         | 6216906                 | DIRECT                    | Y                           | HO                       |                               |                                    | 83 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaemia; Drug Interaction;<br>Mental Status Changes;<br>Oesophagitis                                                                                | Zelapar                 |                           |                             | S                        | Oral                          | 1.25mg Daily Oral                  |                          | Not Reported        |                         |
|                                                                                                                                                     | Lexapro                 |                           |                             | S                        | Oral                          | 10mg Daily Oral                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2007                                                                                                                                         | 6294461                 | NON-EXPEDITED             | Y                           | HO                       | A03200605028                  |                                    |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Pyrexia                                                                                                                           | Demerol                 |                           |                             | S                        |                               |                                    |                          | Not Reported        |                         |
|                                                                                                                                                     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Oral                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jan-2007                                                                                                                                         | 6205027                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S06-FRA-05124-01              |                                    | 41 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                      |   |      |             |              |
|-----------------------|----------------------|---|------|-------------|--------------|
| Gingivitis Ulcerative | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|                       | Magnesium            | C |      |             | Not Reported |
|                       | Prazepam             | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2007              | 6212949       | EXPEDITED (15-DAY) | Y                  | HO              | T06-GER-05321-01     |                      | 53 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression            | Cipralax       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Metformin      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2007              | 6217291       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-05416-01     |                      | 20 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Guttate Psoriasis     | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                       | Depakote                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Mianserin Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                       | Imovane (Zopiclone)      |              |            | S           |              |                    |                 | Not Reported |
|                       | Beta Lactamase Inhibitor |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2007              | 6217292       | EXPEDITED (15-DAY) | Y                  | OT              | S06-DEN-05428-01     |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;<br>Intentional Self-Injury;<br>Nightmare; Skin<br>Laceration; Sleep<br>Disorder; Thinking<br>Abnormal | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jan-2007              | 6217294       | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-05461-01     |                      | 58 YR      | Female     | IRL            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Purpura                                                                                                                                                      | Cipralext                    |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                              | Pravastatin                  |                    |                    | C               |                       |                      | Not Reported    |              |                |
|                                                                                                                                                              | Ideos                        |                    |                    | C               |                       |                      | Not Reported    |              |                |
|                                                                                                                                                              | Stilnoct (Zolpidem Tartrate) |                    |                    | C               |                       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2007                                                                                                                                                  | 6218351                      | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-05457-01      |                      | 31 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura                                                                                                                                                      | Lexapro                      |                    |                    | S               | Oral                  | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                  | 6122906                      | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20060900698 |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Interaction; Drug Withdrawal Syndrome; Nightmare; Panic Attack                                                                     | Ultram Er                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                              | Ultram Er                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                              | Voltaren                     |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                              | Nasonex                      |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                  | 6143635                      | EXPEDITED (15-DAY) |                    | OT              | 2006UW18327           |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Anxiety; Bipolar Disorder; Decreased Appetite; Diarrhoea; Dyskinesia; Hallucination; Headache; Hyperhidrosis; Loss Of Consciousness; Mental | Seroquel                     |                    |                    | S               | Oral                  |                      | 17 MTH          | Zeneca       |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               | Oral                  |                      | 3 MTH           | Not Reported |                |
|                                                                                                                                                              | Lexapro                      |                    |                    | S               | Oral                  |                      | 15 MTH          | Not Reported |                |
|                                                                                                                                                              | Zoloft                       |                    |                    | S               |                       |                      | 17 MTH          | Not Reported |                |
|                                                                                                                                                              | Strattera                    |                    |                    | S               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                         |                      |                     |                    |                 |                                  |                      |                 |                              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|------------------------------|----------------|
| Impairment; Panic Attack;<br>Suicide Attempt; Vomiting                                                                                                                                                  |                      | Atenolol<br>Inderal |                    | C<br>C          |                                  |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                                                             | 6175121              | EXPEDITED (15-DAY)  | Y                  | OT              | S06-GER-04602-01                 |                      |                 | Male                         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Blood Creatine<br>Phosphokinase Increased                                                                                                                                                               | Escitalopram Oxalate |                     |                    | S               |                                  | 20 Mg Qd             |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Seroquel             |                     |                    | S               |                                  |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                                                             | 6180886              | EXPEDITED (15-DAY)  | Y                  | OT              | S06-CAN-04850-01                 |                      | 40 YR           | Male                         | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Atrioventricular Block<br>Second Degree;<br>Dizziness; Hypoaesthesia;<br>Loss Of Consciousness;<br>Peripheral Coldness                                                                                  | Cipralex             |                     |                    | S               | Oral                             | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Cipralex             |                     |                    | S               | Oral                             | 5 Mg Qd Po           |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                                                             | 6209453              | EXPEDITED (15-DAY)  | Y                  | OT              | US-PFIZER INC-<br>2006118689     |                      | 44 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Bipolar Disorder;<br>Decreased Appetite;<br>Diarrhoea; Dyskinesia;<br>Hallucination; Headache;<br>Hyperhidrosis; Insomnia;<br>Mental Impairment; Panic<br>Attack; Suicide Attempt;<br>Vomiting | Zoloft               |                     |                    | S               |                                  |                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Lexapro              |                     |                    | S               | Oral                             |                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Seroquel             |                     |                    | S               |                                  |                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Alcohol              |                     |                    | S               |                                  |                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Atenolol             |                     |                    | C               |                                  |                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                         | Inderal              |                     |                    | C               |                                  |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-Jan-2007                                                                                                                                                                                             | 6209633              | EXPEDITED (15-DAY)  | Y                  | OT              | FR-ABBOTT-06P-056-<br>0354457-00 |                      | 20 YR           | Female                       | FRA            |

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| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Guttate Psoriasis     | Depakote                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                       | Mianserin Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                       | Zopiclone                |              |            | S           |              |                    |                 | Not Reported |
|                       | Beta Lactamase Inhibitor |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2007              | 6220294       | DIRECT           | N                  | OT              |                      |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Abnormal<br>Dreams; Arthralgia; Back<br>Pain; Balance Disorder;<br>Burning Sensation; Chills;<br>Choking; Corneal<br>Infiltrates; Corneal<br>Oedema; Derealisation;<br>Diarrhoea; Diplopia;<br>Dyskinesia; Ecchymosis;<br>Eye Irritation; Fall;<br>Flatulence;<br>Gastrooesophageal Reflux<br>Disease; Hallucination;<br>Headache; Hyperhidrosis;<br>Joint Swelling; Pain In<br>Extremity; Palpitations;<br>Paraesthesia; Pruritus<br>Generalised; Purulence;<br>Raynaud'S Phenomenon;<br>Restless Legs Syndrome;<br>Skin Ulcer; Vision Blurred;<br>Visual Impairment | Lexapro        |              |            | S           |              | 10 Mg 1 Daily      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2007              | 6152626       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04137-01     |                      | 30 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|---------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Drug Interaction; Major Depression; Suicidal Ideation                                       | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Maxalt                 |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Synthroid              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2007                                                                                 | 6161840                | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-04285-01     |                      | 63 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coma; Hypertension; Intentional Overdose; Respiratory Failure; Suicide Attempt; Tachycardia | Lexapro                |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                             | Remeron                |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Remeron                |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Aspirin                |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Toprol XL              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Zetia (Ezetimibe)      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Lipitor                |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Niacin                 |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Vicodin                |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2007                                                                                 | 6213724                | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-05267-01     |                      | 93 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Full Blood Count Decreased; Hypersensitivity                                                | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                                                             | Lexapro                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                                                             | Zestril                |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                             | Unspecified Ingredient |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2007                                                                                 | 6215795                | EXPEDITED (15-DAY) | N                  | HO              | 2006SP004205         |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coma; Hypertension; Overdose                                                                | Wellbutrin             |                    |                    | S               | Unknown              |                      |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                           | Lunesta                |                    | S                  | Oral            | 54mg Single Dose     |                         |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                                           | Lexapro                |                    | S                  | Unknown         |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2007                                                                                                                                                                                                               | 6220931                | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-00016-01     |                         | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Drug Ineffective; Mood Swings; Overdose; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt                                                                                                  | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Lexapro                |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2007                                                                                                                                                                                                               | 6140339                | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04861-02     |                         | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Acoustic Stimulation Tests Abnormal; Bradycardia Neonatal; Cesarean Section; Developmental Delay; Maternal Condition Affecting Foetus; Maternal Exposure During Pregnancy; Premature Baby; Premature Rupture Of Membranes | Lexapro                |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Prenatabs Fa           |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Unspecified Ingredient |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Unspecified Ingredient |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2007                                                                                                                                                                                                               | 6140342                | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-04861-01     |                         | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Acoustic Stimulation Tests Abnormal; Bradycardia Neonatal; Cesarean Section; Dizziness;                                                                                                                                   | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Prenatal Vitamin (Nos) |                    |                    | C               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Feeling Abnormal;  
Infection; Maternal  
Exposure During  
Pregnancy; Paraesthesia;  
Pregnancy; Premature  
Baby; Premature Rupture  
Of Membranes

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| 10-Jan-2007                                                                                  | 6211461        | EXPEDITED (15-DAY) |                    | HO              | PHEH2007US00502                                 |                                        | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt                                                     | Trileptal      |                    |                    | S               |                                                 | Unk, Once/Single                       |                 | Novartis     |                |
|                                                                                              | Lexapro        |                    |                    | S               | Oral                                            | 20 Mg, Qd                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2007                                                                                  | 6211898        | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13223219 |                                        | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Restlessness;<br>Weight Increased                                                   | Abilify        |                    |                    | S               |                                                 |                                        | 1 YR            | Not Reported |                |
|                                                                                              | Lexapro        |                    |                    | S               |                                                 |                                        |                 | Not Reported |                |
|                                                                                              | Tegretol       |                    |                    | C               |                                                 |                                        |                 | Not Reported |                |
|                                                                                              | Lorazepam      |                    |                    | C               |                                                 |                                        |                 | Not Reported |                |
|                                                                                              | Relafen        |                    |                    | C               |                                                 |                                        |                 | Not Reported |                |
|                                                                                              | Plaquenil      |                    |                    | C               |                                                 |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2007                                                                                  | 6212288        | NON-EXPEDITED      | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13370382 |                                        | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia;<br>Communication Disorder;<br>Depression; Drug<br>Interaction; Lethargy; | Abilify        |                    |                    | S               | Oral                                            | Duration Of Therapy: 1.5<br>To 2 Years |                 | Not Reported |                |
|                                                                                              | Lexapro        |                    |                    | S               | Oral                                            |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |           |   |      |              |
|------------|-----------|---|------|--------------|
| Somnolence | Keppra    | S | Oral | Not Reported |
|            | Carbatrol | C |      | Not Reported |
|            | Vitamins  | C |      | Not Reported |
|            | Tegretol  | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2007              | 6212657       | NON-EXPEDITED    | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13503735 |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                          | Cogentin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2007              | 6212743       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13534342 |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Extrapyramidal Disorder | Abilify        |              |            | S           |              |                    | 4 YR            | Not Reported |
|                                           | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2007              | 6221337       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-00061-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder; Bipolar Disorder; Drug Interaction; Incorrect Dose Administered; Product Prescribing Error; Psychotic Disorder | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Biaxin         |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jan-2007                                                           | 6222346                   | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-04786-01          |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;<br>Maternal Exposure During<br>Pregnancy; Pregnancy | Ciprallex                 |                    |                    | S               | Oral                      | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2007                                                           | 6213678                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-MERCK-<br>0701FRA00012 |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hyponatraemia                                                   | Hyzaar                    |                    |                    | S               | Oral                      |                      |                 | Merck        |                |
|                                                                       | Althiazide\Spironolactone |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                       | Carbamazepine             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                       | Risperidone               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                       | Escitalopram Oxalate      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                       | Celiprolol Hydrochloride  |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2007                                                           | 6224728                   | EXPEDITED (15-DAY) | Y                  | OT              | S07-UKI-00039-01          |                      | 67 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Feeling Abnormal;<br>Malaise; Myalgia; Tremor  | Escitalopram Oxalate      |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                       | Atenolol                  |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                       | Kalms                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                       | Paracetamol               |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2007                                                           | 5657242                   | EXPEDITED (15-DAY) | Y                  | DS, OT          | S04-USA-06735-01          |                      | 9 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                  |                                                                                  |                       |      |            |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------|------|------------|--------------|
| Abnormal Behaviour;<br>Affective Disorder;<br>Anxiety; Bipolar Disorder;<br>Chorea; Condition<br>Aggravated; Diarrhoea;<br>Electroencephalogram<br>Abnormal; Enuresis;<br>Libido Increased; Seizure;<br>Self-Injurious Ideation;<br>Sexual Dysfunction;<br>Suicidal Ideation; Suicide<br>Attempt | Lexapro<br>Seroquel<br>Lithium<br>Zyprexa<br>Tenex (Guanfacine<br>Hdyrochloride) | S<br>C<br>C<br>C<br>C | Oral | 5 Mg Qd Po | Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------|------|------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6062210       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-01914-01     |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Bradycardia           | Lexapro<br>Unspecified Ingredient |              |            | S<br>S      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6222626       | DIRECT           |                    | OT              |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Erythema;<br>Infusion Related Reaction;<br>Paraesthesia; Pruritus;<br>Urticaria | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6224231       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00081-01     |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|----------------------------------------------|
| Anticonvulsant Drug Level<br>Below Therapeutic;<br>Disease Recurrence; Drug<br>Interaction; Seizure | Lexapro<br>Lamictal<br>Lovenox |              |            | S<br>S<br>S | Oral         | 40 Mg Qd Po<br>100 Mg Bid |                 | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Synthroid               | S | Not Reported |
| Pentoxifylline          | S | Not Reported |
| Fosamax                 | S | Not Reported |
| Nexium (Esomeprazole)   | S | Not Reported |
| Gabapentin              | S | Not Reported |
| Furosemide              | S | Not Reported |
| Trazodone Hydrochloride | S | Not Reported |
| Aspirin                 | S | Not Reported |
| Calcium                 | S | Not Reported |
| Folic Acid              | S | Not Reported |
| Vitamin D Nos           | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6224367       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-00118-01     |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Carbon Monoxide Poisoning; Completed Suicide; Overdose | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                  | Xanax          |              |            | S           |              |                    |                 | Not Reported |
|                                                                  | Xanax          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6224378       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-00150-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro                   |              |            | S           |              |                    |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2007              | 6224386       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00090-01     |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dissociative Amnesia; Legal Problem | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2007                                                           | 6289002        | NON-EXPEDITED    | N                  |                 | 2006SP004186         |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Amnesia;<br>Confusional State;<br>Depression; Hypotrichosis | Lunesta        |                  |                    | S               | Oral                 | 2 Mg; Oral           |                 | Not Reported |                |
|                                                                       | Lexapro        |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2007                                                           | 6289082        | NON-EXPEDITED    | N                  |                 | 2006SP004237         |                      | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia                                                              | Lunesta        |                  |                    | S               | Oral                 | See Image            |                 | Not Reported |                |
|                                                                       |                |                  |                    |                 | Oral                 | See Image            |                 |              |                |
|                                                                       |                |                  |                    |                 | Oral                 | See Image            |                 |              |                |
|                                                                       |                |                  |                    |                 | Oral                 | See Image            |                 |              |                |
|                                                                       | Lexapro        |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                       | Ambien         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Lexapro        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Paxil          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2007                                                           | 6290138        | NON-EXPEDITED    | N                  |                 | 2006SP003706         |                      | 87 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue                                                               | Lunesta        |                  |                    | S               | Oral                 | Hs;Oral              |                 | Not Reported |                |
|                                                                       | Lexapro        |                  |                    | S               | Oral                 | 10 Mg;Qd;Oral        |                 | Not Reported |                |
|                                                                       | Neurontin      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Xanax          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Amlodipine     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Zestril        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                       | Multivitamins  |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2007                                                                              | 6292290                 | NON-EXPEDITED      | N                  |                 | 2006SP003859         |                      | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased                                                                 | Lunesta                 |                    |                    | S               | Oral                 | 3 Mg;Oral            |                 | Not Reported |                |
|                                                                                          | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg;Qd;Oral        |                 | Not Reported |                |
|                                                                                          | Adderall                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Uroxatral               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                          | Bupropion               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2007                                                                              | 6216569                 | EXPEDITED (15-DAY) | Y                  | OT              | 2007UW00498          |                      | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure | Nexium                  |                    |                    | S               | Oral                 |                      |                 | Astrazeneca  |                |
|                                                                                          | Lamictal                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                          | Lovenox                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Folic Acid              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Synthroid               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Pentoxifylline          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Fosamax                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Gabapentin              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Furosemide              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Trazodone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Aspirin                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Calcium                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                          | Vitamin D2              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2007                                                                              | 6224234                 | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-00073-01     |                      | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;                                                                    | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                       |   |              |
|-------------------------|-----------------------|---|--------------|
| Anxiety; Bipolar II     | Lexapro               | S | Not Reported |
| Disorder; Dizziness;    | Lexapro               | S | Not Reported |
| Feeling Abnormal;       | Adderall Xr           | S | Not Reported |
| Nausea; Overdose; Panic | Dextrostat            | S | Not Reported |
| Attack; Paranoia;       | Advil                 | S | Not Reported |
| Restlessness; Suicidal  | Lamictal              | C | Not Reported |
| Ideation                | Provigil              | C | Not Reported |
|                         | Wellbutrin (Bupropion | C | Not Reported |
|                         | Hydrochloride)        |   |              |
|                         | Cymbalta              | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2007              | 6636400       | EXPEDITED (15-DAY) | N                  | HO              | SPV1-2007-00094      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;       | Adderall Xr                     |              |            | S           |              |                    |                 | Not Reported |
| Accidental Overdose;        | Dextrostat                      |              |            | S           |              |                    |                 | Not Reported |
| Affect Lability; Agitation; | Unspecified Ingredient          |              |            | S           |              |                    |                 | Not Reported |
| Alcohol Use; Anger;         | Lexapro                         |              |            | S           |              |                    |                 | Not Reported |
| Crying; Delusion;           | Effexor /01233801/(Venlafaxine) |              |            | C           |              |                    |                 | Not Reported |
| Depressed Mood;             | Zyprexa                         |              |            | C           |              |                    |                 | Not Reported |
| Dizziness; Dysgeusia;       |                                 |              |            |             |              |                    |                 |              |
| Electrocardiogram           |                                 |              |            |             |              |                    |                 |              |
| Abnormal; Insomnia;         |                                 |              |            |             |              |                    |                 |              |
| Intentional Self-Injury;    |                                 |              |            |             |              |                    |                 |              |
| Irritability; Loss Of       |                                 |              |            |             |              |                    |                 |              |
| Consciousness; Nausea;      |                                 |              |            |             |              |                    |                 |              |
| Panic Attack; Paranoia;     |                                 |              |            |             |              |                    |                 |              |
| Partner Stress; Self-       |                                 |              |            |             |              |                    |                 |              |
| Injurious Ideation; Self-   |                                 |              |            |             |              |                    |                 |              |
| Medication; Skin            |                                 |              |            |             |              |                    |                 |              |
| Laceration; Substance       |                                 |              |            |             |              |                    |                 |              |
| Abuse; Suicide Attempt;     |                                 |              |            |             |              |                    |                 |              |
| Thinking Abnormal;          |                                 |              |            |             |              |                    |                 |              |
| Weight Decreased            |                                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2007              | 6161835       | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-04270-01     |                      |            | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Blood Creatine Phosphokinase Increased; Myalgia                                                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg Qd Po               |                 | Not Reported |                |
|                                                                                                                                       | Escitalopram Oxalate   |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                                                                                                                                       | Unspecified Ingredient |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                                                                                                                                       | Unspecified Ingredient |                    |                    | S               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2007                                                                                                                           | 6176704                | EXPEDITED (15-DAY) | Y                  | DS              | S06-FRA-04633-01     |                          | 51 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematospermia; Mental Disorder                                                                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2007                                                                                                                           | 6207635                | EXPEDITED (15-DAY) | N                  | OT              | PHFR2006GB03759      |                          | 37 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Depression; Fatigue; Gait Disturbance; Hemiparesis; Mental Disorder; Mental Impairment; Paranoia; Partial Seizures | Tegretol               |                    |                    | S               | Unknown              | 800mg Mane & 800mg Nocte |                 | Novartis     |                |
|                                                                                                                                       | Topamax                |                    |                    | S               |                      | 600mg Mane & 600mg Nocte |                 | Not Reported |                |
|                                                                                                                                       | Phenytoin Sodium       |                    |                    | S               |                      | 400mg/Mane               |                 | Not Reported |                |
|                                                                                                                                       | Escitalopram Oxalate   |                    |                    | S               |                      | 10mg Mane                |                 | Not Reported |                |
|                                                                                                                                       | Zyprexa                |                    |                    | S               |                      | 7.5mg Prn                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2007                                                                                                                           | 6216355                | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-05391-01     |                          | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate Aminotransferase Increased; Discomfort;                                                                                     | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |             |   |              |
|-----------------------------------------------------------------------------|-------------|---|--------------|
| Gamma-Glutamyltransferase Increased; Hepatitis A Antibody Positive; Pyrexia | Cyamemazine | C | Not Reported |
|-----------------------------------------------------------------------------|-------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2007              | 6129478       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-03467-01     |                      | 84 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;<br>Agitation; Confusional State; Depressed Mood; Pneumonia; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Lexapro        |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                | Sinemet        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Flomax         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Proscar        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                | Imdur          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2007              | 6218708       | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-477722      |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apnoea; Completed Suicide; Hypotension; Pyrexia; Tachycardia; Unresponsive To Stimuli | Naproxen                      |              |            | S           | Unknown      |                    |                 | Roche        |
|                                                                                       | Cyclobenzaprine Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                       | Acetaminophen And Codeine     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                       | Acetylsalicylic Acid          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                       | Ibuprofen                     |              |            | S           | Unknown      |                    |                 | Roche        |
|                                                                                       | Escitalopram Oxalate          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                       | Pseudoephedrine Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jan-2007                                                                                                                                  | 6224937                 | DIRECT             | N                  | OT              |                              |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Insomnia; Panic Attack                                                                                                        | Lexapro                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2007                                                                                                                                  | 6225060                 | DIRECT             | Y                  | HO              |                              |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Persistent Foetal Circulation; Premature Baby | Lexapro                 |                    |                    | S               | Oral                         | 10mg Daily Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2007                                                                                                                                  | 6552608                 | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-07P-163-0355702-00 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anticonvulsant Drug Level Below Therapeutic; Drug Ineffective; Drug Interaction; Seizure                                                     | Synthroid               |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Lexapro                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Lamotrigine             |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                              | Enoxaparin Sodium       |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Folic Acid              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Pentoxifylline          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Fosamax                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Nexium                  |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Gabapentin              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Furosemide              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Trazodone Hydrochloride |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                              | Calcium                 |                    |                    | S               |                              |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Aspirin                                                                                                               |                      | S                  |                    | Not Reported    |                      |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Ergocalciferol                                                                                                        |                      | S                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2007                                                                                                           | 6205329              | EXPEDITED (15-DAY) | Y                  | LT, OT          | PHEH2006US15365      |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Drug Interaction;<br>Hypersomnia; Insomnia;<br>Nausea; Oesophagitis;<br>Productive Cough | Zelnorm              |                    |                    | S               | Oral                 | 6 Mg, Bid            | 41760 MIN       | Novartis     |                |
|                                                                                                                       | Zelnorm              |                    |                    | S               |                      | 6 Mg, Qd             |                 | Novartis     |                |
|                                                                                                                       | Lexapro              |                    |                    | S               | Oral                 | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                       | Cymbalta             |                    |                    | S               | Oral                 | 30 Mg, Qd            | 86400 MIN       | Not Reported |                |
|                                                                                                                       | Cymbalta             |                    |                    | S               |                      | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                       | Dexidrine            |                    |                    | C               |                      | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                       | Tegretol             |                    |                    | C               | Oral                 | 1200 Mg, Qd          |                 | Not Reported |                |
|                                                                                                                       | Atenolol             |                    |                    | C               | Oral                 | 25 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                       | Doxycycline          |                    |                    | C               | Oral                 | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                       | Lortab               |                    |                    | C               | Oral                 | Unk, Tid             |                 | Not Reported |                |
|                                                                                                                       | Oxycodone            |                    |                    | C               | Oral                 | Unk, Qd2sdo          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2007                                                                                                           | 6225698              | DIRECT             | N                  |                 |                      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia                                                                                                               | Lexapro              |                    |                    | S               |                      | 1 Tablet Daily       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2007                                                                                                           | 6228791              | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-00294-01     |                      | 61 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse;<br>Hypoglycaemia                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                       | Humalog              |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |   |              |
|----------------------------------------|---|--------------|
| Ramipril                               | C | Not Reported |
| Stangyl (Trimipramine Maleate)         | C | Not Reported |
| Aspirin                                | C | Not Reported |
| Cotrim                                 | C | Not Reported |
| Lantus                                 | C | Not Reported |
| Akineton                               | C | Not Reported |
| Fluanxol Depot (Flupentixol Decanoate) | C | Not Reported |
| Zocor                                  | C | Not Reported |
| Levothyroxine Sodium                   | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2007              | 6228892       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-00149-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Physical Assault      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 23-Jan-2007              | 6220532       | EXPEDITED (15-DAY) | Y                  | OT              | US-AVENTIS-200710405US |                      |            | Male       | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction; Seizure | Lovenox                 |              |            | S           | Oral         | Dose: Unk          |                 | Aventis      |
|                                             | Lamictal                |              |            | S           |              |                    |                 | Not Reported |
|                                             | Folic Acid              |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Thyroxine Sodium        |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Pentoxifylline          |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Alendronate Sodium      |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Lexapro                 |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Nexium                  |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Gabapentin              |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Furosemide              |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Trazodone Hydrochloride |              |            | S           |              | Dose: Unk          |                 | Not Reported |
|                                             | Calcium                 |              |            | S           |              | Dose: Unk          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |           |              |
|---------|---|-----------|--------------|
| Aspirin | S | Dose: Unk | Not Reported |
| Vit D   | S | Dose: Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Jan-2007              | 6221057       | EXPEDITED (15-DAY) | DE                 |                 | US-ROXANE<br>LABORATORIES, INC-<br>2007-BP-00824RO |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Death      | Mirtazapine              |              |            | S           |              |                    |                 | Roxane       |
|                       | Codeine                  |              |            | S           |              |                    |                 | Roxane       |
|                       | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                       | Fentanyl                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Hydrocodone/Apap         |              |            | S           |              |                    |                 | Not Reported |
|                       | Zolpidem                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Tizanidine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                       | Lorazepam                |              |            | C           |              |                    |                 | Not Reported |
|                       | Depakote                 |              |            | C           |              |                    |                 | Not Reported |
|                       | Doxepin                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Celecoxib                |              |            | C           |              |                    |                 | Not Reported |
|                       | Neurontin                |              |            | C           |              |                    |                 | Not Reported |
|                       | Zonisamide               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2007              | 6165807       | EXPEDITED (15-DAY) | Y                  | HO              | S06-AUT-04443-01     |                      | 43 YR      | Male       | AUT            |

| <u>Preferred Term</u>     | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Activated | Cipraxel                        |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
| Partial Thromboplastin    | Cipraxel                        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Time Abnormal; Blood      | Cipraxel                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Disorder; International   | Marcumar                        |              |            | S           | Oral         | 1.5 Mg Unk Po      |                 | Not Reported |
| Normalised Ratio          | Marcumar                        |              |            | S           | Oral         | 2.25 Mg Unk Po     |                 | Not Reported |
| Increased; Muscle         | Marcumar                        |              |            | S           | Oral         | 1.5 Mg Unk Po      |                 | Not Reported |
| Haemorrhage; Platelet     | Marcumar                        |              |            | S           | Oral         |                    |                 | Not Reported |
| Disorder; Pneumonia;      | Seroquel                        |              |            | C           |              |                    |                 | Not Reported |
| Prothrombin Time          | Alna (Tamsulosin Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
| Prolonged; White Blood    | Visken                          |              |            | C           |              |                    |                 | Not Reported |
| Cell Count Increased      |                                 |              |            |             |              |                    |                 |              |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Jan-2007                                                                                                                                                                                                                             | 6205503                      | EXPEDITED (15-DAY) | Y                  | HO              | S06-SWE-05057-01     |                      | 86 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia                                                                                                                                                                                                     | Cipralext                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Warfarin Sodium              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Diazepam                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2007                                                                                                                                                                                                                             | 6213887                      | EXPEDITED (15-DAY) | N                  | HO              | S06-USA-04369-01     |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Coronary Artery<br>Bypass; Coronary Artery<br>Thrombosis; Erythema;<br>Feeling Drunk; Feeling<br>Hot; Myocardial Infarction;<br>Nausea; Night Sweats;<br>Peripheral Coldness;<br>Staphylococcal Infection;<br>Swelling; Tremor | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Nitroglycerin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Glucophage                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Insulin Nos                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Lipitor                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Hyzaar                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Prazosin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Captopril                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Hydrochlorothiazide          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Atenolol                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Ultram                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Aspirin                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Metoprolol                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2007                                                                                                                                                                                                                             | 6227736                      | DIRECT             | Y                  | OT              |                      |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Erythema;<br>Hyperhidrosis; Joint<br>Swelling; Nausea;<br>Sunburn                                                                                                                                                            | Lexapro                      |                    |                    | S               | Oral                 | 10mg Daily Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Xanax                        |                    |                    | S               | Oral                 | 1mg Or Less Prn Po   |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Birth Control Pills -Kariva- |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Zyrtec-D                     |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                                             |                                     |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Benadryl                                                    |                                     | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| Ibuprofen                                                   |                                     | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2007                                                 | 6231038                             | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00242-01     |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hyponatraemia                                         | Escitalopram Oxalate                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Aldactazine                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Tegretol                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Risperdal                           |                    |                    | S               | Oral                 | 2 Mg Bid Po          |                 | Not Reported |                |
|                                                             | Hyzaar                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                             | Selectol (Celiprolol Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2007                                                 | 6232303                             | EXPEDITED (15-DAY) | N                  | DE              | S07-USA-00275-01     |                      | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Feeling Of Despair; Gun<br>Shot Wound | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                             | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                             | Lexapro                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jan-2007                                                 | 6232311                             | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00264-01     |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcoholism; Loss Of<br>Consciousness; Thinking<br>Abnormal  | Lexapro                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                             | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                             | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------|---------------------------------------------|-----------------|--------------|----------------|
| 24-Jan-2007                                                                                                                                                                                                        | 6234716                 | DIRECT             | N                  | HO              |                       |                                             | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness                                                                                                                                                                                              | Trazodone Hydrochloride |                    |                    | S               | Oral                  | One 50mg Pill Evenings Po                   |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               | Oral                  | One 10mg Pill Mornings Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2007                                                                                                                                                                                                        | 6168768                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-04431-01      |                                             | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Self-Injurious Ideation                                                                                                                                                                              | Lexapro                 |                    |                    | S               | Oral                  | 10 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               | Oral                  | 5 Mg Qd Po                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               | Oral                  | 20 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               | Oral                  | 10 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Allegra                 |                    |                    | C               |                       |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2007                                                                                                                                                                                                        | 6222786                 | EXPEDITED (15-DAY) | Y                  | HO              | US-BAYER-200710177BCC |                                             | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Lower; Blood Creatinine Increased; Constipation; Decreased Appetite; Flank Pain; Haematuria; Hypertension; Nasal Congestion; Nasal Discomfort; Nausea; Nephrolithiasis; Renal Failure; Rhinorrhoea; | Aleve                   |                    |                    | S               | Oral                  |                                             |                 | Bayer        |                |
|                                                                                                                                                                                                                    | Lexapro                 |                    |                    | S               | Oral                  | Total Daily Dose: 50 Mg<br>Unit Dose: 50 Mg | 1110 DAY        | Not Reported |                |
|                                                                                                                                                                                                                    | Excedrin                |                    |                    | S               | Oral                  |                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Buspar                  |                    |                    | C               |                       |                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                    | Trazodone Hydrochloride |                    |                    | C               |                       |                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Sinus Headache; Sinusitis

| <u>FDA Received Date</u>                             | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2007                                          | 6229237            | DIRECT           | Y                  | HO              |                      |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Dizziness; Paraesthesia | Lexapro            |                  |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                      | Toprol XL          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Zetia              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Allopurinol Sodium |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Benicar Hct        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Vitamins           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Asa                |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Advair Diskus      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Singulair          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Albuterol          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                      | Combivent          |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2007                   | 6229269        | DIRECT           | Y                  | HO              |                      |                      | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash Maculo-Papular | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Po Qd           |                 | Not Reported |                |
|                               | Diabetes Pills |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2007                                     | 6232644                       | EXPEDITED (15-DAY) | Y                  | DE              | T200601597           |                      | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Acetaminophen\Codeine         |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                 | Phosphate                     |                    |                    |                 |                      |                      |                 |              |                |
|                                                 | Pseudoephedrine Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate          |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jan-2007              | 6223677       | EXPEDITED (15-DAY) | Y                  | HO              | PHRM2007FR00519      |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Fall; Hyponatraemia | Tegretol             |              |            | S           | Oral         |                    |                 | Novartis     |
|                                                | Aldactazine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Risperdal            |              |            | S           | Oral         | 2 Mg, Bid          |                 | Not Reported |
|                                                | Hyzaar               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                | Celectol             |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6203606       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-04970-01     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;<br>Alcohol Use; Amnesia;<br>Anxiety; Cognitive<br>Disorder; Delirium; Drug<br>Dependence; Drug<br>Interaction; Drug Screen<br>Positive; Fall; Incorrect<br>Dose Administered; Injury;<br>Insomnia; Irritability; Loss<br>Of Consciousness; Major<br>Depression; Nervous<br>System Disorder;<br>Nightmare; Overdose;<br>Pain; Post-Traumatic<br>Stress Disorder; Psychotic<br>Disorder; Refusal Of<br>Treatment By Patient;<br>Scar; Seizure; Self-<br>Medication; Status<br>Epilepticus; Suicidal | Lexapro                        |              |            | S           | Oral         | 30 Mg Bid Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Gabitril                       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Adderall                       |              |            | S           | Oral         | 30 Mg Bid Po       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Xanax                          |              |            | S           |              | 1 Tablet           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Neurontin                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Synthroid (Levothyroid Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Keppra                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remeron                        |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Behaviour; Suicidal  
Ideation; Suicide Attempt

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6212933       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-USA-05213-01     |                      | 90 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Diastolic Decreased; Bradycardia; Cardiac Failure                                                                                                                                                                        | Lexapro                 |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Congestive; Dehydration; Dialysis; Fall; Haematocrit Decreased; Haematoma; Haemoglobin Decreased; Head Injury; Hyperkalaemia; Hyperphosphataemia; Hypoglycaemia; Renal Failure; Respiratory Rate Increased; Skin Laceration; Somnolence | Levoxyl                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Captopril               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Metoprolol              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Aspirin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Lasix                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Potassium               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Norvasc                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Glucophage              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Glucotrol               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Colace                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                         | Haldol                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6213078       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-05213-02     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine Increased; Renal Disorder | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6216377       | EXPEDITED (15-DAY) | Y                  | DE              | S06-ESP-05375-01     |                      | 65 YR      | Male       | ESP            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Candida Infection; Lung Infection; Neuroleptic Malignant Syndrome; Respiratory Failure; | Ciprallex      |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                         | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |                         |   |      |             |              |
|----------------|-------------------------|---|------|-------------|--------------|
| Rhabdomyolysis | Ciprallex               | S | Oral | 5 Mg Qd Po  | Not Reported |
|                | Mirtazapine             | S | Oral | 30 Mg Qd Po | Not Reported |
|                | Mirtazapine             | S | Oral | 15 Mg Qd Po | Not Reported |
|                | Clorazepate Dipotassium | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6225292       | NON-EXPEDITED    | N                  |                 | S05-USA-05361-01     |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Abdominal Pain Upper;<br>Constipation; Endoscopy<br>Abnormal; Fatigue;<br>Nausea; Weight<br>Decreased | Wellbutrin     |              |            | S           | Oral         |                    | 75 DAY          | Glaxosmithkline |
|                                                                                                       | Lexapro        |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6225327       | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0593706A |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Urticaria             | Wellbutrin     |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6225587       | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0622978A |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Ineffective      | Wellbutrin     |              |            | S           | Oral         |                    | 2 YR            | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Unknown      |                    | 2 YR            | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2007              | 6231181       | DIRECT           | N                  | RI              |                      |                      | 34 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Amnesia; Cognitive Disorder                                                                                              | Lexapro                             |                    |                    | S               | Oral                 | 10mg Daily Po        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2007                                                                                                              | 6235944                             | EXPEDITED (15-DAY) | Y                  | HO              | T07-GER-00282-01     |                      | 63 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hospitalisation                                                                                                          | Cipralexx                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Cipralexx                           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Madopar                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Diclo (Diclofenac Sodium)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Dociton (Propranolol Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2007                                                                                                              | 6235971                             | EXPEDITED (15-DAY) | Y                  | DS              | S07-UKI-00288-01     |                      | 46 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Disturbance In Attention; Dizziness; Fatigue; Hyperhidrosis; Nausea; Overdose; Palpitations; Somnolence; Tremor | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 40 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 30 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 20 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                          | Citalopram Hydrobromide             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2007                                                                                                              | 6581099                             | EXPEDITED (15-DAY) | Y                  | HO              | CHPA2007US01146      |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Lower; Constipation; Decreased Appetite; Haematuria; Headache; Hypertension; Nasal Congestion;            | Lexapro                             |                    |                    | S               | Oral                 | 50 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                                                                          | Excedrin Migraine                   |                    | Y                  | S               |                      | Prn                  |                 | Not Reported |                |
|                                                                                                                          | Aleve                               |                    |                    | S               |                      | Bid                  |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                  |                                   |        |  |                              |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------|--|------------------------------|
| Nausea; Nephrolithiasis;<br>Pain; Renal Failure; Renal<br>Impairment; Rhinorrhoea;<br>Sinusitis; Tenderness;<br>Ureterolithiasis | Buspar<br>Trazodone Hydrochloride | C<br>C |  | Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2007              | 6220412       | EXPEDITED (15-DAY) | N                  | DE, OT          | US-BAYER-<br>200710481GDS |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apnoea; Completed<br>Suicide; Hypotension;<br>Pyrexia; Tachycardia;<br>Unresponsive To Stimuli | Naproxen                      |              |            | S           | Unknown      |                    |                 | Bayer        |
|                                                                                                | Acetaminophen                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Codeine                       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Acetylsalicylic Acid          |              | Y          | S           | Unknown      |                    |                 | Bayer        |
|                                                                                                | Ibuprofen                     |              |            | S           | Unknown      |                    |                 | Bayer        |
|                                                                                                | Cyclobenzaprine Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Pseudoephedrine Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2007              | 6227001       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00155-01     |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Phlebitis; Pulmonary<br>Embolism | Escitalopram Oxalate    |              |            | S           | Oral         | 0.5 Qd Po          |                 | Not Reported |
|                                  | Lexomil (Bromazepam)    |              |            | S           |              |                    |                 | Not Reported |
|                                  | Cerazette (Desogestrel) |              |            | S           | Oral         | 1 Qd Po            |                 | Not Reported |
|                                  | Depakote                |              |            | S           | Oral         | 500 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2007              | 6236992       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-00443-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |         |   |              |
|--------------------------|---------|---|--------------|
| Cerebrovascular Accident | Lexapro | S | Not Reported |
|--------------------------|---------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2007              | 6047953       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S06-USA-01633-01     |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;     | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depression; Focal         | Lexapro        |              |            | S           | Oral         | 20 Mg Once Po      |                 | Not Reported |
| Dyscognitive Seizures;    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Incorrect Dose            | Doxepin        |              |            | S           | Oral         | 2 Tablet Once Po   |                 | Not Reported |
| Administered; Influenza;  | Rebif          |              |            | S           | Subcutaneous | 44 Mcg Tiw Sc      |                 | Not Reported |
| Insomnia; Memory          | Dilantin       |              |            | C           |              |                    |                 | Not Reported |
| Impairment; Overdose;     | Ambien         |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Speech Disorder; | Depakote       |              |            | C           |              |                    |                 | Not Reported |
| Therapy Non-Responder     |                |              |            |             |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2007              | 6104401       | EXPEDITED (15-DAY) | Y                  | HO              | L06-TUR-03075-01     |                      | 33 YR      | Male       | TUR            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase  | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Increased; Aspartate      | Escitalopram Oxalate |              |            | S           |              | 10 Mg Unk          |                 | Not Reported |
| Aminotransferase          | Lithium              |              |            | S           |              | 1200 Mg Unk        |                 | Not Reported |
| Increased; Blood Chloride | Lamotrigine          |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Blood          |                      |              |            |             |              |                    |                 |              |
| Creatine Phosphokinase    |                      |              |            |             |              |                    |                 |              |
| Increased; Blood Creatine |                      |              |            |             |              |                    |                 |              |
| Phosphokinase Mb          |                      |              |            |             |              |                    |                 |              |
| Increased; Blood Lactate  |                      |              |            |             |              |                    |                 |              |
| Dehydrogenase             |                      |              |            |             |              |                    |                 |              |
| Increased; C-Reactive     |                      |              |            |             |              |                    |                 |              |
| Protein Increased;        |                      |              |            |             |              |                    |                 |              |
| Cerebellar Syndrome;      |                      |              |            |             |              |                    |                 |              |
| Electroencephalogram      |                      |              |            |             |              |                    |                 |              |
| Abnormal; Epstein-Barr    |                      |              |            |             |              |                    |                 |              |
| Virus Antigen Positive;   |                      |              |            |             |              |                    |                 |              |
| Hyponatraemia;            |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Lymphocyte Percentage  
Decreased; Nausea;  
Pneumonia; Red Blood  
Cell Sedimentation Rate  
Increased; Toxicity To  
Various Agents; Tremor;  
Vomiting

| <u>FDA Received Date</u>           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2007                        | 6204361                     | EXPEDITED (15-DAY) | Y                  | LT, OT          | S06-GER-05065-01     |                      | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia | Cipralex                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                    | Amitriptyline Hydrochloride |                    |                    | S               | Oral                 | 75 Mg Unk Po         |                 | Not Reported |                |
|                                    | Valproate Sodium            |                    |                    | S               | Oral                 | 1200 Mg Unk Po       |                 | Not Reported |                |
|                                    | Zyprexa                     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2007                                                                                                                                                                                                                                                                                                                                                                           | 6228063              | EXPEDITED (15-DAY) |                    | HO              | TR-ROXANE<br>LABORATORIES, INC-<br>2007-BP-01412RO |                      | 31 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Anxiety;<br>Aspartate<br>Aminotransferase<br>Increased; Blood Chloride<br>Decreased; Blood<br>Creatine Phosphokinase<br>Increased; Blood Creatine<br>Phosphokinase Mb<br>Increased; Blood Lactate<br>Dehydrogenase<br>Increased; Blood Sodium<br>Decreased; C-Reactive<br>Protein Increased;<br>Cerebellar Syndrome;<br>Coordination Abnormal; | Lithium Carbonate    |                    |                    | S               |                                                    | 1200 Mg/Day          | 4 MTH           | Roxane       |                |
|                                                                                                                                                                                                                                                                                                                                                                                       | Lamotrigine          |                    |                    | S               |                                                    | 300 Mg/Day           | 4 MTH           | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               |                                                    | 10 Mg/Day            | 4 MTH           | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                       |                      |                    |                    |                 |                                                    |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysarthria; Dyskinesia;  
Dyspnoea; Gait  
Disturbance; Nausea;  
Nystagmus; Pneumonia;  
Pyrexia; Tremor; Vomiting

| <u>FDA Received Date</u>                           | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|----------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
| 31-Jan-2007                                        | 6228230                                                | EXPEDITED (15-DAY) | Y                  | DE, OT           | US-PFIZER INC-<br>2007006699 |                      | 62 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Completed Suicide;<br>Intentional Overdose         | Xanax<br>Lexapro                                       |                    |                    | S<br>S           |                              |                      |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 31-Jan-2007                                        | 6235812                                                | DIRECT             | Y                  | OT               |                              |                      | 74 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Depression; Mental<br>Impairment                   | Lexapro                                                |                    |                    | S                |                              |                      | 2 MTH           | Not Reported                                                 |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 31-Jan-2007                                        | 6236655                                                | DIRECT             |                    | OT               |                              |                      | 40 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Drug Ineffective                                   | Paxil<br>Unspecified Ingredient<br>Lexapro<br>Cymbalta |                    |                    | S<br>S<br>S<br>S |                              |                      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 31-Jan-2007                                        | 6239758                                                | EXPEDITED (15-DAY) | Y                  | OT               | L07-IND-00341-02             |                      | 65 YR           | Male                                                         | IND            |
| <u>Preferred Term</u>                              | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Generalised Tonic-Clonic<br>Seizure; Hyponatraemia | Escitalopram Oxalate                                   |                    |                    | S                |                              | 10 Mg Qd             |                 | Not Reported                                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                |                    |                    |                 |                          |                      |                 |              |                |
|------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Atenolol                     |                | C                  |                    | Not Reported    |                          |                      |                 |              |                |
| Amlodipine                   |                | C                  |                    | Not Reported    |                          |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2007                  | 7226089        | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-PFIZER INC-2006145694 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anterograde       | Xanax          |                    |                    | S               |                          | Text:Unknown         |                 | Not Reported |                |
| Amnesia; Anxiety;            | Neurontin      |                    |                    | S               |                          | Daily Dose:2400mg    |                 | Not Reported |                |
| Confusional State;           | Lexapro        |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Delirium; Depression;        | Synthroid      |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Drug Interaction; Fall; Ill- | Keppra         |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Defined Disorder;            | Remeron        |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Intentional Overdose;        | Gabitril       |                    |                    | S               | Oral                     | Text:Unknown         |                 | Not Reported |                |
| Irritability; Jamais Vu;     | Gabitril       |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Lethargy; Nervous System     | Adderall       |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Disorder; Pain; Post-        |                |                    |                    |                 |                          |                      |                 |              |                |
| Traumatic Stress Disorder;   |                |                    |                    |                 |                          |                      |                 |              |                |
| Psychotic Disorder;          |                |                    |                    |                 |                          |                      |                 |              |                |
| Retrograde Amnesia;          |                |                    |                    |                 |                          |                      |                 |              |                |
| Scar; Seizure; Speech        |                |                    |                    |                 |                          |                      |                 |              |                |
| Disorder; Suicidal           |                |                    |                    |                 |                          |                      |                 |              |                |
| Ideation; Vitreous Floaters  |                |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2007                  | 5867382        | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-03944-01         |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;      | Lexapro        |                    |                    | S               | Oral                     | 20 Mg Qd Po          |                 | Not Reported |                |
| Choroidal Effusion; Ciliary  | Benadryl       |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Body Disorder                |                |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2007                  | 6151363        | EXPEDITED (15-DAY) | Y                  | HO              | S06-ITA-04131-01         |                      | 34 YR           | Female       | ITA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                     |              |   |      |             |              |
|-------------------------------------------------------------------------------------|--------------|---|------|-------------|--------------|
| Caesarean Section;                                                                  | Ciprallex    | S | Oral | 5 Mg Qd Po  | Not Reported |
| Disease Recurrence;                                                                 | Ciprallex    | S | Oral | 10 Mg Qd Po | Not Reported |
| Investigation Abnormal;                                                             | Lormetazepam | C |      |             | Not Reported |
| Maternal Exposure During Pregnancy; Pregnancy; Therapeutic Product Effect Decreased |              |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2007              | 6211301       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-07P-056-0354840-00 |                      | 52 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyspnoea; Pulmonary Embolism;      | Depakote             |              |            | S           | Oral         |                    |                 | Not Reported |
| Thrombophlebitis; Weight Increased | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                    | Bromazepam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                    | Desogestrel          |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2007              | 6223799       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2006SP004474         |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Condition Aggravated; Depression; Metastases To Lymph Nodes; Stress; Thyroid Cancer | Lunesta        |              |            | S           | Oral         | 3 Mg; Hs; Oral               |                 | Not Reported |
|                                                                                     | Lexapro        |              |            | S           |              | 10 Mg; 20 Mg<br>10 Mg; 20 Mg |                 | Not Reported |
|                                                                                     | Ativan         |              |            | S           |              | 0.5 Mg; Bid                  |                 | Not Reported |
|                                                                                     | Asacol         |              |            | C           |              |                              |                 | Not Reported |
|                                                                                     | Nexium         |              |            | C           |              |                              |                 | Not Reported |
|                                                                                     | Atorvastatin   |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2007              | 6229139       | EXPEDITED (15-DAY) | Y                  | OT              | US-MERCK-0701USA04738 |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                         |   |         |              |
|---------------------------------------------|-------------------------|---|---------|--------------|
| Drug Ineffective; Drug Interaction; Seizure | Fosamax                 | S | Oral    | Merck        |
|                                             | Lamictal                | S | Oral    | Not Reported |
|                                             | Lovenox                 | S | Unknown | Not Reported |
|                                             | Folic Acid              | S | Unknown | Not Reported |
|                                             | Synthroid               | S | Unknown | Not Reported |
|                                             | Pentoxifylline          | S | Unknown | Not Reported |
|                                             | Lexapro                 | S | Unknown | Not Reported |
|                                             | Nexium                  | S | Unknown | Not Reported |
|                                             | Gabapentin              | S | Unknown | Not Reported |
|                                             | Furosemide              | S | Unknown | Not Reported |
|                                             | Trazodone Hydrochloride | S | Unknown | Not Reported |
|                                             | Lonazolac Calcium       | S | Unknown | Not Reported |
|                                             | Aspirin                 | S | Unknown | Not Reported |
|                                             | Vitamin D Nos           | S | Unknown | Not Reported |
|                                             | Calcium (Unspecified)   | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2007              | 6232630       | EXPEDITED (15-DAY) | Y                  | HO              | T07-GER-00239-01     |                      | 55 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                         | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcoholism; Anxiety; Condition Aggravated; Depressive Symptom | Ciprallex                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                               | Ciprallex                        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                               | L-Thyroxin (Levothyroxin Sodium) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2007              | 7385678       | EXPEDITED (15-DAY) | N                  | HO              | US-ABBOTT-07P-163-0356700-00 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder; Bipolar Disorder; Drug Interaction; | Biaxin         |              |            | S           |              |                    |                 | Not Reported |
|                                                         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                        |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Psychotic Disorder                                       | Lexapro                |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2007                                              | 6226235                | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-00132-01     |                      | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Generalised Tonic-Clonic<br>Seizure | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Po             |                 | Not Reported |                |
|                                                          | Seroquel               |                    |                    | S               | Oral                 | 600 Mg Po            |                 | Not Reported |                |
|                                                          | Seroquel               |                    |                    | S               | Oral                 | 400 Mg Po            |                 | Not Reported |                |
|                                                          | Seroquel               |                    |                    | S               | Oral                 | 500 Mg Po            |                 | Not Reported |                |
|                                                          | Levothyroxine Sodium   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Benalapril (Enalapril) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2007                                              | 6241121                | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00476-01     |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased                                 | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                          | Tylenol (Paracetamol)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Albuterol              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Clonidine              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Epogen                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Ferrous Sulfate        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Arixtra                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Lasix                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Kytril                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Insulin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Ativan                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Reglan                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Metoprolol             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Pancrelipase           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Potassium              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Unasyn                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                          | Fentanyl               |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                         | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|----------------------------------------------------|----------------|
| 05-Feb-2007                                                                                           | 6241993                         | EXPEDITED (15-DAY) | Y                  | LT              | L07-LUX-00452-01                     |                      | 60 YR           | Female                                             | LUX            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                         |                |
| Bradycardia; Cerebral Hypoperfusion; Condition Aggravated; Loss Of Consciousness; Respiratory Failure | Escitalopram Oxalate            |                    |                    | S               |                                      | 5 Mg Once            |                 | Not Reported                                       |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                         | <u>Country</u> |
| 06-Feb-2007                                                                                           | 5339538                         | NON-EXPEDITED      | Y                  |                 | 15993                                |                      | 17 YR           | Female                                             | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                         |                |
| Adverse Event; Self Esteem Decreased; Weight Increased                                                | Paxil Cr<br>Lamictal<br>Lexapro |                    |                    | S<br>S<br>S     | Oral<br>Oral                         |                      |                 | Glaxosmithkline<br>Glaxosmithkline<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                         | <u>Country</u> |
| 06-Feb-2007                                                                                           | 6231615                         | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0627555A |                      |                 | Female                                             | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                         |                |
| Headache                                                                                              | Paxil<br>Lexapro                |                    |                    | S<br>S          | Oral<br>Unknown                      |                      |                 | Glaxosmithkline<br>Not Reported                    |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                         | <u>Country</u> |
| 06-Feb-2007                                                                                           | 6238487                         | DIRECT             | N                  |                 |                                      |                      | 28 YR           | Male                                               | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                         |                |
| Weight Increased; Weight Loss Poor                                                                    | Lexapro                         |                    |                    | S               | Oral                                 | 15 Mg Once Daily Po  |                 | Not Reported                                       |                |

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| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Feb-2007                                                  | 6238819                 | DIRECT                    | Y                           | DE                       |                               |                               | 52 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Daily Po                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Feb-2007                                                  | 6202341                 | EXPEDITED (15-DAY)        | Y                           |                          | S06-UKI-04995-01              |                               | 22 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Neuroleptic Malignant Syndrome                               | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                              | Aripiprazole            |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                              | Lorazepam               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                              | Lactulose               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                              | Valproate Sodium        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Feb-2007                                                  | 6242033                 | DIRECT                    | Y                           | DE                       |                               |                               | 82 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspnoea; Serotonin Syndrome                                 | Fluoxetine              |                           |                             | S                        |                               | Pta Not Known Not Sure        |                          | Not Reported        |                         |
|                                                              | Escitalopram Oxalate    |                           |                             | S                        |                               | Pta Not Known Not Sure        |                          | Not Reported        |                         |
|                                                              | Tramadol Hydrochloride  |                           |                             | S                        |                               | Pta Not Known                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Feb-2007                                                  | 6243819                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S07-USA-00484-01              |                               | 38 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Confusional State; Hyponatraemia; Mouth Haemorrhage; Seizure | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                              | Risperdal               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 07-Feb-2007                  | 6245934        | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-00526        |                        | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Lichen Planus                | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po            |                 | Not Reported |                |
|                              | Xanax          |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2007                  | 6242076        | DIRECT             | N                  | LT              |                      |                        | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;            | Lexapro        |                    |                    | S               |                      | 15 Mg Once A Day       |                 | Forest       |                |
| Irritability; Pain; Suicidal | Lexapro        |                    |                    | S               |                      | 10 Mg Once A Day       |                 | Forest       |                |
| Ideation; Tremor             | Wellbutrin     |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Zyprexa        |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Remeron        |                    |                    | C               |                      |                        |                 | Not Reported |                |
|                              | Clonazepam     |                    |                    | C               |                      |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2007                  | 6269151        | DIRECT             | Y                  | LT, RI          |                      |                        | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;            | Lexapro        |                    |                    | S               | Oral                 | 10 Milligrams Daily Po | 1 WEEK          | Forest       |                |
| Dyspnoea;                    |                |                    |                    |                 |                      |                        |                 |              |                |
| Hypoaesthesia;               |                |                    |                    |                 |                      |                        |                 |              |                |
| Hypokinesia; Injury;         |                |                    |                    |                 |                      |                        |                 |              |                |
| Intentional Self-Injury;     |                |                    |                    |                 |                      |                        |                 |              |                |
| Limb Operation;              |                |                    |                    |                 |                      |                        |                 |              |                |
| Musculoskeletal Pain;        |                |                    |                    |                 |                      |                        |                 |              |                |
| Pain; Peroneal Nerve         |                |                    |                    |                 |                      |                        |                 |              |                |
| Palsy; Suicide Attempt;      |                |                    |                    |                 |                      |                        |                 |              |                |
| Surgery                      |                |                    |                    |                 |                      |                        |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2007              | 6093053       | EXPEDITED (15-DAY) | Y                  | OT              | L06-USA-02654-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma;<br>Choroidal Effusion; Ciliary<br>Body Disorder; Corneal<br>Oedema; Drug Ineffective | Lexapro        |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2007              | 6203105       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04921-01     |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>                                                                                                                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                               | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------------------------------------|----------------------|----------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| Affect Lability; Amnesia;<br>Anxiety; Blood Pressure<br>Increased; Chest<br>Discomfort; Condition<br>Aggravated; Crying;<br>Decreased Appetite;<br>Depressed Mood;<br>Diarrhoea; Disturbance In<br>Attention; Dizziness;<br>Dysphemia; Dysuria;<br>Fatigue; Insomnia;<br>Malaise; Memory<br>Impairment; Muscle<br>Rigidity; Nausea;<br>Serotonin Syndrome;<br>Somnolence; Speech<br>Disorder; Thinking<br>Abnormal | Lexapro<br>Prozac<br>Prozac<br>Zithromax<br>Depo-Provera<br>Tylenol With Codeine<br>Tizanidine Hydrochloride<br>Women'S Multivitamin (Nos)<br>Ppd Injection |              |            | S<br>S<br>S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral | 10 Mg Qd; Po<br>20 Mg Qd; Po<br>40 Mg Qd; Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2007              | 6213718       | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-05334-01     |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                         |                               |                    |                    |                 |                               |                       |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------|-----------------------|-----------------|--------------|----------------|
| Headache; Loss Of Consciousness; Seizure                                                                                                                                                                                                | Lexapro                       |                    | S                  | Oral            | 10 Mg Qd; Po                  |                       | Not Reported    |              |                |
|                                                                                                                                                                                                                                         | Multi-Vitamin                 |                    | C                  |                 |                               |                       | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2007                                                                                                                                                                                                                             | 6234859                       | EXPEDITED (15-DAY) | Y                  | HO              | NO-NOMAADVRE-RELISS-2007-3577 |                       | 83 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident; Drug Interaction; Thalamic Infarction                                                                                                                                                                         | Ziprasidone                   |                    |                    | S               |                               |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Magnesium Oxide               |                    |                    | C               |                               | Text:160mg-Freq:Daily |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Insulatard                    |                    |                    | C               |                               |                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Simvastatin                   |                    |                    | C               |                               | Text:20mg-Freq:Daily  |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Ciprallex                     |                    |                    | S               |                               | Text:10mg-Freq:Daily  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2007                                                                                                                                                                                                                             | 6235946                       | EXPEDITED (15-DAY) | Y                  | HO              | T07-GER-00283-01              |                       | 36 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hospitalisation                                                                                                                                                                                                                         | Ciprallex                     |                    |                    | S               | Oral                          | 10 Mg Bid Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2007                                                                                                                                                                                                                             | 6234543                       | EXPEDITED (15-DAY) | Y                  | DE, RI, OT      | PAR_1285_2007                 |                       | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoeic Attack; Blood Methaemoglobin Present; Blood Ph Decreased; Body Temperature Increased; Completed Suicide; Hypotension; Hypotonia; Loss Of Consciousness; Pco2 Increased; Po2 Increased; Pupillary Disorder; Tachycardia; Urinary | Ibuprofen                     |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Naproxen                      |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Acetaminophen And Codeine     |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Acetylsalicylic Acid          |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Cyclobenzaprine               |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Escitalopram Oxalate          |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Pseudoephedrine Hydrochloride |                    |                    | S               |                               | Df                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                         | Guaifenesin                   |                    |                    | S               |                               | Df                    |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Retention

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6213008       | EXPEDITED (15-DAY) | Y                  | HO              | T06-GER-05285-01     |                      | 49 YR      | Female     | DEU            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Condition     | Cipralex       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Aggravated; Depression | Cipralex       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                        | Amitriptyline  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6237344       | EXPEDITED (15-DAY) |                    | HO, OT          | TR-PFIZER INC-2007009017 |                      | 31 YR      | Male       | TUR            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebellar Syndrome;                  | Lamotrigine          |              |            | S           |              | Daily Dose:300mg   | 4 MTH           | Not Reported |
| Depressive Symptom;                   | Escitalopram Oxalate |              |            | S           |              | Daily Dose:10mg    |                 | Not Reported |
| Drug Interaction;                     | Lithium              |              |            | S           |              | Daily Dose:1200mg  | 4 MTH           | Not Reported |
| Pneumonia; Toxicity To Various Agents |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6243821       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-00483-01     |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;                                 | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Diarrhoea; Gun Shot Wound; Intentional Self-Injury | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6247106       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00600-01     |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                               |         |   |      |             |              |
|-----------------------------------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Dizziness; Loss Of Consciousness; Nausea; Seizure; Somnolence; Urinary Incontinence; Vomiting | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                               | Lexapro | S | Oral | 5 Mg Qd Po  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6250506       | EXPEDITED (15-DAY) | Y                  | HO              | S07-NOR-00603-01     |                      | 83 YR      | Male       | NOR            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased; | Cipralext            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Cerebral Infarction;      | Ziprasidone          |              |            | S           | Oral         | 20 Mg Bid Po       |                 | Not Reported |
| Cerebrovascular Accident; | Simvastatin          |              |            | C           |              |                    |                 | Not Reported |
| Confusional State;        | Insulatard Nph Human |              |            | C           |              |                    |                 | Not Reported |
| Depression; Paranoia;     | Albyl-Enterosolubile |              |            | C           |              |                    |                 | Not Reported |
| Restlessness              |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2007              | 6250507       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00604-01     |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Bones Fracture;        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Fall; Orthostatic Hypotension | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                               | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2007              | 5848296       | EXPEDITED (15-DAY) | Y                  | OT              | 2005S1005862         |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tardive Dyskinesia    | Lexapro        |              |            | S           | Oral         | 30 Mg; Daily; Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 15 Mg; Daily; Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg; Daily; Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg; Daily; Oral  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |                    |              |
|-----------|---|------|--------------------|--------------|
| Clozapine | S | Oral | 50 Mg; Daily; Oral | Not Reported |
| Clozapine | S | Oral | See Image          | Not Reported |
|           |   | Oral | See Image          |              |
| Lorazepam | C |      |                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2007              | 6247037       | DIRECT           | Y                  | HO              |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Mental Status Changes; Toxicity To Various Agents | Phenytoin Sodium     |              |            | S           | Oral         | 200 Mg Tid Po      |                 | Not Reported |
|                                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2007              | 6251435       | EXPEDITED (15-DAY) | Y                  | DE              | 2007-00632           |                      | 35 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Clonazepam                |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate      |              |            | S           |              |                    |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2007              | 6773592       | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-07P-163-0357223-00 |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anticonvulsant Drug Level Below Therapeutic; Drug Interaction; Overdose; Seizure | Lexapro                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                  | Synthroid               |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Lamotrigine             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                  | Enoxaparin Sodium       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Pentoxifylline          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Alendronate Sodium      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Esomeprazole            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Gabapentin              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Furosemide              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                  | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |
|----------------------|---|--------------|
| Acetylsalicylic Acid | S | Not Reported |
| Calcium              | S | Not Reported |
| Folic Acid           | S | Not Reported |
| Ergocalciferol       | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2007              | 6240129       | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-04468-01     |                      | 22 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;                                                     | Ciprallex      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Labour Complication;                                                   | Promazine      |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
| Maternal Exposure During Pregnancy; Pregnancy; Treatment Noncompliance |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2007              | 6244814       | DIRECT           | N                  | RI, OT          |                      |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Amenorrhoea; Decreased Appetite; Weight Decreased | Lexapro        |              |            | S           | Oral         | 10 Mg Once Daily Po | 6 WEEK          | Forest       |
|                                                   | Diazepam       |              |            | C           |              |                     |                 | Not Reported |
|                                                   | Lexapro        |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2007              | 6244873       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-00475-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; General Symptom; Loss Of Consciousness; Maternal Exposure During Pregnancy; Premature Menopause; Seizure; Serotonin Syndrome | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                       | Lupron         |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|---------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-------------------|----------------|
| 16-Feb-2007                                                                     | 6146538                        | EXPEDITED (15-DAY) | Y                  | OT              | T06-CAN-02619-01     |                      | 85 YR           | Male              | CAN            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Cerebral Infarction; Loss Of Consciousness                                      | Cipralelex                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported      |                |
|                                                                                 | Phenobarbital                  |                    |                    | C               |                      |                      |                 | Not Reported      |                |
|                                                                                 | Altace                         |                    |                    | C               |                      |                      |                 | Not Reported      |                |
|                                                                                 | Furosemide                     |                    |                    | C               |                      |                      |                 | Not Reported      |                |
|                                                                                 | Lipitor                        |                    |                    | C               |                      |                      |                 | Not Reported      |                |
|                                                                                 | Novasen (Acetylsalicylic Acid) |                    |                    | C               |                      |                      |                 | Not Reported      |                |
|                                                                                 | Allopurinol                    |                    |                    | C               |                      |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 18-Feb-2007                                                                     | 6090967                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-RB-3626-2006      |                      | 93 YR           | Male              | CHE            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>        |                |
| Confusional State; Disorientation; Fatigue; Hallucination; Insomnia; Somnolence | Buprenorphine Hydrochloride    |                    |                    | S               | Oral                 |                      |                 | Reckitt Benckiser |                |
|                                                                                 | Buprenorphine Hydrochloride    |                    |                    | S               | Oral                 |                      |                 | Reckitt Benckiser |                |
|                                                                                 | Cipralelex                     |                    |                    | S               | Oral                 |                      |                 | Not Reported      |                |
|                                                                                 | Trileptal                      |                    |                    | S               | Oral                 |                      |                 | Novartis          |                |
|                                                                                 | Tramadol Hydrochloride         |                    |                    | S               | Oral                 |                      |                 | Not Reported      |                |
|                                                                                 | Tramadol Hydrochloride         |                    |                    | S               | Oral                 |                      |                 | Not Reported      |                |
|                                                                                 | Lyrica                         |                    |                    | C               | Oral                 |                      |                 | Not Reported      |                |
|                                                                                 | Risperdal                      |                    |                    | C               | Oral                 |                      |                 | Janssen           |                |
|                                                                                 | Xatral                         |                    |                    | C               | Oral                 |                      |                 | Not Reported      |                |
|                                                                                 | Brufen                         |                    |                    | C               | Unknown              |                      |                 | Not Reported      |                |
|                                                                                 | Surmontil                      |                    |                    | C               | Unknown              |                      |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 20-Feb-2007                                                                     | 6170318                        | EXPEDITED (15-DAY) | Y                  | HO              | T06-GER-03572-01     |                      | 44 YR           | Male              | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Angina Pectoris; Blood Lactate Dehydrogenase Increased; Cardiac Disorder; Cerebral Infarction; Coronary Artery Occlusion; Hypercholesterolaemia; Hyperlipidaemia; Hypertriglyceridaemia; Myocardial Infarction; Pneumonia; Therapy Non-Responder; Total Cholesterol/Hdl Ratio Increased | Cipralext      |                    |                    | S               | Oral                       | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Cipralext      |                    |                    | S               | Oral                       | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Cipralext      |                    |                    | S               | Oral                       | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Bezafibrate    |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Citalopram     |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2007                                                                                                                                                                                                                                                                             | 6183018        | EXPEDITED (15-DAY) | Y                  | OT              | S06-CAN-04852-01           |                      | 33 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electroencephalogram Abnormal; Overdose; Seizure                                                                                                                                                                                                                                        | Cipralext      |                    |                    | S               | Oral                       | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Seroquel       |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Clonazepam     |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2007                                                                                                                                                                                                                                                                             | 6241503        | EXPEDITED (15-DAY) | N                  | HO, OT          | US-PURDUE-USA_2007_0026467 |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Hallucination; Heart Rate Increased; Hyperhidrosis; Staphylococcal Infection                                                                                                                                                                       | Oxycontin      |                    |                    | S               |                            | Unk, Q12h            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Vicodin        |                    |                    | S               |                            | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Fentanyl       |                    |                    | S               | Transdermal                | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Ambien         |                    |                    | S               |                            | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Lexapro        |                    |                    | S               |                            | Unk, Unk             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                         | Coumadin       |                    |                    | S               |                            | Unk, Unk             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 | Darvocet-N 100       |                    | S                  |                 |                                                 | Unk, Unk             |                 | Not Reported |                |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                 | Dilaudid             |                    | S                  |                 |                                                 | Unk, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2007                                     | 6214800              | EXPEDITED (15-DAY) | Y                  | OT              | S06-FRA-05365-01                                |                      | 47 YR           | Male         | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Seizure                               | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Alcohol              |                    |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                 | Lamictal             |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                 | Keppra               |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2007                                     | 6242429              | EXPEDITED (15-DAY) | Y                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>12956249 |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Suicidal Ideation       | Aripiprazole         |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                 | Lexapro              |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                 | Premarin             |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2007                                     | 6245017              | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00238-01                                |                      | 46 YR           | Male         | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Biliary Dilatation; Hepatitis;<br>Lymphadenitis | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                 | Xanax                |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                 | Imovane (Zopiclone)  |                    |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2007                                     | 6254867              | EXPEDITED (15-DAY) | N                  | OT              | 1022556-2007-00034                              |                      | 52 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                        | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Faeces;<br>Anxiety; Depression; Drug<br>Interaction | Unisom SleepTabs                          |              | Y          | S           |              | 1 Tablet Dsily     |                 | Not Reported |
|                                                              | Lexapro                                   |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
|                                                              | Trazodone Hydrochloride                   |              |            | C           |              |                    |                 | Not Reported |
|                                                              | Tylenol Simply Sleep<br>(Diphenhydramine) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6171825       | EXPEDITED (15-DAY) | Y                  | HO              | 2006-149661-NL       |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Drug Interaction;<br>Electrolyte Imbalance;<br>Fall; Inappropriate<br>Antidiuretic Hormone<br>Secretion | Mirtazapine             |              |            | S           |              | Maintenance Dose   |                 | Not Reported |
|                                                                                                                   | Escitalopram Oxalate    |              |            | S           |              | 10 Mg Daily        |                 | Not Reported |
|                                                                                                                   | Hydrochlorothiazide     |              |            | S           |              | Maintenance Dose   |                 | Not Reported |
|                                                                                                                   | Ramipril                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Donepezil Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Alendronic Acid         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6237027       | EXPEDITED (15-DAY) | Y                  | HO              | S06-ESP-04202-01     |                      | 45 YR      | Female     | ESP            |

| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Drug Interaction;<br>Hyponatraemia | Ciprallex               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                              | Ciprallex               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                              | Oxcarbazepine           |              |            | S           |              |                    |                 | Not Reported |
|                                              | Antabus (Disulfiram)    |              |            | C           |              |                    |                 | Not Reported |
|                                              | Clorazepate Dipotassium |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6251890       | EXPEDITED (15-DAY) | Y                  | HO              | T07-GER-00629-01     |                      | 43 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |           |   |      |             |              |
|-----------------------|-----------|---|------|-------------|--------------|
| Therapy Non-Responder | Ciprallex | S | Oral | 10 Mg Qd Po | Not Reported |
|                       | Ciprallex | S | Oral | 20 Mg Qd Po | Not Reported |
|                       | Lyrica    | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6253185       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00545-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Back Pain; Bone Pain; Depression; Emotional Distress; Hypoaesthesia; Muscle Injury; Myopathy; Nerve Injury; Pain; Pain In Extremity; Self-Injurious Ideation | Lexapro        |              |            | S           | Oral         | 10 M G Qd Po       |                 | Not Reported |
|                                                                                                                                                                          | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                          | Klonopin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6256678       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00682-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness; Seizure | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2007              | 6310472       | NON-EXPEDITED    | N                  | DE              | HQWYE284115DEC06     |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Effexor        |              |            | S           |              |                    | 6 DAY           | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    | 4 WEEK          | Not Reported |
|                       | Remeron        |              |            | S           |              |                    | 5 WEEK          | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Feb-2007                                                                                                                                                                                                  | 6108920                               | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-02841-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Inhibitory Drug Interaction;<br>Suicidal Ideation                                                                                                                                    | Lexapro                               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Aripiprazole                          |                    |                    | S               |                      | 2 Mg Qd              |                 | Not Reported |                |
|                                                                                                                                                                                                              | Premarin                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2007                                                                                                                                                                                                  | 6209799                               | EXPEDITED (15-DAY) |                    | HO              | S06-FRA-05152-01     |                      | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bilirubin Increased;<br>Blood Creatine Increased;<br>Blood Glucose Increased;<br>Blood Urea Increased;<br>Diarrhoea; Faecaloma;<br>Proteus Infection; Urinary<br>Retention; Urinary Tract<br>Infection | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Seropram (Citalopram<br>Hydrobromide) |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Tramadol Hydrochloride                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Prednisone                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Naproxen Sodium                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Clonazepam                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Lansoprazole                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              | Tamoxifen Citrate                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                              |                                       |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2007                                                                                                                                                                                                  | 6253017                               | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00614-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition<br>Aggravated; Major<br>Depression; Suicidal<br>Ideation                                                                                                                                  | Lexapro                               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                              | Aripiprazole                          |                    |                    | S               |                      | 2 Mg Qd              |                 | Not Reported |                |
|                                                                                                                                                                                                              | Premarin                              |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2007              | 6259962       | EXPEDITED (15-DAY) | N                  | HO, OT          | L07-USA-00671-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| C-Reactive Protein Increased; Caesarean Section; Foetal Disorder; Haematochezia; Hypophagia; Lethargy; Lung Disorder; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Necrotising Colitis; Neonatal Respiratory Distress Syndrome; Pneumatoxis Intestinalis | Escitalopram Oxalate |              |            | S           |                | 20 Mg Qd Bf             |                 | Not Reported |
|                                                                                                                                                                                                                                                                                          | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
|                                                                                                                                                                                                                                                                                          | Prenatal Vitamins    |              |            | C           |                |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2007              | 6255920       | DIRECT           | Y                  | HO, OT          |                      |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Arrhythmia; Bradycardia; Depressed Level Of Consciousness; Drug Withdrawal Syndrome; Fatigue; Heart Rate Irregular; Hypersomnia; Hypotension; Mood Altered; Muscle Twitching; Personality Change; Sleep Apnoea Syndrome; Tremor; Ventricular Extrasystoles | Lexapro        |              |            | S           | Buccal       | 20 Mg Every Evening Buccal |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2007              | 4006525       | EXPEDITED (15-DAY) | N                  | OT              | S03-USA-03330-01     |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Abdominal Distension;<br>Abdominal Pain; Abnormal<br>Dreams; Animal Scratch;<br>Back Pain; Balance<br>Disorder; Chills; Choking;<br>Corneal Infiltrates; Corneal<br>Oedema; Diarrhoea;<br>Drooling; Dyskinesia;<br>Ecchymosis; Eye Irritation;<br>Fall; Flatulence;<br>Gastrooesophageal Reflux<br>Disease; Hallucination,<br>Visual; Headache;<br>Hyperhidrosis;<br>Hypoaesthesia Oral; Joint<br>Swelling; Middle Insomnia;<br>Nausea; Neuralgia;<br>Neurosis;<br>Ophthalmoplegia; Pain In<br>Extremity; Palpitations;<br>Paraesthesia; Pruritus<br>Generalised; Rash<br>Vesicular; Restless Legs<br>Syndrome; Skin Disorder;<br>Vision Blurred; Vitreous<br>Floaters | Lexapro<br>Inderal<br>Premarin<br>Valium<br>Tylenol (Paracetamol) |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Feb-2007              | 6149138       | EXPEDITED (15-DAY) | Y                  | HO              | US-MERCK-<br>0610USA09501 |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>            |
|-------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------------|
| Drug Interaction; Major<br>Depression; Suicidal<br>Ideation | Maxalt<br>Lexapro |              |            | S<br>S      | Oral<br>Oral |                    | 52 DAY          | Merck<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       |                        |                    |                    |                 |                                          |                      |                 |                      |                |
|-------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Synthroid                                             |                        |                    | C                  |                 | Unknown                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Feb-2007                                           | 6216872                | EXPEDITED (15-DAY) | Y                  | HO              | US-MERCK-0701USA01266                    |                      | 30 YR           | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Major Depression; Suicidal Ideation | Maxalt                 |                    |                    | S               | Unknown                                  |                      |                 | Merck                |                |
|                                                       | Lexapro                |                    |                    | S               | Oral                                     |                      | 52 DAY          | Not Reported         |                |
|                                                       | Synthroid              |                    |                    | C               | Unknown                                  |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Feb-2007                                           | 6237318                | EXPEDITED (15-DAY) | Y                  | DE              | ES-BRISTOL-MYERS SQUIBB COMPANY-13673223 |                      | 75 YR           | Male                 | ESP            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Neuroleptic Malignant Syndrome; Respiratory Arrest    | Sinemet                |                    |                    | S               |                                          |                      |                 | Bristol Myers Squibb |                |
|                                                       | Neurontin              |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                       | Cipralext              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Feb-2007                                           | 6258882                | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00797-01                         |                      | 47 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Overdose; Seizure                                     | Escitalopram Oxalate   |                    |                    | S               | Oral                                     | 30 Mg Qd Po          |                 | Not Reported         |                |
|                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                                     | 20 Mg Qd Po          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Feb-2007                                           | 6258902                | EXPEDITED (15-DAY) | Y                  | OT              | S07-ESP-00816-01                         |                      |                 | Male                 | ESP            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Product Dose Omission; Serotonin    | Cipralext              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                       | Unspecified Ingredient |                    |                    | S               |                                          |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                  |                        |                    |                    |                 |                                      |                      |                 |            |                 |
|--------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|------------|-----------------|
| Syndrome                                                                                         | Ertapenem              |                    | S                  |                 | Not Reported                         |                      |                 |            |                 |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 27-Feb-2007                                                                                      | 6262246                | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-00823-01                     |                      | 41 YR           | Male       | USA             |
| <u>Preferred Term</u>                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Drug Screen Positive;<br>Loss Of Employment                                                      | Lexapro                |                    |                    | S               |                                      |                      |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 28-Feb-2007                                                                                      | 6247904                | NON-EXPEDITED      | N                  |                 | S06-USA-00217-01                     |                      |                 | Female     | USA             |
| <u>Preferred Term</u>                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Chest Pain; Drug<br>Interaction; Muscular<br>Weakness; Neck Pain;<br>Sluggishness;<br>Somnolence | Imitrex                |                    |                    | S               |                                      |                      |                 |            | Glaxosmithkline |
|                                                                                                  | Lexapro                |                    |                    | S               | Oral                                 | 40mg Per Day         |                 |            | Not Reported    |
|                                                                                                  | Celexa                 |                    |                    | C               |                                      |                      |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 28-Feb-2007                                                                                      | 6248630                | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0599517A |                      | 15 YR           | Male       | USA             |
| <u>Preferred Term</u>                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Muscular Weakness                                                                                | Lamictal               |                    |                    | S               | Oral                                 | 10mg Per Day         |                 |            | Glaxosmithkline |
|                                                                                                  | Lexapro                |                    |                    | S               | Oral                                 |                      |                 |            | Not Reported    |
|                                                                                                  | Unspecified Ingredient |                    |                    | C               |                                      |                      |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 28-Feb-2007                                                                                      | 6248731                | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0601692A |                      | 13 YR           | Female     | USA             |
| <u>Preferred Term</u>                                                                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                 |
| Abnormal Behaviour; Drug<br>Ineffective                                                          | Lamictal               |                    |                    | S               | Oral                                 | 25mg Per Day         |                 |            | Glaxosmithkline |

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|                                                                            | Lexapro                |                  | S                  | Oral            | 5mg Per Day                          | 29 WEEK              | Not Reported    |                 |                |
|----------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
|                                                                            | Strattera              |                  | S                  | Oral            | 80mg Per Day                         |                      | Not Reported    |                 |                |
|                                                                            | Zyprexa                |                  | S                  | Oral            | 2.5mg Per Day                        | 21 DAY               | Not Reported    |                 |                |
|                                                                            | Unspecified Ingredient |                  | C                  |                 |                                      |                      | Not Reported    |                 |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Feb-2007                                                                | 6248794                | NON-EXPEDITED    | Y                  | OT              | US-<br>GLAXOSMITHKLINE-<br>A0603221A |                      | 53 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Mania; Sleep Disorder                                             | Lamictal               |                  |                    | S               | Oral                                 | 25mg Per Day         | 3 DAY           | Glaxosmithkline |                |
|                                                                            | Lexapro                |                  |                    | S               | Oral                                 | 10mg Unknown         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Feb-2007                                                                | 6249372                | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0617683A |                      | 16 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Galactorrhoea                                                              | Lamictal               |                  |                    | S               | Oral                                 | 100mg Per Day        |                 | Glaxosmithkline |                |
|                                                                            | Lexapro                |                  |                    | S               | Oral                                 | 10mg Per Day         | 2 YR            | Not Reported    |                |
|                                                                            | Unspecified Ingredient |                  |                    | C               |                                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Feb-2007                                                                | 6249478                | NON-EXPEDITED    | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0620094A |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Ill-Defined Disorder; Sensory Disturbance; Skin Reaction | Lamictal               |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                            | Wellbutrin             |                  |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                            | Lithium                |                  |                    | S               |                                      | 600mg Per Day        | 2 YR            | Glaxosmithkline |                |
|                                                                            | Lexapro                |                  |                    | S               |                                      | 10mg Per Day         |                 | Not Reported    |                |
|                                                                            | Amiloride              |                  |                    | S               |                                      | 5mg Per Day          | 2 YR            | Not Reported    |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Feb-2007                           | 6249934                   | NON-EXPEDITED      | N                  |                 | S06-USA-03747-01             |                      | 33 YR           | Male            | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Product Counterfeit | Lamictal                  |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                       | Lexapro                   |                    |                    | S               | Oral                         | 20mg Per Day         | 4 YR            | Not Reported    |                |
|                                       | No Concurrent Medications |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Mar-2007                           | 6250934                   | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0628004A |                      | 41 YR           | Female          | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alopecia                              | Lamotrigine               |                    |                    | S               | Oral                         | 200mg Per Day        |                 | Glaxosmithkline |                |
|                                       | Lexapro                   |                    |                    | S               | Oral                         | 20mg Per Day         |                 | Not Reported    |                |
|                                       | Vistaril                  |                    |                    | C               | Oral                         | 100mg Unknown        |                 | Not Reported    |                |
|                                       | Abilify                   |                    |                    | C               | Oral                         | 15mg Unknown         |                 | Not Reported    |                |
| <u>FDA Received Date</u>              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Mar-2007                           | 6250965                   | NON-EXPEDITED      | N                  |                 | S06-USA-04809-01             |                      | 43 YR           | Female          | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dry Eye; Insomnia; Thirst             | Lamotrigine               |                    |                    | S               | Oral                         |                      | 241 DAY         | Glaxosmithkline |                |
|                                       | Lexapro                   |                    |                    | S               | Oral                         | 15mg Per Day         |                 | Not Reported    |                |
|                                       | Vitamins                  |                    |                    | C               |                              |                      |                 | Not Reported    |                |
|                                       | Unspecified Ingredient    |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Mar-2007                           | 6142511                   | EXPEDITED (15-DAY) | Y                  | DE              | S06-DEN-03800-01             |                      | 43 YR           | Female          | DNK            |
| <u>Preferred Term</u>                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |



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|                   |             |   |      |             |              |
|-------------------|-------------|---|------|-------------|--------------|
| Completed Suicide | Lexapro     | S | Oral | 15 Mg Qd Po | Not Reported |
|                   | Alprazolam  | S |      |             | Not Reported |
|                   | Alprazolam  | S |      |             | Not Reported |
|                   | Mirtazapine | S |      | 15 Mg Qd    | Not Reported |
|                   | Propranolol | S |      | 40 Mg Qd    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2007              | 6235653       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00393-01     |                      | 45 YR      | Male       | USA            |

  

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Alcohol Use;<br>Drug Withdrawal<br>Syndrome; Homicide;<br>Imprisonment | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                    | Alcohol        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                    | Avalide        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2007              | 6252123       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FI-ROCHE-483628      |                      | 56 YR      | Female     | FIN            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                        | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Asthenia;<br>Depressed Level Of<br>Consciousness; Hepatic<br>Enzyme Increased;<br>Hypotension; Intentional<br>Overdose; Intentional<br>Overdose; Somnolence;<br>Suicide Attempt;<br>Tachycardia; Vomiting | Xeloda              |              |            | S           | Oral                                     |                    |                 | Roche        |
|                                                                                                                                                                                                                                                                                              | Xeloda              |              |            | S           | Oral                                     |                    | 1 DAY           | Roche        |
|                                                                                                                                                                                                                                                                                              | Ciprallex           |              |            | S           | Unknown                                  |                    | 1 DAY           | Not Reported |
|                                                                                                                                                                                                                                                                                              | Zopiclone           |              |            | S           | Unknown                                  |                    | 1 DAY           | Not Reported |
|                                                                                                                                                                                                                                                                                              | Herceptin           |              |            | C           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                              | Aromasin            |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                              | Clodronate Disodium |              |            | C           |                                          |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 02-Mar-2007              | 6252560       | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-07P-163-<br>0360123-00 |                      | 21 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Agitation; Anger;<br>Conversion Disorder;<br>Crying; Mental Disorder                                    | Depakote                                |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                                                                                         | Depakote                                |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                         | Lexapro                                 |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                                                                                                         | Lorazepam                               |                    |                    | C               | Oral                 |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2007                                                                                             | 6264101                                 | EXPEDITED (15-DAY) |                    |                 | 2007-154951-NL       |                         | 52 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                                                | Mirtazapine                             |                    |                    | S               |                      | Df                      |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate                    |                    |                    | S               |                      | Df                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2007                                                                                             | 6264647                                 | DIRECT             | Y                  | OT              |                      |                         | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Anger; Depression; Drug<br>Interaction; Emotional<br>Disorder; Suicidal Ideation | Nortriptyline Hydrochloride             |                    |                    | S               | Oral                 | 25 - 50 Mg 1 @ Night Po |                 | Danbury      |                |
|                                                                                                         | Lexapro                                 |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                         | Vivactil                                |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2007                                                                                             | 6264356                                 | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-03192-01     |                         | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Pregnancy               | Lexapro                                 |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                         | Lexapro                                 |                    |                    | S               | Oral                 | 40 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                         | Wellbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                         | Buspar                                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                         | Trazodone Hydrochloride                 |                    |                    | C               |                      |                         |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 05-Mar-2007                                                                                                                   | 6264365                                               | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00819-01     |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Nasopharyngitis; Seizure;<br>Tonic Clonic Movements                                                 | Lexapro                                               |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                               | Nyquil<br>(Acetaminophen/Dextromethorphan/Doxylamine) |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2007                                                                                                                   | 6245932                                               | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWI-00551-01     |                         | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Balance Disorder; Blood Creatine Increased; Loss Of Personal Independence In Daily Activities; Sedation; Somnolence | Escitalopram Oxalate                                  |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                               | Escitalopram Oxalate                                  |                    |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Escitalopram Oxalate                                  |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 3 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 3 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 0.5 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 1 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 2 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 3 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                               | Risperidone                                           |                    |                    | S               | Oral                 | 4 Mg Qd Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2007                                                                                                                   | 6263867                                               | DIRECT             | Y                  | OT              |                      |                         | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction;<br>Heart Rate Irregular                                                                                | Lexapro                                               |                    |                    | S               | Oral                 | 20mg Once A Day Po      |                 | Forest       |                |
|                                                                                                                               | Imitrex                                               |                    |                    | S               | Oral                 | Imitrex 50 Mg As Needed |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|----------------------------------------------|----------------|
| 06-Mar-2007                                                                    | 6264786                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-DEN-00968-01     |                                          |                 | Female                                       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Coordination Abnormal;<br>Drug Interaction; Muscular<br>Weakness; Syncope      | Escitalopram Oxalate<br>Levonorgestrel |                    |                    | S<br>S          | Oral<br>Oral         | 10 Mg Qd Po<br>1.5 Mg Qd Po              |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 07-Mar-2007                                                                    | 6254036                                | EXPEDITED (15-DAY) | Y                  | DE              | S07-ESP-00707-01     |                                          | 75 YR           | Male                                         | ESP            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Neuroleptic Malignant<br>Syndrome; Respiratory<br>Failure                      | Ciprallex<br>Neurontin<br>Sinemet      |                    |                    | S<br>S<br>S     | Oral<br>Oral         | 15 Mg Po<br>300 Mg Po                    |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 07-Mar-2007                                                                    | 6265536                                | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00886-01     |                                          | 40 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Amnesia; Drug Interaction                                                      | Lexapro<br>Wine                        |                    |                    | S<br>S          | Oral                 | 10 Mg Qd Po                              |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Mar-2007                                                                    | 5734947                                | EXPEDITED (15-DAY) | Y                  | CA              | S05-USA-00377-01     |                                          | 18 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abortion Induced;<br>Congenital Nose<br>Malformation;<br>Dysmorphism; Maternal | Lexapro<br>Lexapro<br>Lexapro          |                    |                    | S<br>S<br>S     | Oral<br>Oral<br>Oral | 20 Mg Qd Po<br>10 Mg Qd Po<br>5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported |                |

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Exposure During  
Pregnancy; Pregnancy

| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Mar-2007                                               | 6217295                 | EXPEDITED (15-DAY) | Y                  | DS              | S06-SWI-05427-01     |                      | 71 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract; Drug Ineffective;<br>Dry Eye; Visual Impairment | Cipralex                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                           | Cipralex                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                           | Zocor                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                           | Nebivolol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                           | Aspirin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2007                                               | 6259094                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-484932      |                      | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiopulmonary Failure                                   | Pegasys                 |                    |                    | S               | Subcutaneous         |                      |                 | Roche        |                |
|                                                           | Copegus                 |                    |                    | S               | Oral                 |                      |                 | Roche        |                |
|                                                           | Klonopin                |                    |                    | S               | Unknown              |                      |                 | Roche        |                |
|                                                           | Lithium                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                           | Topamax                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                           | Ambien                  |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                           | Seroquel                |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
|                                                           | Lexapro                 |                    |                    | S               | Unknown              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2007                                               | 6268712                 | DIRECT             | N                  | OT              |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory                                   | Lexapro                 |                    |                    | S               |                      | 10mg Once Daily      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2007              | 6269424       | EXPEDITED (15-DAY) | N                  | OT              | S07-ISR-01029-02     |                      |            | Unknown    | ISR            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During Pregnancy; Seizure | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2007              | 6224220       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00084-01     |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Depression; Stress; Thyroid Cancer | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                          | Lexapro               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                          | Lunesta               |              |            | S           |              | 3 Mg Qhs           |                 | Not Reported |
|                                                          | Ativan                |              |            | S           |              | 0.5 Mg Bid         |                 | Not Reported |
|                                                          | Asacol                |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Lipitor               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2007              | 6242009       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00445-01     |                      | 84 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional State; Gait Inability; Haematocrit Decreased; Haemoglobin Decreased; Hypovolaemia; Inappropriate Antidiuretic Hormone Secretion; Incoherent | Lexapro                      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                   | Toprol XL                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Actonel                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Cosopt (Dorzolamide/Timolol) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Travatan                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Plavix                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Lorazepam                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Pravachol                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Centrum                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Micardis                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Hydrochlorothiazide          |              |            | C           |              |                    |                 | Not Reported |

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| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 15-Mar-2007                                                                                                                                     | 6262350                 | EXPEDITED (15-DAY)        | Y                           | OT                       | DE-JNJFOC-20070300852         |                               | 46 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Intentional Overdose;<br>Somnolence; Suicide<br>Attempt; Tachycardia                                                                            | Risperdal               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                 | Amisulpride             |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                 | Cipralex                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                 | Rivotril                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Mar-2007                                                                                                                                     | 6274354                 | EXPEDITED (15-DAY)        | N                           | DE                       | S07-USA-01063-01              |                               | 16 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Akathisia; Completed<br>Suicide; Discomfort;<br>Emotional Distress; Gun<br>Shot Wound; Heart Injury;<br>Hypophagia; Pain;<br>Psychotic Disorder | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                 | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Mar-2007                                                                                                                                     | 6274355                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S07-USA-01098-01              |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arrhythmia; Cardiac<br>Failure Congestive;<br>Orthostatic Hypertension                                                                          | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Mar-2007                                                                                                                                     | 6329398                 | NON-EXPEDITED             | Y                           | OT                       | PHEH2006US04704               |                               | 23 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                                                                                                                                                                                                                       |                           |                    |                    |                 |                      |                      |                    |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|--------------------|--------------|----------------|
| Increased Tendency To Bruise; Platelet Count Decreased                                                                                                                                                                | Trileptal                 |                    | S                  |                 |                      |                      | 300 Mg, Bid        |              | Not Reported   |
|                                                                                                                                                                                                                       | Lexapro                   |                    | S                  |                 |                      |                      | 5 Mg, Qd, 10 Mg Qd |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2007                                                                                                                                                                                                           | 6272987                   | DIRECT             | Y                  | OT              |                      |                      | 39 YR              | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>    | <u>Mfr</u>   |                |
| Blood Pressure Increased                                                                                                                                                                                              | Lexapro                   |                    |                    | S               | Oral                 | 10mg One Daily Po    |                    | Forest       |                |
|                                                                                                                                                                                                                       | Xanax                     |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Ambien                    |                    |                    | C               |                      |                      |                    | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2007                                                                                                                                                                                                           | 6276763                   | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-01085-01     |                      | 60 YR              | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>    | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Polymyalgia Rheumatica; Transaminases Increased; Viral Infection | Seroplex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Seroplex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Seroplex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Seroplex                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Prednisone                |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Estradiol                 |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Actonel                   |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Inexium (Esomeprazole)    |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Cacit [Calcium Carbonate] |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Zolpidem Tartrate         |                    |                    | C               |                      |                      |                    | Not Reported |                |
|                                                                                                                                                                                                                       | Meteoxane                 |                    |                    | C               |                      |                      |                    | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2007                                                                                                                                                                                                           | 6232300                   | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-00224-01     |                      | 32 YR              | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u>    | <u>Mfr</u>   |                |
| Cardiac Arrest; Myocardial Infarction                                                                                                                                                                                 | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                    | Not Reported |                |



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|  |            |   |      |             |              |
|--|------------|---|------|-------------|--------------|
|  | Lexapro    | S | Oral | 10 Mg Qd Po | Not Reported |
|  | Geodon     | C |      |             | Not Reported |
|  | Lyrica     | C |      |             | Not Reported |
|  | Esgic      | C |      |             | Not Reported |
|  | Glucophage | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2007              | 6277236       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01082-01     |                      | 75 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Pulmonary Oedema; Cardiac Failure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2007              | 6277237       | EXPEDITED (15-DAY) | Y                  | DE, OT          | S07-FRA-01083-01     |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure; Condition Aggravated | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2007              | 6214600       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PFIZER INC-2007001346 |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcoholism; Cardiac Arrest; Lethargy; Somnolence | Geodon         |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Geodon         |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Geodon         |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Geodon         |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Lyrica         |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Esgic          |              |            | C           |              |                    |                 | Not Reported |
|                                                  | Glucophage     |              |            | C           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2007                                                                   | 6265439                          | EXPEDITED (15-DAY) | N                  | HO              | NL-ROCHE-481272      |                      | 49 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis;<br>Pulmonary Embolism                                   | Peginterferon Alfa-2a            |                    |                    | S               | Unknown              |                      | 27 DAY          | Roche        |                |
|                                                                               | Ribavirin                        |                    |                    | S               | Unknown              |                      | 27 DAY          | Roche        |                |
|                                                                               | Escitalopram Oxalate             |                    |                    | S               | Oral                 |                      | 29 DAY          | Not Reported |                |
|                                                                               | Methadone                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Valium                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2007                                                                   | 6148520                          | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-04008-01     |                      | 50 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Potassium<br>Decreased; Extrasystoles;<br>Flushing                      | Lexapro                          |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                               | Mirtazapine                      |                    |                    | S               |                      | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                               | Albuterol                        |                    |                    | S               |                      | 100 Mcg/Kg           |                 | Not Reported |                |
|                                                                               | Ventolin                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                               | Xanax                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Alvesco (Cislesonid)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Cefaclor                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Gyno-Pevaryl (Econazole Nitrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2007                                                                   | 6280419                          | EXPEDITED (15-DAY) | Y                  | OT              | S07-UKI-01198-01     |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury;<br>Memory Impairment;<br>Paranoia; Suicidal Ideation | Escitalopram Oxalate             |                    |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Mar-2007                                                                                 | 6280592                              | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-01180-01     |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Visual Field Defect                                                                         | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                             | Olanzapine                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Depakote                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Antivirals (Three Other)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2007                                                                                 | 6270719                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-NOR-01049-01     |                      | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatinine Decreased; Blood Magnesium Decreased; Haemoglobin Decreased; Hyponatraemia | Ciprallex                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Lekovit Ca                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Selozok                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Cozaar                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                             | Vitamin B12 Depot (Hydroxocobalamin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2007                                                                                 | 6282773                              | EXPEDITED (15-DAY) | Y                  | DE              | 2007-01365           |                      | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest                                                                   | Clonazepam                           |                    |                    | S               |                      |                      |                 | Watson       |                |
|                                                                                             | Escitalopram Oxalate                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Acetaminophen                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2007                                                                                 | 6282849                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-00531-01     |                      | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Swelling Face                                                                               | Ciprallex                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                        |                                    |                    |                    |                 |                      |                              |                 |            |                |
|--------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|------------|----------------|
| Alcohol (Ethanol)<br>Contraceptives (Nos)              |                                    |                    | S<br>C             |                 |                      | Not Reported<br>Not Reported |                 |            |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Mar-2007                                            | 6282850                            | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-05459-01     |                              |                 | Female     | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Purpura; Somatic Symptom Disorder                      | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2007                                            | 6281589                            | DIRECT             | Y                  | OT              |                      |                              | 16 YR           | Female     | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Dystonia; Muscle Spasms                                | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg 1 X A Day Po           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2007                                            | 6282848                            | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01265-01     |                              | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Appendicitis; Myocardial Infarction; Qrs Axis Abnormal | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po                  |                 |            | Not Reported   |
|                                                        | Lexapro                            |                    |                    | S               | Oral                 | 5 Mg Qd Po                   |                 |            | Not Reported   |
|                                                        | Percocet                           |                    |                    | C               |                      |                              |                 |            | Not Reported   |
|                                                        | Lisinopril And Hydrochlorothiazide |                    |                    | C               |                      |                              |                 |            | Not Reported   |
|                                                        | Spironolactone                     |                    |                    | C               |                      |                              |                 |            | Not Reported   |
| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2007                                            | 6283571                            | EXPEDITED (15-DAY) | Y                  | DE              | 2007-01396           |                              | 58 YR           | Unknown    | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Death                                                  | Lorazepam                          |                    |                    | S               |                      |                              |                 |            | Watson         |
|                                                        | Valproic Acid                      |                    |                    | S               |                      |                              |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                   |                                                         |                    |                    |                 |                      |                             |                 |                                              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|----------------------------------------------|----------------|
| Escitalopram Oxalate                                                                                                                                              |                                                         |                    | S                  |                 |                      | Not Reported                |                 |                                              |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 23-Mar-2007                                                                                                                                                       | 6283659                                                 | EXPEDITED (15-DAY) | N                  | OT              | L07-ISR-01234-01     |                             | 24 YR           | Female                                       | ISR            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Lichenification;<br>Pigmentation Lip                                                                                                                              | Escitalopram Oxalate<br>Harmonet                        |                    |                    | S<br>C          |                      |                             |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 23-Mar-2007                                                                                                                                                       | 6283813                                                 | EXPEDITED (15-DAY) | Y                  | DE              | 2007-01411           |                             | 16 YR           | Unknown                                      | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Death                                                                                                                                                             | Dextroamphetamine Saccharate<br>Escitalopram Oxalate    |                    |                    | S<br>S          |                      |                             |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 26-Mar-2007                                                                                                                                                       | 6265534                                                 | EXPEDITED (15-DAY) | Y                  | DE, HO          | S07-USA-00973-01     |                             | 68 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Completed<br>Suicide; Diarrhoea;<br>Dizziness; Dry Mouth; Gun<br>Shot Wound; Head Injury;<br>Headache; Hyperhidrosis;<br>Insomnia; Nausea;<br>Somnolence | Lexapro<br>Coumadin<br>Ativan                           |                    |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po                 |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 26-Mar-2007                                                                                                                                                       | 6267422                                                 | EXPEDITED (15-DAY) | Y                  | OT              | T06-GER-02691-00     |                             | 19 YR           | Male                                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Affect Lability; Aggression;<br>Agitation; Depression;<br>Fall; Impulse-Control                                                                                   | Escitalopram Oxalate<br>Pegasys (Peginterferon Alfa-2a) |                    |                    | S<br>S          | Oral<br>Subcutaneous | 10 Mg Qd Po<br>180mcg Qw Sc |                 | Not Reported<br>Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                  |                                                           |                    |                    |                 |                      |                           |                 |                              |                                              |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|------------------------------|----------------------------------------------|
| Disorder; Intentional Self-Injury                                                                | Ribavirin<br>Paracetamol                                  |                    |                    | C<br>C          |                      |                           |                 | Not Reported<br>Not Reported |                                              |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u>                               |
| 26-Mar-2007                                                                                      | 6280858                                                   | DIRECT             | N                  | OT              |                      |                           | 25 YR           | Female                       | USA                                          |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                                              |
| Alcoholism                                                                                       | Lexapro                                                   |                    |                    | S               | Oral                 | 15mg 1 Times A Day Po     |                 |                              | Not Reported                                 |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u>                               |
| 26-Mar-2007                                                                                      | 6281965                                                   | DIRECT             | Y                  | RI              |                      |                           | 43 YR           | Female                       | USA                                          |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                                              |
| Bruxism; Tardive Dyskinesia; Throat Irritation; Tooth Disorder                                   | Lexapro                                                   |                    |                    | S               | Oral                 | 10mg 1/2 - 1 Tab Daily Po |                 |                              | Not Reported                                 |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u>                               |
| 27-Mar-2007                                                                                      | 6288318                                                   | EXPEDITED (15-DAY) | Y                  | OT              | S07-CAN-01272-01     |                           | 52 YR           | Female                       | DNK                                          |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                                              |
| Anxiety; Joint Swelling; Oedema Peripheral; Pain; Rash Erythematous; Swelling; Thinking Abnormal | Cipralext<br>Wellbutrin Sr                                |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po               |                 |                              | Not Reported<br>Not Reported                 |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u>                               |
| 27-Mar-2007                                                                                      | 6288421                                                   | EXPEDITED (15-DAY) | Y                  | OT              | S07-CAN-01273-01     |                           | 76 YR           | Female                       | DNK                                          |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                                              |
| Blood Osmolarity Decreased; Confusional State; Decreased                                         | Cipralext<br>Atacand (Candesartan Cilexetil)<br>Lorazepam |                    |                    | S<br>C<br>C     | Oral                 | 12.5 Mg Qd; Po            |                 |                              | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                           |                                      |        |                              |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------|--------|------------------------------|
| Appetite; Epistaxis; Facial Pain; Fall; Gait Disturbance; Hyponatraemia; Somnolence; Urine Flow Decreased | Simvastatin<br>Sotalol Hydrochloride | C<br>C | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2007              | 6288422       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01250-01     |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Disorder; Electroencephalogram Abnormal; Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2007              | 6244872       | EXPEDITED (15-DAY) | Y                  | CA              | S07-USA-00480-02     |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|------------------------------|
| Atrioventricular Septal Defect; Cardiac Malposition; Cardiac Murmur; Cardiac Ventricular Disorder; Dextrocardia; Heart Disease Congenital; Malformation Venous; Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Pulmonary Valve Stenosis Congenital; Spleen Malformation; Unintended Pregnancy | Lexapro<br>Prenatal Vitamin (Nos) |              |            | S<br>C      | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-Mar-2007                | 6289038              | EXPEDITED (15-DAY) | Y                  | DE              | 2007-01508           |                      | 40 YR           | Unknown      | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest  | Clonazepam           |                    |                    | S               |                      |                      |                 | Watson       |                |
|                            | Quetiapine Fumarate  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2007                | 6331407              | NON-EXPEDITED      | Y                  | HO              | K200600280           |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pyrexia                    | Altace               |                    |                    | S               |                      | 5 Mg, Qd             |                 | Not Reported |                |
|                            | Lexapro              |                    |                    | S               | Oral                 | 20 Mg, Qd, Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2007                | 6202807              | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-05038-01     |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Akathisia; Anxiety;        | Xanax                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Arthropathy; Asphyxia;     | Serzone              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Asthenia; Blood Chloride   | Cozaar               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Blood Glucose   | Humulin N            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Increased; Blood Ketone    | Humalog              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Body Present; Blood        | Klonopin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Sodium Decreased;          | Ambien               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Carbon Dioxide             |                      |                    |                    |                 |                      |                      |                 |              |                |
| Decreased; Cold Sweat;     |                      |                    |                    |                 |                      |                      |                 |              |                |
| Completed Suicide; Drug    |                      |                    |                    |                 |                      |                      |                 |              |                |
| Screen Positive; Fear; Hot |                      |                    |                    |                 |                      |                      |                 |              |                |
| Flush; Hyperhidrosis;      |                      |                    |                    |                 |                      |                      |                 |              |                |
| Major Depression; Panic    |                      |                    |                    |                 |                      |                      |                 |              |                |
| Attack; Poor Quality       |                      |                    |                    |                 |                      |                      |                 |              |                |
| Sleep; Refusal Of          |                      |                    |                    |                 |                      |                      |                 |              |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment By Patient;  
Restlessness; Suicidal  
Ideation; Tearfulness;  
Tremor

| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Mar-2007                                                                                                                       | 6234709                   | EXPEDITED (15-DAY) | N                  | DE              | S07-USA-00274-01         |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriosclerosis; Chest Injury; Completed Suicide; Emphysema; Gun Shot Wound; Hepatic Steatosis; Stress At Work; Weight Decreased | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2007                                                                                                                       | 6274910                   | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007006695 |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Extrapyramidal Disorder; Tardive Dyskinesia; Torticollis                                                                 | Geodon                    |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2007                                                                                                                       | 6285282                   | DIRECT             |                    | HO              |                          |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Nausea; Vomiting                                                                                                  | Gemcitabine Hydrochloride |                    |                    | S               |                          | 1520 Mg              |                 | Not Reported |                |
|                                                                                                                                   | Fentanyl Patch            |                    |                    | S               |                          | 150mcg               |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                   |                    |                    | S               |                          | 10mg                 |                 | Not Reported |                |
|                                                                                                                                   | Vicodin                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                   | Ambien                    |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                   | Lexapro                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                   | Vicodin                   |                    |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                | <a href="#">Case #</a>                                                | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 29-Mar-2007                                                                                                                                      | 6289353                                                               | EXPEDITED (15-DAY)        | Y                           | DE                       | S07-USA-01298-01              |                               | 22 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                   | <a href="#">Product</a>                                               | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                                                                                                | Lexapro                                                               |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                                                | <a href="#">Case #</a>                                                | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Mar-2007                                                                                                                                      | 6289357                                                               | EXPEDITED (15-DAY)        | Y                           | DE                       | S07-USA-01298-02              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                   | <a href="#">Product</a>                                               | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                                                                                                | Lexapro                                                               |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                                                | <a href="#">Case #</a>                                                | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Mar-2007                                                                                                                                      | 6168772                                                               | EXPEDITED (15-DAY)        | N                           | DE                       | S06-USA-04490-01              |                               | 53 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                   | <a href="#">Product</a>                                               | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Affective Disorder;<br>Asphyxia; Completed<br>Suicide; Disturbance In<br>Attention; Paranoia;<br>Psychomotor<br>Hyperactivity; Vision<br>Blurred | Lexapro                                                               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                                                                                | <a href="#">Case #</a>                                                | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Mar-2007                                                                                                                                      | 6173998                                                               | EXPEDITED (15-DAY)        | N                           | DE                       | S06-USA-04663-01              |                               | 34 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                   | <a href="#">Product</a>                                               | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asphyxia; Completed<br>Suicide; Condition                                                                                                        | Lexapro                                                               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          |                     | Not Reported            |
| Aggravated; Depression;                                                                                                                          | Naproxen Sodium                                                       |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| Feeling Jittery; Insomnia;                                                                                                                       | Ambien                                                                |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| Mood Swings; Paranoia                                                                                                                            | Smz/Tmp Ds 800-160<br>(Sulfamethoxazole800<br>Mg/Trimethoprim 160 Mg) |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |

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| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2007                | 6205605                   | EXPEDITED (15-DAY) | N                  | HO, OT          | US-PFIZER INC-2005170543 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug            | Neurontin                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Ineffective;               | Neurontin                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Encephalopathy;            | Paxil                     |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Headache; Mental Status    | Gabitril                  |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Changes; Nausea;           | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Overdose; Seizure;         | Depakote                  |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Suicide Attempt;           | Alprazolam                |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Tachycardia; Vomiting      | Acetaminophen\Hydrocodone |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                            | Bitartrate                |                    |                    |                 |                          |                      |                 |              |                |
|                            | Remeron                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2007                | 6239777                   | EXPEDITED (15-DAY) | Y                  | DE, OT          | ES-PFIZER INC-2007009855 |                      | 75 YR           | Male         | ESP            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuroleptic Malignant      | Neurontin                 |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Syndrome; Respiratory      | Carbidopa And Levodopa    |                    |                    | S               |                          | Text:200/50 Mg       |                 | Not Reported |                |
| Arrest                     | Escitalopram Oxalate      |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Mar-2007                | 6289535                   | EXPEDITED (15-DAY) | N                  | HO, LT          | S06-USA-04278-01         |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Blood  | Lexapro                   |                    |                    | S               | Oral                     | 20 Mg Qd Po          |                 | Not Reported |                |
| Ph Decreased; Contusion;   | Lovenox                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Depressed Mood; Drug       | Lamictal                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Ineffective; Fall; Feeling | Prevacid                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Hot; Fractured Sacrum;     | Singulair                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
| General Physical Health    | Advair                    |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Deterioration;             | Albuterol                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Haematoma; Hostility; Jaw  | Ativan                    |                    |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                       |   |              |
|----------------------------|-----------------------|---|--------------|
| Fracture; Lumbar           | Phenergan             | C | Not Reported |
| Vertebral Fracture;        | Clonazepam            | C | Not Reported |
| Multiple Fractures; Neck   | Wellbutrin (Bupropion | C | Not Reported |
| Pain; Pelvic Fracture;     | Hydrochloride)        |   |              |
| Radial Pulse; Sciatic      |                       |   |              |
| Nerve Injury; Suicidal     |                       |   |              |
| Ideation; Suicide Attempt; |                       |   |              |
| Ulna Fracture; White       |                       |   |              |
| Blood Cell Count           |                       |   |              |
| Increased                  |                       |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2007              | 6331529       | NON-EXPEDITED    | Y                  | HO              | 2007UW00835          |                      | 93 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypersensitivity      | Zestril        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Antibiotic     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2007              | 6161500       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04272-01     |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Blood    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Ethanol Increased;           | Vicodin        |              |            | C           |              |                    |                 | Not Reported |
| Completed Suicide;           |                |              |            |             |              |                    |                 |              |
| Condition Aggravated;        |                |              |            |             |              |                    |                 |              |
| Depression; Drug Screen      |                |              |            |             |              |                    |                 |              |
| Positive; General Physical   |                |              |            |             |              |                    |                 |              |
| Health Deterioration; Gun    |                |              |            |             |              |                    |                 |              |
| Shot Wound; Head Injury;     |                |              |            |             |              |                    |                 |              |
| Hostility; Insomnia; Patella |                |              |            |             |              |                    |                 |              |
| Fracture; Suicidal Ideation; |                |              |            |             |              |                    |                 |              |
| Weight Decreased             |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2007              | 6347510       | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20061106436 |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure<br>Congestive; Delirium;<br>Delusion; Hallucination;<br>Overdose; Paranoia;<br>Pericardial Effusion;<br>Pleural Effusion;<br>Tachycardia | Tylenol                  |              | Y          | S           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Tylenol                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Flexeril                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Oxycontin                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                          | Lortab                   |              |            | S           |              | 5/5000 Mg          |                 | Not Reported |
|                                                                                                                                                          | Lexapro                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                          | Fentanyl Citrate         |              |            | S           | Buccal       |                    |                 | Not Reported |
|                                                                                                                                                          | Fentanyl Citrate         |              |            | S           | Buccal       |                    |                 | Not Reported |
|                                                                                                                                                          | Anti-Anxiety Medications |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Zithromax                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Seroquel                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Albuterol                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Bayer Aspirin            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Synthroid                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Lyrica                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Combivent                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                          | Nexium                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 02-Apr-2007              | 6347511       | EXPEDITED (15-DAY) | N                  | HO, OT          | US-PURDUE-USA_2006_0025759 |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                   | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Blood Gases<br>Abnormal; Breakthrough<br>Pain; Cognitive Disorder;<br>Delirium; Delusion; Drug<br>Tolerance; Hallucination;<br>Lethargy; Mental Status<br>Changes; Overdose;<br>Oxygen Saturation<br>Decreased; Pco2<br>Decreased; Pericardial | Oxycontin        |              |            | S           | Oral         | 160 Mg, Daily      |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Lortab           |              |            | S           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Tylenol          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Flexeril         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Lexapro          |              |            | S           | Oral         | 10 Unk, Unk        |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Fentanyl Citrate |              |            | S           | Buccal       | 600 Mcg, Prn       | 270 DAY         | Not Reported |
|                                                                                                                                                                                                                                                         | Fentanyl Citrate |              |            | S           | Buccal       | 400 Mcg, Prn       | 44640 MIN       | Not Reported |
|                                                                                                                                                                                                                                                         |                  |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |              |   |  |  |  |          |  |              |
|--------------------------|--------------|---|--|--|--|----------|--|--------------|
| Effusion; Pericarditis;  | Synthroid    | C |  |  |  |          |  | Not Reported |
| Pleural Effusion;        | Combivent    | C |  |  |  |          |  | Not Reported |
| Pneumonia; Po2           | Azithromycin | C |  |  |  |          |  | Not Reported |
| Decreased; Pyrexia;      | Seroquel     | C |  |  |  |          |  | Not Reported |
| Tachycardia; White Blood | Aspirin      | C |  |  |  |          |  | Not Reported |
| Cell Count Increased     | Albuterol    | C |  |  |  |          |  | Not Reported |
|                          | Nexium       | C |  |  |  | Unk, Unk |  | Not Reported |
|                          | Lyrica       | C |  |  |  |          |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Apr-2007              | 6227521       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00139-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Eruption;             | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Hypersensitivity; Skin     | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Disorder; Skin Exfoliation | Ambien         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Apr-2007              | 6278459       | EXPEDITED (15-DAY) | Y                  | HO              | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13725650 |                      | 44 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;     | Abilify              |              |            | S           | Oral         |                    |                 | Not Reported |
| Serotonin Syndrome;   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
| Somnolence            |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2007              | 6168684       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S06-USA-04318-01     |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Bundle Branch  | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Block Right; Condition   | Diazepam       |              |            | C           |              |                    |                 | Not Reported |
| Aggravated; Dizziness;   | Mucinex        |              |            | C           |              |                    |                 | Not Reported |
| Electrocardiogram Qrs    | Flomax         |              |            | C           |              |                    |                 | Not Reported |
| Complex Prolonged; Fall; | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
| Hypertension; Loss Of    |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                          |   |              |
|---------------------------|--------------------------|---|--------------|
| Consciousness; Nausea;    | Zetia (Ezetimibe)        | C | Not Reported |
| Palpitations; Presyncope; | Synthroid                | C | Not Reported |
| Sinus Node Dysfunction;   | Lisinopril               | C | Not Reported |
| Supraventricular          | Centrum Silver (Vitamin) | C | Not Reported |
| Extrasystoles; Syncope;   | Norvasc                  | C | Not Reported |
| Ventricular Hypertrophy;  | Triamterene And          | C | Not Reported |
| Vomiting                  | Hydrochlorothiazide      |   |              |
|                           | Singulair                | C | Not Reported |
|                           | Nexium (Esomeprazole)    | C | Not Reported |
|                           | Astelin                  | C | Not Reported |
|                           | Fluticasone              | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2007              | 6192004       | EXPEDITED (15-DAY) | Y                  | HO              | S06-USA-04908-01     |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Failure            | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Congestive; Delusion;      | Fentanyl Citrate      |              |            | S           | Oral         | 600 Mg Prn Po      |                 | Not Reported |
| Disorientation;            | Fentanyl Citrate      |              |            | S           | Oral         | 400 Mg Prn Po      |                 | Not Reported |
| Hallucination; Lethargy;   | Oxycontin             |              |            | S           | Oral         | 160 Mg Qd Po       |                 | Not Reported |
| Mental Status Changes;     | Lortab                |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Paranoia;        | Tylenol (Paracetamol) |              |            | S           |              |                    |                 | Not Reported |
| Pericardial Effusion;      | Flexeril              |              |            | S           |              |                    |                 | Not Reported |
| Pericarditis; Pleural      | Synthroid             |              |            | C           |              |                    |                 | Not Reported |
| Effusion; Pneumonia; Self- | Lyrica                |              |            | C           |              |                    |                 | Not Reported |
| Medication                 | Combivent             |              |            | C           |              |                    |                 | Not Reported |
|                            | Seroquel              |              |            | C           |              |                    |                 | Not Reported |
|                            | Albuterol             |              |            | C           |              |                    |                 | Not Reported |
|                            | Aspirin               |              |            | C           |              |                    |                 | Not Reported |
|                            | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2007              | 6279605       | EXPEDITED (15-DAY) | N                  | DE              | US-GLAXOSMITHKLINE-A0645845A |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Completed Suicide     | Paxil          |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  | Valium                 |                    |                    | S               |                      |                         |                 |              | Glaxosmithkline |
|--------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|-----------------|
|                                                  | Lexapro                |                    |                    | S               |                      |                         |                 |              | Not Reported    |
|                                                  | Risperdal              |                    |                    | S               |                      |                         |                 |              | Not Reported    |
|                                                  | Naproxen               |                    |                    | S               |                      |                         |                 |              | Not Reported    |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>  |
| 04-Apr-2007                                      | 6333984                | NON-EXPEDITED      | Y                  | OT              | 2007006695           |                         |                 | Female       | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                 |
| Extrapyramidal Disorder;<br>Tardive Dyskinesia   | Geodon                 |                    |                    | S               |                      |                         |                 | Not Reported |                 |
|                                                  | Lexapro                |                    |                    | S               |                      |                         |                 | Not Reported |                 |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>  |
| 04-Apr-2007                                      | 6334880                | NON-EXPEDITED      | N                  | OT              | 2006155743           |                         | 26 YR           | Male         | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                 |
| Drug Interaction; Pain In<br>Jaw; Swollen Tongue | Geodon                 |                    |                    | S               |                      | (2 In 1 D)              |                 | Not Reported |                 |
|                                                  | Lexapro                |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |                 |
|                                                  | Unspecified Ingredient |                    |                    | S               |                      |                         |                 | Not Reported |                 |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>  |
| 04-Apr-2007                                      | 6335708                | NON-EXPEDITED      | Y                  | OT              | 2006132809           |                         | 35 YR           | Female       | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                 |
| Tardive Dyskinesia                               | Geodon                 |                    |                    | S               |                      |                         |                 | Not Reported |                 |
|                                                  | Carbamazepine          |                    |                    | S               |                      |                         |                 | Not Reported |                 |
|                                                  | Lexapro                |                    |                    | S               |                      |                         |                 | Not Reported |                 |
|                                                  | Unspecified Ingredient |                    |                    | S               |                      |                         |                 | Not Reported |                 |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>  |
| 05-Apr-2007                                      | 5910006                | EXPEDITED (15-DAY) | N                  | DE              | S05-USA-04577-01     |                         | 32 YR           | Male         | USA             |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                 |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                        |                                           |      |              |                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Anxiety; Completed<br>Suicide; Condition<br>Aggravated; Diarrhoea;<br>Fatigue; Feeling<br>Abnormal; Intentional Self-<br>Injury; Nausea; Overdose;<br>Pulmonary Congestion;<br>Pulmonary Oedema;<br>Restlessness; Social<br>Avoidant Behaviour;<br>Suicidal Ideation; Thinking<br>Abnormal; Toxicity To<br>Various Agents; Tremor;<br>Visceral Congestion;<br>Vomiting | Lexapro<br>Oxycodone<br>Diazepam<br>Zolpidem<br>Nordazepam<br>Morphine<br>Hydrocodone<br>Glucophage<br>Diovan Hcl (Valsartan)<br>Xanax | S<br>S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Oral | 10 Mg Qd; Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2007              | 6281063       | EXPEDITED (15-DAY) | Y                  | HO              | 2007CG00548          |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholestasis; Hepatitis | Omeprazole           |              |            | S           | Oral         |                    | 20 DAY          | Not Reported |
|                        | Caffeine             |              |            | S           | Oral         |                    | 11 DAY          | Not Reported |
|                        | Cefpodoxime Proxetil |              |            | S           | Oral         |                    | 11 DAY          | Not Reported |
|                        | Zyprexa              |              |            | S           | Oral         |                    | 19 DAY          | Not Reported |
|                        | Activelle            |              |            | S           | Oral         |                    | 11 DAY          | Not Reported |
|                        | Escitalopram Oxalate |              |            | S           | Oral         |                    | 17 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2007              | 6296055       | EXPEDITED (15-DAY) |                    | DS, HO          | 2007-156434-NL       |                      | 68 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Depersonalisation/Dereali-<br>sation Disorder; Drug<br>Ineffective; Dysphagia;<br>Dystonia | Mirtazapine          |              |            | S           | Oral         | 30 Mg Qd/15 Mg Qd Oral | 97 DAY          | Not Reported |
|                                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg Qd/15 Mg Qd Oral | 148 DAY         | Not Reported |
|                                                                                            |                      |              |            |             |              | 10 Mg Qd Oral          | 22 DAY          | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |      |               |       |              |
|--|-----------------|---|------|---------------|-------|--------------|
|  | Citalopram      | S | Oral | 20 Mg Qd Oral | 3 DAY | Not Reported |
|  | Co-Amilofruse   | C |      |               |       | Not Reported |
|  | Diazepam        | C |      |               |       | Not Reported |
|  | Digoxin         | C |      |               |       | Not Reported |
|  | Nicorandil      | C |      |               |       | Not Reported |
|  | Paracetamol     | C |      |               |       | Not Reported |
|  | Perindopril     | C |      |               |       | Not Reported |
|  | Senna           | C |      |               |       | Not Reported |
|  | Simvastatin     | C |      |               |       | Not Reported |
|  | Warfarin Sodium | C |      |               |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2007              | 6161841       | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-04284-01     |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Chest Pain; Completed Suicide; Depressed Mood; Dyspepsia; Dyspnoea; Fatigue; Feeling Cold; Feeling Hot; Gun Shot Wound; Head Injury; Hostility; Tremor | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                            | Zestril               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                            | Ativan                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                            | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2007              | 6254731       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00457-01     |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ankle Fracture; Basedow'S Disease; Fall; Foot Fracture; Hypothyroidism | Lexapro                                      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                        | Lexapro                                      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                        | Seasonale (Ethinyl Estradiol/Levonorgestrel) |              |            | C           |              |                    |                 | Not Reported |
|                                                                        | Calcium                                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2007              | 6295979       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01470-01     |                      | 50 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abdominal Pain Upper;<br>Diarrhoea; Hepatitis;<br>Jaundice; Nausea;<br>Pruritus; Pyrexia                                                                                                                                                                                                                 | Escitalopram Oxalate                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Mopral (Omeprazole)                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Zyprexa                                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Orelox (Cefpodoxime Proxetil)               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Activella                                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Acetaminophen\Caffeine                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2007                                                                                                                                                                                                                                                                                              | 6296234                                     | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-01369-01     |                      | 30 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Physical Assault                                                                                                                                                                                                                                                                             | Lexapro                                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2007                                                                                                                                                                                                                                                                                              | 6347512                                     | EXPEDITED (15-DAY) | Y                  | HO              | T200601348           |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angiopathy; Cardiac Failure Congestive;<br>Delusion; Drug Screen Positive;<br>Electrocardiogram St-T Change; Hallucination;<br>Lethargy; Overdose;<br>Paranoia; Pericardial Effusion; Pleural Effusion;<br>Self-Medication; Sinus Tachycardia; Treatment Noncompliance; White Blood Cell Count Increased | Lortab                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Fentanyl Citrate                            |                    |                    | S               | Buccal               | 600 Ug, Prn Buccal   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Fentanyl Citrate                            |                    |                    | S               | Buccal               | 400 Ug, Prn Buccal   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Oxycontin                                   |                    |                    | S               | Oral                 | 160 Mg, Qd, Oral     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Lexapro                                     |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Tylenol (Paracetamol)                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Flexeril                                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Seroquel                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Albuterol (Salbutamol)                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Aspirin                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Nexium (Esomeprazole                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Magnesium)                                  |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                          | Synthroid                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Lyrica                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                          | Combivent (Ipratropium Bromide, Salbutamol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Zithromax                                                                                                                                                                                                                                                                                                |                                             |                    | C                  |                 |                      |                      | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2007              | 6023873       | EXPEDITED (15-DAY) | N                  | HO              | PHNR2006AU00661      |                      | 77 YR      | Female     | AUS            |

| <u>Preferred Term</u>                           | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|-----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Amnesia; Confusional State; Fall; Hallucination | Stalevo         |              |            | S           |              | 6 Tablets (100/25/200mg) Per Day |                 | Orion        |
|                                                 | Lexapro         |              |            | S           |              | 10 Mg, Mane                      |                 | Not Reported |
|                                                 | Lasix           |              |            | C           |              | 40 Mg, Unk                       |                 | Not Reported |
|                                                 | Lanoxin         |              |            | C           |              | 125 Mg, Unk                      |                 | Not Reported |
|                                                 | Lansoprazole    |              |            | C           |              | 30 Mg, Nocte                     |                 | Not Reported |
|                                                 | Zocor           |              |            | C           |              | 10 Mg, Nocte                     |                 | Not Reported |
|                                                 | Sinemet Cr      |              |            | C           |              | 1 Tablet (200 Mg) Nocte          |                 | Not Reported |
|                                                 | Cabergoline     |              |            | C           |              | 2 Mg, Nocte                      |                 | Not Reported |
|                                                 | Diazepam        |              |            | C           |              | 2.5 Mg, Nocte                    |                 | Not Reported |
|                                                 | Warfarin Sodium |              |            | C           |              | 2/3mg Alternating                |                 | Not Reported |
|                                                 | Sinemet         |              |            | C           |              | 100/25 X 5 Or 6 Per Day          |                 | Not Reported |
|                                                 | Symmetrel       |              |            | C           |              | 1 Tablet Bd                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2007              | 6292113       | DIRECT           | Y                  |                 |                      |                      | 43 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Marital Problem; Personality Change | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2007              | 6292566       | DIRECT           | Y                  | HO              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Nausea; Presyncope; Skin | Lexapro        |              |            | S           |              | 10mg 1 Time/Day    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                          |                       |                    |                    |                 |                      |                      |                 |              |                |
|----------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Discolouration; Vomiting                                                                                 |                       | Levaquin           |                    | C               |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2007                                                                                              | 6296972               | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01463-01     |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Chest Pain; Diarrhoea; Drug Interaction; Nausea; Presyncope; Vomiting                  | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                          | Levaquin              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Nexium (Esomeprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Diovan                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Apr-2007                                                                                              | 6300068               | EXPEDITED (15-DAY) | Y                  | OT              | S07--01386-01        |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Leukopenia; Platelet Count Decreased                                                                     | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                          | Restoril              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Librium               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Ritalin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                          | Nexium (Esomeprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2007                                                                                              | 6296887               | DIRECT             | N                  |                 |                      |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Medication Error; Product Dispensing Error; Wrong Product Administered | Lisinopril            |                    |                    | S               | Oral                 | 10mg One Daily Po    | 5 DAY           | Mylan        |                |
|                                                                                                          | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2007                                                                                              | 6299540               | EXPEDITED (15-DAY) | N                  | CA              | S07-USA-01504-02     |                      |                 | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Heart Disease Congenital;<br>Maternal Exposure Before<br>Pregnancy; Maternal<br>Exposure During<br>Pregnancy; Transposition<br>Of The Great Vessels | Lexapro                                                                      |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                                                                     | Tylenol (Paracetamol)                                                        |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                     | Alka-Seltzer Cold Plus                                                       |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                     | (Acetaminophen/Chlorphenirami<br>ne/Phenylephrine)<br>Prenatal Vitamin (Nos) |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2007                                                                                                                                         | 6299552                                                                      | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01503-01     |                         | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Gastrointestinal<br>Haemorrhage                                                                                                | Lexapro                                                                      |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                     | Ibuprofen                                                                    |                    |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2007                                                                                                                                         | 6296261                                                                      | DIRECT             | N                  | DE              |                      |                         | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Injury                                                                                                                           | Lexapro                                                                      |                    |                    | S               |                      |                         |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2007                                                                                                                                         | 6296663                                                                      | DIRECT             | N                  | RI              |                      |                         | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia                                                                                                                                          | Lexapro                                                                      |                    |                    | S               | Oral                 | 25mg Once A Day Po      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2007                                                                                                                                         | 6335959                                                                      | NON-EXPEDITED      |                    |                 | 2007SP000781         |                         | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                 |           |   |      |               |              |
|-----------------|-----------|---|------|---------------|--------------|
| Middle Insomnia | Lunesta   | S | Oral | See Image     | Not Reported |
|                 |           |   | Oral | See Image     |              |
|                 | Lexapro   | S | Oral | 10 Mg;Qd;Oral |              |
|                 | Paxil     | C |      |               |              |
|                 | Pravachol | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2007              | 6337212       | NON-EXPEDITED    | N                  |                 | 2007SP000185         |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u>         | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Glaucoma; Headache | Lunesta                  |              |            | S           | Oral         | 3 Mg;Oral          |                 | Not Reported |
|                               | Lexapro                  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                               | Lorazepam                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                               | Tamsulosin Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                               | Saw Palmetto             |              |            | C           |              |                    |                 | Not Reported |
|                               | Cozaar                   |              |            | C           |              |                    |                 | Not Reported |
|                               | Amlodipine               |              |            | C           |              |                    |                 | Not Reported |
|                               | Lopresor                 |              |            | C           |              |                    |                 | Not Reported |
|                               | Digoxin                  |              |            | C           |              |                    |                 | Not Reported |
|                               | Xalatan                  |              |            | C           |              |                    |                 | Not Reported |
|                               | Solu-Medrol              |              |            | C           |              |                    |                 | Not Reported |
|                               | Warfarin Sodium          |              |            | C           |              |                    |                 | Not Reported |
|                               | Fish Oil                 |              |            | C           |              |                    |                 | Not Reported |
|                               | Icaps                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2007              | 6340007       | NON-EXPEDITED    | Y                  |                 | 2007SP000029         |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysgeusia             | Lunesta        |              |            | S           | Oral         | 3 Mg; Hs; Oral     |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg;Qd;Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2007              | 6288424       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01270-01     |                      | 18 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hallucination;<br>Neutropenia; Sinusitis                                                                                         | Escitalopram Oxalate  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram Oxalate  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                  | Zyprexa               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                  | Spektramox            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2007                                                                                                                      | 6297278               | DIRECT             | Y                  | CA, OT          |                      |                      | 121 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniosynostosis;<br>Maternal Exposure During<br>Pregnancy; Pregnancy                                                            | Lexapro               |                    |                    | S               | Oral                 | 20mg 1 Time Daily Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2007                                                                                                                      | 6304591               | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01551-01     |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Loss<br>Of Consciousness;<br>Suicide Attempt                                                               | Lexapro               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                  | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                  | Lexapro               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                  | Xanax                 |                    |                    | S               | Oral                 | 0.25 Mg Prn Po       |                 | Not Reported |                |
|                                                                                                                                  | Xanax                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Alcohol                                                                                                                          |                       |                    | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2007                                                                                                                      | 6306653               | EXPEDITED (15-DAY) | N                  | DE, HO          | 2007S1001632         |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Blood<br>Urine Present; Chest Pain;<br>Completed Suicide;<br>Cystitis; Headache;<br>Hypoaesthesia; Insomnia; | Diazepam Tablets, Usp |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                  | Lexapro               |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                  | Naproxen              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                            |            |   |       |       |              |
|----------------------------------------------------------------------------------------------------------------------------|------------|---|-------|-------|--------------|
| Neck Pain; Nervousness;<br>Post-Traumatic Stress<br>Disorder; Restlessness;<br>Road Traffic Accident;<br>Suicidal Ideation | Rhinocort  | S | Nasal | Nasal | Not Reported |
|                                                                                                                            | Paxil      | S | Oral  | Oral  | Not Reported |
|                                                                                                                            | Risperdal  | S | Oral  | Oral  | Not Reported |
|                                                                                                                            | Paxil Cr   | S | Oral  | Oral  | Not Reported |
|                                                                                                                            | Buspirone  | S | Oral  | Oral  | Not Reported |
|                                                                                                                            | Gabapentin | S | Oral  | Oral  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2007              | 6291710       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20070402130 |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dehydration; Drug<br>Interaction; Dry Eye;<br>Dysphagia; Tremor | Topamax        |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Seroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Klonopin       |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Depakote       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2007              | 6297715       | DIRECT           | N                  | DE, HO, LT      |                      |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 20 Mg 1 Per Day Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2007              | 6297725       | DIRECT           | N                  | DE, LT          |                      |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 20 Mg 1 Per Day Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2007              | 6262279       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00773-01     |                      | 56 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| Chorea; Fall; Tardive<br>Dyskinesia; Tremor                             | Lexapro                                                                    |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                         | Lexapro                                                                    |                    |                    | S               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Lexapro                                                                    |                    |                    | S               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Glucovance                                                                 |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | (Glyburide/Metformin)                                                      |                    |                    |                 |                                      |                      |                 |                 |                |
|                                                                         | Unspecified Ingredient                                                     |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Ultram                                                                     |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Adipex-P                                                                   |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Levothyroxine                                                              |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Unspecified Ingredient                                                     |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
|                                                                         | Unspecified Ingredient                                                     |                    |                    | C               |                                      |                      | Not Reported    |                 |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Apr-2007                                                             | 6292913                                                                    | EXPEDITED (15-DAY) | N                  | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0453335A |                      | 84 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Coordination Abnormal;<br>Dyskinesia; Fall;<br>Musculoskeletal Disorder | Lamictal                                                                   |                    |                    | S               | Oral                                 |                      | 2 MTH           | Glaxosmithkline |                |
|                                                                         | Escitalopram Oxalate                                                       |                    |                    | S               | Oral                                 | 10mg Per Day         | 3 MTH           | Unknown         |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Apr-2007                                                             | 6305367                                                                    | EXPEDITED (15-DAY) | Y                  | HO              | S06-UKI-05173-01                     |                      | 49 YR           | Female          | GBR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Psychosis; Mania                                                  | Escitalopram Oxalate                                                       |                    |                    | S               | Oral                                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                         | Escitalopram Oxalate                                                       |                    |                    | S               | Oral                                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                         | Ispaghula Husk Sachets<br>(Ispaghula Husk)                                 |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                         | Lactulose Solution (Lactulose)                                             |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                         | Diclofenac With Misoprostol<br>(Galenic /Misoprostol/Diclofenac<br>Sodium) |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                         | Co-Dydramol                                                                |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                         | Gaviscon                                                                   |                    |                    | C               |                                      |                      |                 | Not Reported    |                |
|                                                                         | Levothyroxine                                                              |                    |                    | C               |                                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |   |  |  |  |  |  |  |              |
|--|---------------------|---|--|--|--|--|--|--|--------------|
|  | Gabapentin Capsules | C |  |  |  |  |  |  | Not Reported |
|  | (Gabapentin)        | C |  |  |  |  |  |  | Not Reported |
|  | Risperidone         | C |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Apr-2007              | 6561655       | EXPEDITED (15-DAY) | N                  | DE, OT          | 2007-01857           |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;         | Oxycodone And Acetaminophen |              |            | S           |              |                    |                 | Watson       |
| Acute Pulmonary             | Hydrocodone Bitartrate And  |              |            | S           |              |                    |                 | Watson       |
| Oedema; Anxiety;            | Acetaminophen               |              |            |             |              |                    |                 |              |
| Completed Suicide;          | Lexapro                     |              |            | S           | Oral         | 10 Mg, Daily, Oral |                 | Not Reported |
| Diarrhoea; Fatigue;         | Diazepam                    |              |            | S           |              |                    |                 | Not Reported |
| Feeling Abnormal;           | Zolpidem                    |              |            | S           |              |                    |                 | Not Reported |
| Intentional Overdose;       | Nordazepam                  |              |            | S           |              |                    |                 | Not Reported |
| Intentional Self-Injury;    | Morphine                    |              |            | S           |              |                    |                 | Not Reported |
| Nausea; Partner Stress;     | Glucophage                  |              |            | C           |              |                    |                 | Not Reported |
| Pulmonary Congestion;       | Valsartan                   |              |            | C           |              |                    |                 | Not Reported |
| Skin Laceration; Social     | Xanax                       |              |            | C           |              |                    |                 | Not Reported |
| Avoidant Behaviour;         |                             |              |            |             |              |                    |                 |              |
| Suicidal Ideation; Thinking |                             |              |            |             |              |                    |                 |              |
| Abnormal; Toxicity To       |                             |              |            |             |              |                    |                 |              |
| Various Agents; Tremor;     |                             |              |            |             |              |                    |                 |              |
| Visceral Congestion;        |                             |              |            |             |              |                    |                 |              |
| Vomiting                    |                             |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Apr-2007              | 6265349       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00981-01     |                      | 27 YR      | Female     | FRA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase    | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Increased; Arteritis; Brain | Xanax (Escitalopram) |              |            | C           |              |                    |                 | Not Reported |
| Oedema; Central Nervous     | Effexor              |              |            | C           |              |                    |                 | Not Reported |
| System Vasculitis;          |                      |              |            |             |              |                    |                 |              |
| Cerebral Haematoma;         |                      |              |            |             |              |                    |                 |              |
| Conjunctivitis;             |                      |              |            |             |              |                    |                 |              |
| Hemianopia; Hemiparesis;    |                      |              |            |             |              |                    |                 |              |
| Meningorrhagia; Protein     |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Total Increased; Pupils  
Unequal; Urinary Tract  
Infection; Urine Alcohol  
Test Positive

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2007                                                                                                                                                                                                                  | 6275501                         | EXPEDITED (15-DAY) | Y                  | DS, HO          | S07-FRA-01073-01     |                      | 85 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Activated Partial<br>Thromboplastin Time<br>Prolonged; Blood<br>Creatinine Increased;<br>Blood Urea Increased;<br>Fall; Haematocrit<br>Decreased; Head Injury;<br>Red Blood Cell Count<br>Decreased; Subdural<br>Haemorrhage | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Aspirin Lysine                  |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Atacand (Candesartan Cilexetil) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Covarsal (Molsidomine)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Nitriderm (Glyceryl Trinitrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Amlodipine Besylate             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Ebixa                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Modopar                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Tadenan (Pygeum Africanum)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Vastarel                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Dafalgan (Paracetamol)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Xanax                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Pravastatin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Apr-2007                                                                                                                                          | 6295114                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00281-01     |                      | 85 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Bilirubin<br>Increased; Blood Chloride<br>Decreased; Cognitive<br>Disorder; Fall;<br>Haemodilution;<br>Hyponatraemia;<br>Hypotension | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                      | Furosemide                     |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                      | Kenzen (Candesartan Cilexetil) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                      | Sintrom                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                      | Sotalol Hydrochloride          |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|----------------|
| 23-Apr-2007                                                                                                                                                                                                                                                                                                                                                                                                         | 6300990                                                                                                               | DIRECT             | Y                  | CA                                   |                      |                      | 193 DAY         | Male                                                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Cardiac Disorder;<br>Congenital Anomaly;<br>Maternal Exposure During<br>Pregnancy                                                                                                                                                                                                                                                                                                                                   | Lexapro                                                                                                               |                    |                    | S                                    | Oral                 | 20 Mg Once Daily Po  |                 | Not Reported                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 23-Apr-2007                                                                                                                                                                                                                                                                                                                                                                                                         | 6301058                                                                                                               | DIRECT             | Y                  | LT                                   |                      |                      | 50 YR           | Female                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Suicide Attempt                                                                                                                                                                                                                                                                                                                                                                                                     | Lexapro                                                                                                               |                    |                    | S                                    |                      |                      |                 | Not Reported                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                                                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 24-Apr-2007                                                                                                                                                                                                                                                                                                                                                                                                         | 6306834                                                                                                               | EXPEDITED (15-DAY) | Y                  | DE                                   | 2007S1003092         |                      | 32 YR           | Male                                                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Abnormal Behaviour;<br>Anxiety; Completed<br>Suicide; Diarrhoea;<br>Fatigue; Feeling<br>Abnormal; General<br>Physical Health<br>Deterioration; Intentional<br>Self-Injury; Nausea;<br>Overdose; Pulmonary<br>Congestion; Pulmonary<br>Oedema; Self-Injurious<br>Ideation; Skin Laceration;<br>Sleep Disorder; Social<br>Avoidant Behaviour;<br>Stress; Suicidal Ideation;<br>Thinking Abnormal;<br>Tremor; Visceral | Lexapro<br>Oxycodone<br>Diazepam Tablets, Usp<br>Zolpidem<br>Morphine<br>Hydrocodone<br>Glucophage<br>Diovan<br>Xanax |                    |                    | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Oral                 | 10 Mg;Daily;Oral     |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congestion; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2007              | 6307460       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-01647-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperemesis Gravidarum; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy; Pregnancy; Suppressed Lactation | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2007              | 6307462       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01671-01     |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Energy Increased; Feeling Abnormal; Grandiosity; Hypomania; Mania; Psychotic Disorder; Thinking Abnormal | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2007              | 6310341       | EXPEDITED (15-DAY) | N                  | HO              | 070409-0000375       |                      | 80 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort; Asthenia; Dermatitis                                                                               | Tranxene T-Tab |              |            | S           | Oral         | 3.75 Mg; Qd; Po    |                 | Not Reported |
| Allergic; Disorientation; Dyssomnia; Headache; Hypersensitivity; Nausea; Presyncope; Rash; Somnolence; Tremor; Urticaria | Lexapro        |              |            | S           | Oral         | 10 Mg; Po          |                 | Not Reported |
|                                                                                                                          | Paxil          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------------|-----------------|--------------|----------------|
| 26-Apr-2007                                                                        | 6290707                 | EXPEDITED (15-DAY) | Y                  | HO              | DEWYE412411APR07      |                                      | 18 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Drunk; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Vomiting | Pantozol (Pantoprazole) |                    |                    | S               | Oral                  | 1 Tablet (Overdose Amount 40 Mg)     | 1 DAY           | Wyeth        |                |
|                                                                                    | Tavor (Lorazepam)       |                    |                    | S               | Oral                  | 2 Tablets (Overdose Amount 2 Mg)     | 1 DAY           | Wyeth        |                |
|                                                                                    | Risperidone             |                    |                    | S               | Oral                  | 1 Tablet (Overdose Amount Unknown)   | 1 DAY           | Unknown      |                |
|                                                                                    | Alcohol                 |                    |                    | S               | Oral                  | Half A Bottle Of Liqueur             | 1 DAY           | Unknown      |                |
|                                                                                    | Cipralex                |                    |                    | S               | Oral                  | 1 Tablet (Overdose Amount 10 Mg )    | 1 DAY           | Lundbeck     |                |
|                                                                                    | Clonidine               |                    |                    | S               | Oral                  | 3 Tablets (Overdose Amount 0,225 Mg) | 1 DAY           | Unknown      |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2007                                                                        | 6308710                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-00243-01      |                                      | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal; Dyskinesia; Epilepsy; Fall; Muscle Disorder                 | Escitalopram Oxalate    |                    |                    | S               | Oral                  | 10 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                    | Lamictal                |                    |                    | S               | Oral                  | 100 Mg Qd Po                         |                 | Not Reported |                |
|                                                                                    | Lamictal                |                    |                    | S               | Oral                  | 75 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                    | Lamictal                |                    |                    | S               | Oral                  | 50 Mg Qd Po                          |                 | Not Reported |                |
|                                                                                    | Lamictal                |                    |                    | S               | Oral                  | 25 Mg Qd Po                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2007                                                                        | 6375835                 | NON-EXPEDITED      | Y                  | HO              | US-JNJFOC-20060401363 |                                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;                                                                  | Ultram                  |                    |                    | S               |                       |                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |                        |                    |                    |                 |                          |                      |                 |              |                |
|--------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Serotonin Syndrome                               | Lexapro                |                    |                    | S               |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2007                                      | 6296970                | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01500-01         |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                 | Lexapro                |                    |                    | S               | Oral                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                  | Many Medications (Nos) |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2007                                      | 6298637                | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-PFIZER INC-2007032266 |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness; Overdose; Suicide Attempt | Xanax                  |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                  | Lexapro                |                    |                    | S               |                          | Daily Dose:20mg      |                 | Not Reported |                |
|                                                  | Lexapro                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                  | Alcohol                |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2007                                      | 6299441                | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20070404377    |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Drug Interaction; Nausea; Presyncope  | Levaquin               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                  | Nexium                 |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                  | Diovan                 |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                  | Lexapro                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2007                                      | 6300500                | NON-EXPEDITED      |                    |                 | 2006UW18374              |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Drug Interaction                         | Nexium                 |                    |                    | S               | Oral                     |                      |                 | Astrazeneca  |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |              |
|---------|---|------|--------------|
| Levoxyl | C |      | Not Reported |
| Allegra | C |      | Not Reported |
| Lexapro | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2007              | 6306351       | DIRECT           | Y                  | HO, LT          |                      |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Respiratory Arrest;<br>Seizure | Tramadol Hydrochloride |              |            | S           | Oral         | 400 Mg Daily Po    |                 | Not Reported |
|                                | Escitalopram Oxalate   |              |            | S           | Oral         | 30 Mg Daily Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2007              | 6310991       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01245-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dystonia; Intervertebral<br>Disc Protrusion; Muscle<br>Spasms | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                               | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                               | Mirapex        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2007              | 6267526       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00985-01     |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Hepatic Cirrhosis; Hepatic<br>Failure; Hyponatraemia;<br>Tremor | Lexapro         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Lexapro         |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                            | Lasix           |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |
|                                                                                            | Lasix           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                            | Spironolactone  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Quinine Sulfate |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Neomycin        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Prevacid        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Magnesium       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Lactulose       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                         |                         |                    |                    |                 |                          |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Oxazepam                                                                                                                                                                                |                         | C                  |                    | Not Reported    |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2007                                                                                                                                                                             | 6283414                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2007024784 |                      | 26 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Enzyme Increased; Hyperventilation; Lymphadenopathy; Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Weight Decreased | Unspecified Ingredient  |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Levothyroxine           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Indomethacin            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Caffeine\Opium Tincture |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Tetrazepam              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Virginiamycin           |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2007                                                                                                                                                                             | 6286532                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-NOVOPROD-262406       |                      | 50 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                                                                               | Activelle               |                    |                    | S               | Oral                     |                      | 10 DAY          | Novo Nordisk |                |
|                                                                                                                                                                                         | Omeprazole              |                    |                    | S               |                          |                      | 19 DAY          | Not Reported |                |
|                                                                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               |                          |                      | 16 DAY          | Not Reported |                |
|                                                                                                                                                                                         | Zyprexa                 |                    |                    | S               |                          |                      | 18 DAY          | Not Reported |                |
|                                                                                                                                                                                         | Orelox                  |                    |                    | S               |                          |                      | 10 DAY          | Not Reported |                |
|                                                                                                                                                                                         | Caffeine                |                    |                    | S               |                          |                      | 10 DAY          | Not Reported |                |
|                                                                                                                                                                                         | Fluoxetine              |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-May-2007                                                                                                                                                                             | 6292727                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01358-01         |                      | 26 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;                                                                                                                                                                    | Escitalopram Oxalate    |                    |                    | S               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                        |   |      |                |              |
|----------------------------|------------------------|---|------|----------------|--------------|
| Cholestasis;               | Levothyroxine          | S | Oral | 125 Mcg Qd Po  | Not Reported |
| Cytomegalovirus Test       | Sulfasalazine          | S | Oral | 1000 Mg Bid Po | Not Reported |
| Positive; Disease          | Acetaminophen\Caffeine | S |      |                | Not Reported |
| Recurrence; Drug           | Indomethacin           | S | Oral | 75 Mg Bid Po   | Not Reported |
| Reaction With Eosinophilia | Tetrazepam             | S | Oral | 50 Mg, Po      | Not Reported |
| And Systemic Symptoms;     | Mopral (Omeprazole)    | C |      |                | Not Reported |
| Epstein-Barr Virus         | Daivobet               | C |      |                | Not Reported |
| Antibody Positive; Hepatic | Virginiamycin          | C |      |                | Not Reported |
| Neoplasm; Hepatitis;       |                        |   |      |                |              |
| Lymphadenopathy;           |                        |   |      |                |              |
| Oxygen Saturation          |                        |   |      |                |              |
| Decreased; Protein Total   |                        |   |      |                |              |
| Increased; Pustular        |                        |   |      |                |              |
| Psoriasis; Splenomegaly    |                        |   |      |                |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2007              | 6312010       | EXPEDITED (15-DAY) | Y                  | OT              | S07-UKI-01762-01     |                      |            | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aplastic Anaemia      | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2007              | 6312021       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01760-01     |                      | 33 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2007              | 6290189       | EXPEDITED (15-DAY) | Y                  | HO              | 6031105              |                      | 26 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Acute Kidney Injury;  | Levothyroxine Sodium |              |            | S           |              | 125 Mcg (125 Mcg, 1 D); |                 | Not Reported |
| Cytomegalovirus Test  | Sulfasalazine        |              |            | S           | Oral         | 20000,0 Mg; (1000 Mg, 1 | 41 DAY          | Not Reported |
| Positive; Disease     |                      |              |            |             |              | In 1 D) Oral            |                 |              |
| Recurrence; Hepatic   | Escitalopram Oxalate |              |            | S           | Oral         | Oral                    | 2 DAY           | Not Reported |
| Enzyme Increased;     |                      |              |            |             |              |                         |                 |              |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                |                                                                    |   |      |                                              |        |       |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|---|------|----------------------------------------------|--------|-------|--------------|
| Hypersensitivity;<br>Hyperventilation; Liver<br>Disorder;<br>Lymphadenopathy;<br>Mononucleosis Syndrome;<br>Oxygen Saturation<br>Decreased; Pustular<br>Psoriasis; Pyrexia; Rash<br>Maculo-Papular;<br>Splenomegaly; Urticaria | Acetaminophen\Belladonna<br>Extract\Caffeine\Papaverine<br>Indocin | S |      |                                              |        | 2 DAY | Not Reported |
|                                                                                                                                                                                                                                |                                                                    | S | Oral | 150,000 Mg (75 Mg, 2 In 1 49 DAY<br>D); Oral |        |       | Not Reported |
|                                                                                                                                                                                                                                | Tetrazepam                                                         | S | Oral | Oral                                         |        |       | Not Reported |
|                                                                                                                                                                                                                                | Virginiamycin                                                      | S | Oral | Oral                                         | 6 WEEK |       | Not Reported |
|                                                                                                                                                                                                                                |                                                                    |   | Oral | Oral                                         |        |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2007              | 6213818       | EXPEDITED (15-DAY) | Y                  | HO              | PAR_1160_2006        |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u>                                                                                                                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                                    | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------------------------------------|--------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Affect Lability; Amnesia;<br>Anxiety; Apathy; Chest<br>Discomfort; Crying;<br>Decreased Appetite;<br>Depression; Diarrhoea;<br>Disturbance In Attention;<br>Dizziness Postural; Drug<br>Ineffective; Dysphemia;<br>Dysuria; Fatigue; Flight Of<br>Ideas; Insomnia; Malaise;<br>Nausea; Serotonin<br>Syndrome | Cyproheptadine Hydrochloride<br>Lexapro<br>Prozac<br>Prozac<br>Zithromax<br>Depo-Provera<br>Tylenol With Codeine<br>Tizanidine Hydrochloride<br>Multi-Vitamin<br>Ppd Disposable |              |            | S<br>S<br>S<br>S<br>C<br>C<br>C<br>C<br>C<br>C |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2007              | 6316461       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S07-NOR-01831-01     |                      | 65 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>                                                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------------|
| Akathisia; Aphasia; Blood<br>Bilirubin Increased; Blood<br>Calcium Increased; Blood<br>Creatine Abnormal; Blood<br>Phosphorus Decreased;<br>Blood Potassium | Ciprallex<br>Aldomet<br>Diural (Furosemide)<br>Ramipril<br>Etalpa (Colecalciferol)<br>Renavit |              |            | S<br>S<br>C<br>C<br>C<br>C | Oral         | 20 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                       |   |              |
|---------------------------|-----------------------|---|--------------|
| Increased; Blood Pressure | Nexium (Esomeprazole) | C | Not Reported |
| Fluctuation; Body         | Paracet (Paracetamol) | C | Not Reported |
| Temperature Increased;    | Albyl-E               | C | Not Reported |
| Brain Injury; C-Reactive  | Irbesartan            | C | Not Reported |

Protein Increased;  
Cerebral Infarction;  
Confusional State; Csf  
Test Abnormal; Culture  
Urine Positive; Drug  
Interaction; Dysarthria;  
Dyspraxia; Enterococcal  
Infection; Generalised  
Tonic-Clonic Seizure;  
Haemoglobin Decreased;  
High Density Lipoprotein  
Abnormal; Hypertensive  
Crisis; Muscle Spasticity;  
Neglect Of Personal  
Appearance; Neurological  
Symptom; Oedema  
Peripheral; Osteoarthritis;  
Red Blood Cell  
Sedimentation Rate  
Increased; Retinopathy  
Hypertensive; Serotonin  
Syndrome; Serum Ferritin  
Increased; Somnolence;  
Spinal Osteoarthritis;  
Tachycardia;  
Unresponsive To Stimuli;  
Visual Acuity Reduced;  
White Blood Cell Count  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-May-2007              | 6282306       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-07P-056-0363384-00 |                      | 26 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Cell<br>Death; Cholestasis; Drug | Levothyrox     |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                  |                                           |                                                              |                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Reaction With Eosinophilia<br>And Systemic Symptoms;<br>Eosinophil Count<br>Increased; Hepatomegaly;<br>Hyperventilation; Lip<br>Oedema;<br>Lymphadenopathy;<br>Lymphocyte Count<br>Increased; Oxygen<br>Saturation Decreased;<br>Protein Total Increased;<br>Pustular Psoriasis; Rash<br>Maculo-Papular;<br>Splenomegaly; Urticaria;<br>White Blood Cell Count<br>Increased | Escitalopram Oxalate<br>Sulfasalazine<br>Acetaminophen\Belladonna\Caff<br>eine\Opium<br>Indomethacin<br>Tetrazepam<br>Omeprazole<br>Betamethasone Dipropionate<br>Virginiamycin<br>Virginiamycin | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br><br><br><br><br><br> | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-May-2007              | 6305283       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2007034094 |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Abdominal Distension;<br>Aggression; Back Pain;<br>Flatulence; Insomnia;<br>Nausea; Nightmare;<br>Parosmia; Weight<br>Increased | Chantix<br>Lexapro<br>Lipitor<br>Lisinopril<br>Synthroid<br>Premarin<br>Sinemet |              |            | S<br>S<br>C<br>C<br>C<br>C<br>C |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2007              | 6312109       | DIRECT           | N                  | OT              |                      |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Emotional Disorder;<br>Weight Increased | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 09-May-2007                                  | 6212932           | EXPEDITED (15-DAY) | Y                  | OT              | S06-USA-05338-01           |                               | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Glaucoma; Macular Degeneration               | Lexapro           |                    |                    | S               | Oral                       | 20 Mg Qd Po                   |                 | Not Reported |                |
|                                              | Lexapro           |                    |                    | S               | Oral                       | 5 Mg Qd Po                    |                 | Not Reported |                |
|                                              | Lexapro           |                    |                    | S               | Oral                       | 10 Mg Qd Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2007                                  | 6264631           | EXPEDITED (15-DAY) | Y                  | DE, LT          | DE-ASTRAZENECA-2007PK00643 |                               | 52 YR           | Female       | DEU            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Abuser; Restlessness | Seroquel          |                    |                    | S               | Oral                       | 75 Mg To 250 Mg Per Day 8 DAY |                 | Zeneca       |                |
|                                              | Seroquel          |                    |                    | S               | Oral                       | 75 Mg To 250 Mg Per Day 3 DAY |                 | Zeneca       |                |
|                                              | Ciprallex         |                    |                    | S               | Oral                       |                               | 15 DAY          | Not Reported |                |
|                                              | Tavor (Lorazepam) |                    |                    | C               | Oral                       |                               | 8 DAY           | Not Reported |                |
|                                              | Lorazepam         |                    |                    | C               | Oral                       |                               | 1 DAY           | Not Reported |                |
|                                              | Lorazepam         |                    |                    | C               | Oral                       |                               | 1 DAY           | Not Reported |                |
|                                              | Lorazepam         |                    |                    | C               | Oral                       |                               | 3 DAY           | Not Reported |                |
|                                              | Lorazepam         |                    |                    | C               | Oral                       |                               | 4 DAY           | Not Reported |                |
|                                              | Lorazepam         |                    |                    | C               | Oral                       |                               | 1 DAY           | Not Reported |                |
|                                              | Stilnox           |                    |                    | C               | Oral                       |                               | 16 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2007                                  | 6265287           | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-00895-01           |                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Retinal Haemorrhage                          | Lexapro           |                    |                    | S               |                            |                               |                 | Not Reported |                |
|                                              | Lamictal          |                    |                    | C               |                            |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------|--------------------|----------------------------|--------------------------------------|---------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| 09-May-2007                                                                                                                           | 6289588                                                                  | EXPEDITED (15-DAY) | Y                  | HO                         | S07-GER-01312-01                     |                           | 27 YR           | Female                                                                                       | DEU            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Caesarean Section; Hellp Syndrome; Maternal Exposure During Pregnancy; Thrombocytopenia                                               | Ciprallex<br>Citalopram Hydrobromide                                     |                    |                    | S<br>S                     |                                      |                           |                 | Not Reported<br>Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 09-May-2007                                                                                                                           | 6307827                                                                  | EXPEDITED (15-DAY) | Y                  | HO                         | CH-ASTRAZENECA-2007PK00952           |                           | 85 YR           | Female                                                                                       | CHE            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Extrapyramidal Disorder; Parkinsonism; Product Prescribing Error; Transient Ischaemic Attack                                          | Seroquel<br>Risperdal<br>Ciprallex<br>Trazodone Hydrochloride<br>Stilnox |                    |                    | S<br>S<br>S<br>S<br>C      | Oral<br>Oral<br>Oral<br>Oral<br>Oral |                           |                 | Zeneca<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                       |                |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                 | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 09-May-2007                                                                                                                           | 6313644                                                                  | EXPEDITED (15-DAY) | Y                  | HO                         | S07-USA-01753-01                     |                           | 90 YR           | Female                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Anxiety; Asthenia; Condition Aggravated; Constipation; Dehydration; Dizziness; Feeling Hot; Insomnia; Nausea; Orthostatic Hypotension | Lexapro<br>Lexapro<br>Metoprolol<br>Isosorbide<br>Cardizem<br>Synthroid  |                    |                    | S<br>S<br>C<br>C<br>C<br>C | Oral<br>Oral                         | 10 Mg Qd Po<br>5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |



# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-May-2007              | 6159729       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20061006565 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                               | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Insomnia; Language<br>Disorder | Pepcid Ac        |              | Y          | S           |              |                    |                 | Not Reported |
|                                                     | Pepcid Ac        |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Nexium           |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Toprol XL        |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Ambien           |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Zocor            |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Lexapro          |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Dyazide          |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Iron             |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Calcium Chloride |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Multi-Vitamin    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-May-2007              | 6300662       | EXPEDITED (15-DAY) | Y                  | HO, LT          | NO-MERCK-0704NOR00006 |                      | 65 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Autonomic<br>Nervous System<br>Imbalance; Blood<br>Pressure Fluctuation;<br>Body Temperature<br>Increased; Confusional<br>State; Drug Interaction;<br>Dyspraxia; Generalised<br>Tonic-Clonic Seizure;<br>Hypertension; Neglect Of<br>Personal Appearance;<br>Neurological Symptom;<br>Serotonin Syndrome;<br>Somnolence; Tachycardia;<br>Unresponsive To Stimuli | Aldomet                 |              |            | S           | Oral         |                    | 2 DAY           | Merck        |
|                                                                                                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate    |              |            | S           | Oral         |                    | 18 MTH          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Ramipril                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Furosemide              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Aspirin\Magnesium Oxide |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Acetaminophen           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Alfacalcidol            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Esomeprazole Magnesium  |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                             | Irbesartan              |              |            | C           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 10-May-2007                                                                                                | 6318283                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | DSA_29749_2007        |                      | 18 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Drunk; Intentional Overdose; Nausea; Somnolence; Suicide Attempt; Vomiting                         | Tavor /00273201/ (Lorazepam) Tablet |                    |                    | S               | Oral                  | 2 Mg 1x Oral         |                 | Not Reported |                |
|                                                                                                            | Ciprallex                           |                    |                    | S               | Oral                  | 10 Mg 1x Oral        |                 | Not Reported |                |
|                                                                                                            | Clonidine                           |                    |                    | S               | Oral                  | 225 Mg 1x Oral       |                 | Not Reported |                |
|                                                                                                            | Pantozol                            |                    |                    | S               | Oral                  | 40 Mg 1x Oral        |                 | Not Reported |                |
|                                                                                                            | Risperidone                         |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
|                                                                                                            | Alcohol                             |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2007                                                                                                | 6129750                             | EXPEDITED (15-DAY) | Y                  | DE, HO          | US-JNJFOC-20060901000 |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Intentional Overdose; Multiple Organ Dysfunction Syndrome; Pneumonia Aspiration; Sepsis | Tramadol Hydrochloride              |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                            | Diphenhydramine                     |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Propranolol                         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Hydrocodone/Apap                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Escitalopram Oxalate                |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                            | Nortriptyline Hydrochloride         |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                            | Oxycodone                           |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2007                                                                                                | 6309638                             | EXPEDITED (15-DAY) | Y                  | HO              | CH-JNJFOC-20070501238 |                      | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Extrapyramidal Disorder; Product Prescribing Error                       | Risperdal                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Seroquel                            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Ciprallex                           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

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|                                              |                | Trazodone Hydrochloride | S                  | Oral            |                          |                      |                 | Not Reported |                |
|----------------------------------------------|----------------|-------------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                              |                | Stilnox                 | C                  | Oral            |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2007                                  | 6308153        | EXPEDITED (15-DAY)      | N                  | OT              | US-PFIZER INC-2007035757 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                            | Neurontin      |                         |                    | S               |                          |                      |                 | Not Reported |                |
|                                              | Lexapro        |                         |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2007                                  | 6320090        | EXPEDITED (15-DAY)      | Y                  |                 | S07-USA-01931-01         |                      | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Glaucoma; Nausea; Vomiting; Weight Decreased | Lexapro        |                         |                    | S               | Oral                     | 5 Mg Qd Po           |                 | Not Reported |                |
|                                              | Flomax         |                         |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2007                                  | 6321096        | EXPEDITED (15-DAY)      | Y                  | HO              | S07-USA-01917-01         |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Status Epilepticus               | Lexapro        |                         |                    | S               | Oral                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Lexapro        |                         |                    | S               | Oral                     | 20 Mg Qd Po          |                 | Not Reported |                |
|                                              | Depakote       |                         |                    | C               |                          |                      |                 | Not Reported |                |
|                                              | Lamictal       |                         |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2007                                  | 6321099        | EXPEDITED (15-DAY)      | Y                  | HO              | S07-USA-01950-01         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident                     | Lexapro        |                         |                    | S               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-May-2007                                                                                                               | 6316743                                     | DIRECT             |                    | OT              |                          |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paraesthesia                                                                                                              | Lexapro                                     |                    |                    | S               | Oral                     | 10 Mg Once Daily Po  | 1 YR            | Forest       |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2007                                                                                                               | 6315916                                     | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007015509 |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;                                                                                                      | Chantix                                     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Cognitive Disorder;                                                                                                       | Gabapentin                                  |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| Depression;                                                                                                               | Lexapro                                     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Disorientation; Dizziness;                                                                                                | Nefazodone Hydrochloride                    |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Drug Interaction; Feeling Abnormal; Impatience; Mental Impairment                                                         |                                             |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                                                                                                               | 5654038                                     | EXPEDITED (15-DAY) | Y                  | DE              | DSA_25093_2004           |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block                                                                                                    | Diltiazem Hydrochloride                     |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
| Second Degree; Blood Pressure Decreased;                                                                                  | Lexapro                                     |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
| Cardio-Respiratory Arrest; Completed Suicide; Heart Rate Increased; Lethargy; Overdose; Somnolence; Therapy Non-Responder | Unspecified Ingredient                      |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
|                                                                                                                           | Calcium Chloride                            |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                           | Iron\Vitamins Nos                           |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                           | Ascorbic Acid                               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                           | Ibuprofen And Pseudoephedrine Hydrochloride |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                                                                                                               | 5654260                                     | EXPEDITED (15-DAY) | Y                  | DE              | DSA_25108_2004           |                      | 25 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                                                                                                                                                                              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Blood Ph Decreased; Cardiac Arrest; Completed Suicide; Electrocardiogram Qt Prolonged; Haemodialysis; Hypotension; Hypoxia; Pneumonia Aspiration; Renal Failure; Respiratory Arrest; Supraventricular Tachycardia; Toxicity To Various Agents | Lorazepam             |              |            | S           | Oral         | (Oral)             |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Diltiazem             |              |            | S           | Oral         | (Oral)             |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Benzotropine Mesylate |              |            | S           | Oral         | (Oral)             |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Escitalopram Oxalate  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Ziprasidone           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Fexofenadine          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                    | Oxcarbazepine         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-May-2007              | 6276767       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01100-02     |                      | 1 DAY      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Agitation Neonatal; Blood Glucose Decreased; C-Reactive Protein Increased; Cyanosis Neonatal; Drug Withdrawal Syndrome; Feeding Disorder; Haemoglobin Increased; Heart Rate Decreased; Hypocalcaemia; Large For Dates Baby; Maternal Exposure During Pregnancy; Respiratory Distress; Tachypnoea; Tremor Neonatal; White Blood Cell Count Decreased | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                     | Escitalopram Oxalate |              |            | S           | Transplacental | 5 Mg Transplacental     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                     | Nicotine             |              |            | C           |                |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-May-2007              | 6284566       | EXPEDITED (15-DAY) |                    | HO              | S07-CAN-01255-01     |                      | 96 YR      | Female     | CAN            |

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| <u>Preferred Term</u>                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cyanosis; Dysphonia;<br>Laryngospasm; Vocal<br>Cord Disorder | Cipralext                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Actonel                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Hyzaar                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Atenolol                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Asa (Acetylsalicylic Acid)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Calcium Chloride                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Ativan                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                                                  | 6324430                              | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-02026-01     |                      | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Terminal Insomnia                                            | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate                 |                    |                    | S               |                      | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate                 |                    |                    | S               |                      | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                              | Athymil (Mianserin<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                              | Clonazepam                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                                                  | 6325383                              | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-02030-01     |                      | 28 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Asthenia; Iron<br>Deficiency;<br>Menometrorrhagia   | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                                                  | 6325684                              | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-01984-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide                               | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-May-2007                              | 6326392                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01955-01                         |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gallbladder Disorder;<br>Pancreatitis    | Lexapro                              |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Lexapro                              |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Lexapro                              |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported |                |
|                                          | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2007                              | 6328784                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02053-01                         |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Discomfort;<br>Syncope       | Lexapro                              |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                          | Remicade                             |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2007                              | 6317907                              | EXPEDITED (15-DAY) | Y                  | OT              | BE-PFIZER INC-2007038432                 |                      |                 | Male         | BEL            |
| <u>Preferred Term</u>                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Irritability; Mania | Champix                              |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                          | Escitalopram Oxalate                 |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2007                              | 6318605                              | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-13788740 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose                      | Escitalopram Oxalate                 |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                          | Unspecified Ingredient               |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                          | Placebo                              |                    |                    | S               |                                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-May-2007                                                                                                                                                                         | 6322250                                   | DIRECT             | N                  | DS, RI          |                      |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Derealisation; Economic Problem; Fear; Flushing; Headache; Insomnia; Loss Of Employment; Nausea; Nervousness; Paraesthesia; Partner Stress; Psychomotor Hyperactivity; Restlessness | Lexapro                                   |                    |                    | S               | Oral                 | 10mg. Once A Day Po  | 1 DAY           | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2007                                                                                                                                                                         | 6328512                                   | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02046-01     |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia; Thrombocytopenia                                                                                                                                                       | Lexapro                                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2007                                                                                                                                                                         | 6330908                                   | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01647        |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Food Poisoning; Hyperemesis Gravidarum; Maternal Exposure During Pregnancy; Nausea; Pregnancy; Suppressed Lactation                                               | Lexapro                                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                     | Guaifenesin\Pseudoephedrine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Tums (Calcium Carbonate)                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                     | Zantac                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2007                                                                                                                                                                         | 6324084                                   | DIRECT             | N                  | OT              |                      |                      | 25 YR           | Male         | USA            |



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| <u>Preferred Term</u>                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Affect Liability; Confusional State; Drug Withdrawal Syndrome; Influenza; Mental Disorder; Seizure; Suicidal Ideation | Lexapro                    |                    |                    | S               | Oral                 | 20mn 1 Per Day Po    |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2007                                                                                                           | 6205486                    | EXPEDITED (15-DAY) | Y                  | OT              |                      | S06-GER-04879-01     | 33 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Convulsions; Dry Mouth; Electroencephalogram Abnormal; Fall; Loss Of Consciousness; Muscle Rigidity   | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                                       | Clonazepam                 |                    |                    | S               | Ophthalmic           | 6 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                       | Clonazepam                 |                    |                    | S               | Oral                 | 0.5 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                       | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 80 Mg Qd Po          |                 | Asta         |                |
|                                                                                                                       | Subutex                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2007                                                                                                           | 6293782                    | EXPEDITED (15-DAY) | Y                  | OT              |                      | S07-ITA-01364-01     | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Respiratory Disorder; Seizure; Speech Disorder; Swelling Face; Swollen Tongue                                         | Cipralext                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2007                                                                                                           | 6316206                    | EXPEDITED (15-DAY) | Y                  | HO              |                      | S06-GER-04667-01     | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Maternal Exposure During Pregnancy                                                                 | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Femigoa                    |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2007                                                                            | 6229489        | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-00232-01     |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Fall;<br>Nervous System Disorder;<br>Road Traffic Accident;<br>Syncope | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-May-2007                                                         | 6296228                                             | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01345-01     |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Decreased;<br>Dizziness; Fatigue; Mass;<br>Somnolence | Lexapro                                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                     | Humalog                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Lantus                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Fosamax                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Lisinopril And<br>Hydrochlorothiazide               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Synthroid                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Aspirin                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Tylenol Arthritis (Paracetamol)                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Neurontin                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Lipitor                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Lunesta                                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Clarinet                                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Betagen (Levobunolol<br>Hydrochloride)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Prednisone                                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Omega-3/Omega-6 Fish Oil                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Chondroitin Sulfate<br>(Bovine)\Glucosamine Sulfate |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Multivitamin (Nos)                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Zinc                                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Magnesium                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Calcium + D                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Biotin                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2007              | 6325413       | EXPEDITED (15-DAY) | Y                  | HO              | S07-AUT-02017-01     |                      | 71 YR      | Female     | AUT            |

| <u>Preferred Term</u>                                            | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder;<br>Overdose; Salivary<br>Hypersecretion | Cipralelex            |              |            | S           | Oral         | 50 Mg, Qd; Po      |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 40 Mg Qd; Po       |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 30 Mg Qd;Po        |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 20 Mg Qd;Po        |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 30 Mg Qd; Po       |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 40 Mg, Qd; Po      |                 | Not Reported |
|                                                                  | Cipralelex            |              |            | S           | Oral         | 10 Mg Qd; Po       |                 | Not Reported |
|                                                                  | Lithium Carbonate     |              |            | S           |              | 450 Mg Qd;         |                 | Not Reported |
|                                                                  | Lithium Carbonate     |              |            | S           |              | 675 Mg Daily;      |                 | Not Reported |
|                                                                  | Risperdal             |              |            | S           |              | 1 Mg; Qd;          |                 | Not Reported |
|                                                                  | Risperdal             |              |            | S           |              | 2 Mg Qd;           |                 | Not Reported |
|                                                                  | Edronax               |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Clonazepam            |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Cerebrosyl            |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2007              | 6328590       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-GER-02063-01     |                      | 18 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Drunk; Intentional<br>Overdose; Nausea;<br>Somnolence; Suicide<br>Attempt; Urine Alcohol<br>Test Positive; Vomiting | Cipralelex                     |              |            | S           | Oral         | 1 Tablet Once; Po  |                 | Not Reported |
|                                                                                                                             | Pantozol (Pantoprazole Sodium) |              |            | S           | Oral         | 1 Tablet Once; Po  |                 | Not Reported |
|                                                                                                                             | Lorazepam                      |              |            | S           | Oral         | 2 Tablet Once; Po  |                 | Not Reported |
|                                                                                                                             | Clonidine                      |              |            | S           | Oral         | 3 Tablet Once; Po  |                 | Not Reported |
|                                                                                                                             | Risperidone                    |              |            | S           | Oral         | 1 Tablet Once; Po  |                 | Not Reported |
|                                                                                                                             | Alcohol                        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| 30-May-2007                                             | 6326349              | DIRECT             | Y                  | RI              |                                          |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hallucination; Tremor             | Linezolid            |                    |                    | S               | Intravenous (not<br>otherwise specified) | Iv Q12h              |                 | Not Reported |                |
|                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                                     | Po Daily             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-May-2007                                             | 6330904              | EXPEDITED (15-DAY) | Y                  | DE              | 2007-159055-NL                           |                      | 75 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Skin<br>Laceration                   | Mirtazapine          |                    |                    | S               | Oral                                     | 45 Mg, Oral          | 20 DAY          | Not Reported |                |
|                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 35 Mg, Oral          | 7 WEEK          | Not Reported |                |
|                                                         | Bromazepam           |                    |                    | S               | Oral                                     | 30 Mg, Oral          | 19 WEEK         | Not Reported |                |
|                                                         | Cosaar Plus          |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                         | Pantoprazole Sodium  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                                         | Yeast Dried          |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2007                                             | 6323276              | EXPEDITED (15-DAY) |                    | HO, LT          | PHEH2007US07957                          |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Hypoxic-<br>Ischaemic<br>Encephalopathy | Ritalin              |                    |                    | S               |                                          |                      |                 | Novartis     |                |
|                                                         | Metadate Cd          |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                         | Lexapro              |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2007                                             | 6330902              | DIRECT             | N                  | DE              |                                          |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |            |   |                      |              |
|-------------------|------------|---|----------------------|--------------|
| Completed Suicide | Lexapro    | S | 1 Tablet Every Day   | Not Reported |
|                   | Clonazepam | S | 1 Tablet Twice A Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2007              | 6332730       | EXPEDITED (15-DAY) | Y                  |                 | S07-USA-02223-01     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Cholestasis; Induced<br>Labour; Maternal<br>Exposure During<br>Pregnancy; Pregnancy;<br>Premature Labour | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2007              | 6335357       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02223-02     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Caesarean Section;<br>Induced Labour; Jaundice<br>Neonatal; Maternal<br>Exposure During<br>Pregnancy; Premature<br>Baby | Lexapro        |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2007              | 6325574       | EXPEDITED (15-DAY) | N                  | HO              | A0653841A            |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Aggression; Agitation;    | Wellbutrin XI  |              |            | S           | Oral         | 300mg Per Day      | 33 DAY          | Glaxosmithkline |
| Alcoholism; Asthenia;     | Lexapro        |              |            | S           | Oral         | 10mg Per Day       | 40 DAY          | Not Reported    |
| Blood Pressure Increased; | Alcohol        |              |            | S           | Oral         |                    |                 | Not Reported    |
| Cardiac Murmur;           | Lotrel         |              |            | C           |              |                    |                 | Not Reported    |
| Decreased Appetite;       |                |              |            |             |              |                    |                 |                 |
| Dehydration; Depression;  |                |              |            |             |              |                    |                 |                 |
| Drug Screen Positive;     |                |              |            |             |              |                    |                 |                 |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Drug Withdrawal  
 Syndrome; Feeling Guilty;  
 Grandiosity; Hypophagia;  
 Impulsive Behaviour;  
 Insomnia; Irritability;  
 Mania; Suicidal Ideation;  
 Tachycardia; Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2007              | 6329395       | EXPEDITED (15-DAY) | Y                  | HO              | L07-ESP-01966-01     |                      | 44 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Dystonia;<br>Movement Disorder;<br>Muscle Contracture; Pain;<br>Torticollis | Escitalopram Oxalate |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2007              | 6325381       | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-02015-01     |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mechanical Urticaria  | Escitalopram Oxalate     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lorazepam                |              |            | C           |              |                    |                 | Not Reported |
|                       | Noctamide (Lormetazepam) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jun-2007              | 6328589       | EXPEDITED (15-DAY) | Y                  | HO              | S07-CAN-02084-01     |                      | 16 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Head Banging; Intentional<br>Self-Injury; Suicidal<br>Ideation | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                | Paxil          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2007              | 6289590       | EXPEDITED (15-DAY) | Y                  | HO              | S06-ISR-05456-01     |                      | 52 YR      | Male       | ISR            |

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| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Acute Myocardial Infarction; Coronary Artery Disease; Left Ventricular Dysfunction                                                                                                                                        | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2007                                                                                                                                                                                                               | 6299488                 | EXPEDITED (15-DAY) | Y                  | OT              | S07-JPN-01469-01     |                      | 32 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Potassium Decreased; Condition Aggravated; Decreased Appetite; Depressive Symptom; Diarrhoea; Insomnia; Nasopharyngitis; Protein Total Decreased | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Selbex (Teprenone)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Eve (Ibuprofen)         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2007                                                                                                                                                                                                               | 6329216                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWI-02134-01     |                      | 57 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                                                                                                                                                                               | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Ciprallex               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Ciprallex               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Risperdal               |                    |                    | S               | Oral                 | 2 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Risperdal               |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Dipiperon (Pipamperone) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                           | Glucophage              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Ibuprofen                                                                                                                                                                                                                 |                         |                    | C                  |                 |                      |                      | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-Jun-2007                                                                                                                                                                                            | 6337377              | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-02282-01     |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Pregnancy Of Partner                                                                                                                                                          | Lexapro              |                    |                    | S               |                      | 20 Mg Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2007                                                                                                                                                                                            | 6337387              | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02269-01     |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Cardiac Arrest; Ejection Fraction Decreased; Hypoxic-Ischaemic                                                                                                                            | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Encephalopathy; Left Ventricular Dysfunction; Loss Of Consciousness; Malaise; Oedema; Palpitations; Pericardial Effusion; Right Ventricular Dysfunction; Sinus Tachycardia; Tachycardia; Tongue Biting | Metadate Cd          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Ritalin              |                    |                    | S               |                      | 5 Mg Tid             |                 | Not Reported |                |
|                                                                                                                                                                                                        | Risperdal            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Melatonin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                        | Rozarem (Ramelteon)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jun-2007                                                                                                                                                                                            | 6337715              | EXPEDITED (15-DAY) | Y                  | OT              | S07-UKI-02386-01     |                      | 41 YR           | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Nail Disorder                                                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2007                                                                                                                                                                                            | 6108642              | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-02936-02     |                      | 24 YR           | Male         | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>Preferred Term</u>                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Asphyxia;<br>Completed Suicide;<br>Discomfort; Feeling<br>Abnormal; Nervousness;<br>Palpitations | Lexapro                                     |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2007                                                                                               | 6108644                                     | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-02936-01          |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound                                                                      | Lexapro                                     |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2007                                                                                               | 6330540                                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20070601540 |                      | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome;<br>Suicide Attempt                                               | Tramadol Hydrochloride And<br>Acetaminophen |                    |                    | S               | Oral                      |                      | 4 DAY           | Not Reported |                |
|                                                                                                           | Unspecified Ingredient                      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                           | Xanax                                       |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Voltaren                                    |                    |                    | C               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Escitalopram Oxalate                        |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2007                                                                                               | 6338282                                     | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02308-01          |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                   | Lexapro                                     |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2007                                                                                               | 6329256                                     | EXPEDITED (15-DAY) | Y                  | OT              | S07-SWI-02141-01          |                      | 56 YR           | Female       | CHE            |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Generalised Tonic-Clonic Seizure; Sedation; Somnolence                                                                                            | Cipralext                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Remeron                    |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2007                                                                                                                                       | 6331086                    | EXPEDITED (15-DAY) | Y                  | HO              | S07-AUT-02229-01     |                      | 21 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Antisocial Behaviour; Apathy; Extrapyramidal Disorder; Fatigue; Ill-Defined Disorder; Musculoskeletal Stiffness; Parkinsonism; Psychotic Disorder | Cipralext                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Cipralext                  |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                    |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                    |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                   | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 80 Mg Daily Po       |                 | Not Reported |                |
|                                                                                                                                                   | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                   | Oxazepam                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2007                                                                                                                                       | 6338755                    | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02405-01     |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure Before Pregnancy; Pregnancy; Seizure                                                                                            | Lexapro                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2007                                                                                                                                       | 6344747                    | DIRECT             | Y                  | HO              |                      |                      | 64 YR           | Male         | SWE            |

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| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Condition Aggravated;<br>Delusion; Fear;<br>Hallucination;<br>Hallucination, Auditory;<br>Loss Of Employment;<br>Major Depression;<br>Paranoia; Psychotic<br>Disorder | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg Od - Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Glimepiride          |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Quinapril            |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Carvedilol           |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        |                      |                    |                    |                 |                       |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jun-2007                                                                                                                                                                                                            | 6339809              | DIRECT             | N                  | DE              |                       |                      | 14 YR           | Male         | USA            |
|                                                                                                                                                                                                                        |                      |                    |                    |                 |                       |                      |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Completed Suicide;<br>Condition Aggravated;<br>Depression; Irritability;<br>Panic Attack                                                                                                     | Depakote             |                    |                    | S               | Oral                  | 2 A Day Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                  | 1 A Day Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                        |                      |                    |                    |                 |                       |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jun-2007                                                                                                                                                                                                            | 6317326              | EXPEDITED (15-DAY) | Y                  | OT              | CH-JNJFOC-20070503161 |                      | 45 YR           | Male         | CHE            |
|                                                                                                                                                                                                                        |                      |                    |                    |                 |                       |                      |                 |              |                |
| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Leukopenia; Neutropenia                                                                                                                                                                                                | Risperdal            |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Risperdal            |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Pipamperone          |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Pipamperone          |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                        | Glucophage           |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |              |
|------------|---|------|--------------|
| Glucophage | C | Oral | Not Reported |
| Glucophage | C | Oral | Not Reported |
| Ibuprofen  | C | Oral | Not Reported |
| Ibuprofen  | C | Oral | Not Reported |
| Ibuprofen  | C | Oral | Not Reported |
| Ibuprofen  | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 14-Jun-2007              | 6331884             | EXPEDITED (15-DAY) | Y                  | DE              | S07-SWI-02228-01     |                      |                 | Male                         | CHE            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide        | Ciprallex<br>Zoloft |                    |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2007                                                      | 6339367        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02339-01     |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased;<br>White Blood Cell Count<br>Decreased | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jun-2007                            | 6339391        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02466-01     |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Homicidal Ideation | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 14-Jun-2007              | 6340572        | EXPEDITED (15-DAY) | Y                  | OT              | S07-CAN-02503-01     |                      | 37 YR           | Female     | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |           |   |      |             |              |
|-------------------------------------------------------------------------------|-----------|---|------|-------------|--------------|
| Choking;<br>Depersonalisation/Derealisation Disorder; Salivary Hypersecretion | Ciprallex | S | Oral | 10 Mg Qd Po | Not Reported |
|-------------------------------------------------------------------------------|-----------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2007              | 6340577       | EXPEDITED (15-DAY) | Y                  | DE              | S07-CAN-02490-01     |                      | 44 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Completed Suicide; Impulsive Behaviour; Insomnia | Ciprallex           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                             | Imovane (Zopiclone) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2007              | 6626006       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02491-01     |                      | 62 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug Screen Positive; Serotonin Syndrome | Escitalopram Oxalate                     |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Tramadol Hydrochloride And Acetaminophen |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Xanax                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Voltaren                                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2007              | 6306415       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-01141-01     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Decreased Appetite; Disturbance In Attention; Dizziness; Drug Withdrawal Syndrome; Emotional Disorder; Heart Rate Increased; Increased Appetite; Libido Decreased; Palpitations; Paraesthesia; Tremor; Weight Increased | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qod Po        |                 | Not Reported |
|                                                                                                                                                                                                                                   | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                                                                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                     |                |                    |                    |                 |                          |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Lexapro Oral Solution<br>(Escitalopram)                                                                             |                |                    | C                  |                 |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2007                                                                                                         | 6325710        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02005-01         |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Self-Medication; Suicide Attempt                                                                  | Lexapro        |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2007                                                                                                         | 7385679        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2007046318 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Bipolar Disorder; Disorientation; Emotional Distress; Hallucination; Movement Disorder; Nausea; Overdose | Zoloft         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Chantix        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Lexapro        |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Prempro        |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Vitamins Nos   |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2007                                                                                                         | 6336833        | EXPEDITED (15-DAY) | Y                  | LT              | S07-NLD-02414-01         |                      | 35 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dystonia; Facial Paresis; Sinusitis                                                                     | Lexapro        |                    |                    | S               | Oral                     | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2007                                                                                                         | 6339403        | DIRECT             |                    |                 |                          |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error; Product Dispensing Error                                                                          | Lexapro        |                    |                    | S               |                          | Tablet               |                 | Forest       |                |
|                                                                                                                     | Lexapro        |                    |                    | S               |                          | Tablet               |                 | Forest       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 18-Jun-2007                                                                                                                                                                                                                                                                 | 6343653                            | EXPEDITED (15-DAY) | Y                  | HO              | 6034371              |                                           | 78 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Asthenia;<br>Dilatation Atrial; General<br>Physical Health<br>Deterioration;<br>Hypervolaemia;<br>Hypochloraemia;<br>Hypokalaemia;<br>Hyponatraemia;<br>Hypovolaemia; Mitral<br>Valve Incompetence;<br>Myocardial Strain;<br>Nausea; Orthostatic<br>Intolerance | Bisoprolol Fumarate                |                    |                    | S               | Oral                 | 12, 5000 Mg (12, 5 Mg, 1<br>In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Toraseam                           |                    |                    | S               | Oral                 | 5,00 Mg (5 Mg, 1 In 1 D),<br>Oral         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Indapamide\Perindopril<br>Erbumine |                    |                    | S               | Oral                 | 0,6250 Mg (0, 625 Mg, 1<br>In 1 D), Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Cipralelex                         |                    |                    | S               | Oral                 | Oral                                      | 2 DAY           | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Metamucil                          |                    |                    | C               |                      |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jun-2007                                                                                                                                                                                                                                                                 | 6325370                            | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWI-02038-01     |                                           | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Akinesia; C-Reactive<br>Protein Increased; Chills;<br>Extrapyramidal Disorder;<br>Facial Paralysis; Loss Of<br>Consciousness; Product<br>Prescribing Error                                                                                                                  | Cipralelex                         |                    |                    | S               | Oral                 | 10 Mg Qd Po                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Seroquel                           |                    |                    | S               | Oral                 | 25 Mg Qd Po                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Trittico (Trazodone)               |                    |                    | S               | Oral                 | 100 Mg Qd Po                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Risperdal                          |                    |                    | S               | Oral                 | 2 Mg Tid Po                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Zolpidem Tartrate                  |                    |                    | C               |                      |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2007                                                                                                                                                                                                                                                                 | 6303484                            | EXPEDITED (15-DAY) | Y                  | HO              | S07-ISR-01602-01     |                                           | 31 YR           | Female       | ISR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Delusion; Psychotic                                                                                                                                                                                                                             | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 20 Mg Qd Po                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                             | Risperdal                          |                    |                    | C               |                      |                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                                   |   |              |
|----------|-----------------------------------|---|--------------|
| Disorder | Fluphenazine Decanoate            | C | Not Reported |
|          | Dekinet (Biperiden Hydrochloride) | C | Not Reported |
|          | Glucopahge (Metformin)            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2007              | 6347170       | DIRECT           | Y                  | HO              |                      |                      | 64 YR      | Male       | SWE            |

| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Delusion; Economic<br>Problem; Fear;<br>Hallucination;<br>Hallucination, Auditory;<br>Major Depression;<br>Paranoia; Psychotic<br>Disorder; Unemployment | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Od - Oral    |                 | Not Reported |
|                                                                                                                                                                                                           | Glimepiride          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                           | Quinapril            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                           | Carvedilol           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2007              | 6347705       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-02540-01     |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Screen False<br>Positive; Impaired Driving<br>Ability; Legal Problem;<br>Loss Of Employment | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2007              | 5930133       | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | S05-BEL-04979-01     |                      | 60 YR      | Female     | LUX            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Carotid<br>Artery Occlusion; Carotid<br>Artery Stenosis;<br>Hemiparesis;<br>Hypertension; Ischaemic | Escitalopram Oxalate         |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                  | Enoxaparin Sodium            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Rosuvastatine (Rosuvastatin) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Pantoprazole Sodium          |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                   |   |              |
|-----------------------------------------------------------------|-------------------|---|--------------|
| Cerebral Infarction;<br>Malaise; Respiratory<br>Arrest; Syncope | Enoxaparin Sodium | C | Not Reported |
|-----------------------------------------------------------------|-------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Jun-2007              | 6340604       | EXPEDITED (15-DAY) |                    | HO              | US-ROXANE<br>LABORATORIES, INC-<br>2007-DE-03406GD |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Mirtazapine                   |              |            | S           |              |                    | 3 DAY           | Not Reported |
|                       | Trazodone Hydrochloride       |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamotrigine                   |              |            | S           |              |                    |                 | Not Reported |
|                       | Venlafaxine Hydrochloride     |              |            | S           |              |                    |                 | Not Reported |
|                       | Gabapentin                    |              |            | S           |              |                    | 3 DAY           | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           |              |                    | 2 DAY           | Not Reported |
|                       | Methylphenidate Hydrochloride |              |            | S           |              |                    | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2007              | 6347957       | EXPEDITED (15-DAY) | N                  | CA              | S07-USA-02549-02     |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Congenital Anomaly;<br>Intellectual Disability;<br>Maternal Exposure During<br>Pregnancy | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                          | Oxycodone      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jun-2007              | 6348252       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02579-01     |                      | 63 YR      | Male       | FRA            |

| <u>Preferred Term</u>                              | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Nervous<br>System Disorder; Seizure | Escitalopram Oxalate              |              |            | S           | Oral         | Tablet Unk Po      |                 | Not Reported |
|                                                    | Gemzar                            |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Taxol                             |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Tareg                             |              |            | C           |              |                    |                 | Not Reported |
|                                                    | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 25-Jun-2007                                                                                  | 6350070                                | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02568-01     |                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen Positive;<br>Road Traffic Accident                                               | Lexapro                                |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2007                                                                                  | 6348323                                | DIRECT             | N                  | LT              |                      |                              | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Myocardial<br>Infarction; Nervousness                                               | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg 1 Tablet Per Day<br>Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2007                                                                                  | 6349960                                | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02521-01     |                              |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinson'S Disease                                                                          | Lexapro                                |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                              | Welbutrin (Bupropion<br>Hydrochloride) |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2007                                                                                  | 6329303                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02164-01     |                              | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Asthenia; Blood<br>Calcium Decreased; Blood<br>Chloride Decreased;                  | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 0.5 Units Qd Po              |                 | Not Reported |                |
| Blood Pressure Increased;<br>Body Temperature<br>Decreased; C-Reactive<br>Protein Increased; | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 1.5 Units Qd Po              |                 | Not Reported |                |
| Creatinine Renal                                                                             | Lexomil (Bromazepam)                   |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                              | Fludex (Indapamide)                    |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                              | Ossopan (Durapatite)                   |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                              | Teveten                                |                    |                    | C               |                      |                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clearance Decreased;  
Dyskinesia; Fall;  
Hyponatraemia; Loss Of  
Consciousness;  
Medication Error; Urine  
Potassium Decreased;  
Urine Sodium Decreased

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
|---------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------------|----------------|
| 27-Jun-2007                                                                                 | 6336378                | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02359-01     |                          | 76 YR           | Female             | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>         |                |
| Amnesia; Confusional<br>State; Hyponatraemia;<br>Loss Of Consciousness;<br>Malaise; Seizure | Escitalopram Oxalate   |                    |                    | S               |                      |                          |                 | Not Reported       |                |
|                                                                                             | Atenolol               |                    |                    | S               |                      |                          |                 | Not Reported       |                |
|                                                                                             | Lormetazepam           |                    |                    | S               | Oral                 | 2 Mg Qd Po               |                 | Not Reported       |                |
|                                                                                             | Amlodipine Besylate    |                    |                    | C               |                      |                          |                 | Not Reported       |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
| 28-Jun-2007                                                                                 | 6314050                | EXPEDITED (15-DAY) | Y                  | CA              | S06-USA-05333-02     |                          | < 1 DAY         | Male               | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>         |                |
| Atrioventricular Septal<br>Defect; Maternal Exposure<br>During Pregnancy;<br>Trisomy 21     | Lexapro                |                    |                    | S               | Transplacental       | 10 Mg Qd; Transplacental |                 | Not Reported       |                |
|                                                                                             | Prenatal Vitamin (Nos) |                    |                    | C               |                      |                          |                 | Not Reported       |                |
|                                                                                             | Levoxyl                |                    |                    | C               |                      |                          |                 | Not Reported       |                |
|                                                                                             | Rhogam                 |                    |                    | C               |                      |                          |                 | Not Reported       |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>         | <u>Country</u> |
| 28-Jun-2007                                                                                 | 6343828                | EXPEDITED (15-DAY) | N                  | OT              | HQWYE696119JUN07     |                          | 42 YR           | Female             | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>         |                |
| Dyspnoea;<br>Hypersensitivity;<br>Pharyngeal Oedema;<br>Swelling Face                       | Advil                  |                    |                    | S               | Unknown              | Unknown                  |                 | Wyeth              |                |
|                                                                                             | Aleve                  |                    |                    | S               | Unknown              | Unknown                  |                 | Procter And Gamble |                |
|                                                                                             | Lexapro                |                    |                    | S               | Oral                 |                          |                 | Not Reported       |                |
|                                                                                             | Lexapro                |                    |                    | S               |                      |                          |                 | Not Reported       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 28-Jun-2007                                                                                                                    | 6351767                                                       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02714-01     |                      | 16 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Chest Pain; Dizziness;<br>Dyspnoea; Headache;<br>Nausea; Psychotic<br>Disorder; Throat Tightness                               | Lexapro<br>Ambien                                             |                    |                    | S<br>C          | Oral                 | 10 Mg Once Po        |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Jun-2007                                                                                                                    | 6353024                                                       | DIRECT             | N                  | OT              |                      |                      | 47 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Depression;<br>Dissociation; Disturbance<br>In Attention; Feeling<br>Abnormal; Impaired Work<br>Ability; Paraesthesia | Lexapro                                                       |                    |                    | S               |                      | 5 Mg 1 Time Daily    |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-Jul-2007                                                                                                                    | 6340974                                                       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02492-01     |                      |                 | Male                         | FRA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hepatitis                                                                                                                      | Escitalopram Oxalate<br>Anticoagulant Cit Pros Dex<br>Adenine |                    |                    | S<br>C          | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-Jul-2007                                                                                                                    | 6354618                                                       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-02674-01     |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dehydration; Drug<br>Interaction; Nausea;<br>Retching                                                                          | Lexapro<br>Nicotrol                                           |                    |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Jul-2007                                                                                                                                               | 6320314        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01860-01     |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Condition Aggravated;<br>Depression; Gun Shot<br>Wound; Intentional Self-<br>Injury                                                 | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Cymbalta       |                    |                    | S               | Oral                 | 60 Mg Po             |                 | Not Reported |                |
|                                                                                                                                                           | Effexor        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Xanax          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Effexor        |                    |                    | S               |                      | 300 Mg Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2007                                                                                                                                               | 6328580        | EXPEDITED (15-DAY) | Y                  | OT              | S07-NLD-02014-01     |                      | 22 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature<br>Increased; Dizziness;<br>Feeling Abnormal;<br>Gastrointestinal<br>Haemorrhage;<br>Hyperhidrosis; Nausea;<br>Tremor; Visual Impairment | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Ibuprofen      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Vitamins Nos   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jul-2007                                                                                                                                               | 6332754        | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02306-01     |                      | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Emotional<br>Distress; Fatigue; Malaise;<br>Seizure; Stress                                                                                      | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Ibuprofen      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2007                                                                                                                                               | 6127072        | EXPEDITED (15-DAY) | Y                  | OT              | S06-UKI-03379-01     |                      | 43 YR           | Female       | GBR            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Glossodynia                                                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2007                                                            | 6325378              | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01919-01     |                      | 48 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose;<br>Thrombophlebitis                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Lorazepam            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Imovane (Zopiclone)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Lovenox              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2007                                                            | 6331550              | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02226-01     |                      | 33 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention; Urinary<br>Tract Disorder                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                        | Tranxene T-Tab       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Trileptal            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Lexomil (Bromazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Polyethylene Glycols |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                        | Daflon (Diosmin)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2007                                                            | 6357638              | EXPEDITED (15-DAY) | N                  | DE              | S07-USA-02804-01     |                      | 74 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Asphyxia; Completed<br>Suicide; Depressed Mood; | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hostility

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2007                | 6357643        | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-02764-01     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                            | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2007                                                    | 6357645                 | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-02819-01     |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Dehydration; Urinary Tract Infection | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd; Po         |                 | Not Reported |                |
|                                                                | Namenda                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Aricept                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Fosamax                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Flecainide              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                | Trazodone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jul-2007                 | 6357647        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02772-01     |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence; Seizure | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Jul-2007                                                    | 6352986              | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02699-01     |                      | 75 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Fatigue; Inappropriate Antidiuretic Hormone | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
|                                                                | Motilium             |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Secretion; Nausea

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6330702       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02090-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>                                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Blood Sodium Decreased;<br>Breech Presentation;<br>Caesarean Section; Eating<br>Disorder; Insomnia;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Premature Labour;<br>Vomiting | Lexapro<br>Prenatal Vitamins (Nos)<br>Ambien<br>Fioricet<br>(Butalbital/Acetaminophen/Caffeine) |              |            | S<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6330735       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02090-02     |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>                                                   |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------|------------|------------------|----------------|-------------------------|-----------------|--------------------------------------------------------------|
| Apgar Score Low; Breech<br>Presentation; Caesarean<br>Section; Maternal<br>Exposure During<br>Pregnancy; Premature<br>Baby | Lexapro<br>Prenatal Vitamin (Nos)<br>Ambien<br>Fioricet<br>(Butalbital/Acetaminophen/Caffeine) |              |            | S<br>C<br>C<br>C | Transplacental | 10 Mg Qd Transplacental |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6348438       | EXPEDITED (15-DAY) | N                  | HO, OT          | B0477468A            |                      | 50 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------|------------|------------------|------------------------------|--------------------|-----------------|-----------------------------------------------------------------|
| Depressed Level Of<br>Consciousness;<br>Electrocardiogram Qt<br>Prolonged; Intentional<br>Overdose; Myoclonus;<br>Pneumonia; Pyrexia; | Lamotrigine<br>Escitalopram Oxalate<br>Olanzapine<br>Zopiclone |              |            | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral |                    |                 | Glaxosmithkline<br>Not Reported<br>Not Reported<br>Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Serotonin Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6353210       | EXPEDITED (15-DAY) | Y                  | OT              | US-ROCHE-504894      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Brain Neoplasm;<br>Dizziness; Drug<br>Ineffective; Drug<br>Intolerance; Fall | Valium                 |              |            | S           | Unknown      |                               | 3 MTH           | Roche        |
|                                                                                                        | Klonopin               |              |            | S           | Unknown      |                               |                 | Roche        |
|                                                                                                        | Diazepam               |              |            | S           | Unknown      |                               |                 | Roche        |
|                                                                                                        | Lexapro                |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Cymbalta               |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Geodon                 |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Ativan                 |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Xanax                  |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Zoloft                 |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Zonisamide             |              |            | S           | Unknown      |                               |                 | Not Reported |
|                                                                                                        | Zonisamide             |              |            | S           | Unknown      | Dose Adjusted                 |                 | Not Reported |
|                                                                                                        | Lipitor                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                        | Prozac                 |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                        | Unspecified Ingredient |              |            | C           |              | Reported As "Pain Medication" |                 | Not Reported |
|                                                                                                        | Lopresor               |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6354335       | EXPEDITED (15-DAY) | Y                  | HO              | 163-20785-07060907   |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|---------------------------------------|----------------------|-----------------|--------------|
| Cerebral Ischaemia; Chest Pain; Colitis; Device Related Infection; Febrile Neutropenia; Haemoglobin Decreased; Hypersomnia; Hypotension; Muscular | Thalomid                      |              |            | S           | Oral                                  | 100 Mg, Qd; Oral     |                 | Not Reported |
|                                                                                                                                                   | Dexamethasone (Dexamethasone) |              |            | S           | Oral                                  | 40 Mg, Oral          |                 | Not Reported |
|                                                                                                                                                   | Velcade                       |              |            | S           | Intravenous (not otherwise specified) | 1 Mg/M2; Intravenous |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                         |                                     |   |                                       |                        |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---|---------------------------------------|------------------------|--------------|
| Weakness; Nuclear Magnetic Resonance Imaging Brain Abnormal; Parainfluenzae Virus Infection; Pneumonia; Sinusitis; Streptococcal Infection; Tachycardia | Cisplatin                           | S | Intravenous (not otherwise specified) | 10 Mg/M2, Intravenous  | Not Reported |
|                                                                                                                                                         | Adriamycin                          | S | Intravenous (not otherwise specified) | 10 Mg/M2, Intravenous  | Not Reported |
|                                                                                                                                                         | Cyclophosphamide (Cyclophosphamide) | S | Intravenous (not otherwise specified) | 400 Mg/M2; Intravenous | Not Reported |
|                                                                                                                                                         | Etoposide (Etoposide)               | S | Intravenous (not otherwise specified) | 40 Mg/M2, Intravenous  | Not Reported |
|                                                                                                                                                         | Melphalan                           | S |                                       | 200 Mg/M2;             | Not Reported |
|                                                                                                                                                         | Ambien                              | S | Oral                                  | 5 Mg, Qhs; Oral        | Not Reported |
|                                                                                                                                                         | Lexapro                             | S | Oral                                  | 20 Mg, Oral            | Not Reported |
|                                                                                                                                                         | Acyclovir                           | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Folic Acid                          | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Levaquin                            | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Famotidine (Famotidine)             | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Heparin                             | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Flagyl                              | C |                                       |                        | Not Reported |
|                                                                                                                                                         | Imodium                             | C |                                       |                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6359568       | EXPEDITED (15-DAY) | Y                  | DE              | S07-NOR-02886-01     |                      | 51 YR      | Male       | NOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Cipraxel       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6359748       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-02775-01     |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gamma-Glutamyltransferase Increased; Road Traffic Accident; Transaminases Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                     | Prazepam             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                     | Zolpidem Tartrate    |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6366585       | EXPEDITED (15-DAY) | N                  | DE, HO          | 2007SI001632         |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Completed Suicide;<br>Cystitis; Decreased<br>Appetite; Dyspnoea; Ear<br>Discomfort; Ear<br>Haemorrhage; General<br>Physical Health<br>Deterioration;<br>Hypoaesthesia; Injury;<br>Insomnia; Intervertebral<br>Disc Degeneration;<br>Lethargy; Musculoskeletal<br>Stiffness; Nervousness;<br>Paraesthesia;<br>Restlessness; Throat<br>Irritation | Diazepam       |              |            | S           | Oral         | 5 Mg; 3 Times A Day; Oral      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                        | Lexapro        |              |            | S           | Oral         | Oral                           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                        | Paxil          |              |            | S           | Oral         | See Image                      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                        | Risperdal      |              |            | S           | Oral         | 0.5 Mg; 3 Times A Day;<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                        | Paxil Cr       |              |            | S           | Oral         | See Image                      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                        | Gabapentin     |              |            | S           | Oral         | 300 Mg; At Bedtime; Oral       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jul-2007              | 6381123       | NON-EXPEDITED    | Y                  | HO              | US-2006-033668       |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------------------------|
| Foot Fracture; Pulmonary<br>Embolism | Yasmin               |              |            | S           | Oral         | 1 Tab(S), 1x/Day, Oral |                 | Not Reported                 |
|                                      | Lexapro              |              |            | S           | Oral         | See Image              |                 | Not Reported                 |
|                                      |                      |              |            |             | Oral         | See Image              |                 |                              |
|                                      | Abilify<br>Carbatrol |              |            | C<br>C      |              |                        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2007              | 6317210       | EXPEDITED (15-DAY) | Y                  | DS, OT          | S07-UKI-01809-01     |                      | 32 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                               |                                                                |                       |      |              |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------|------|--------------|--------------|
| Agitation; Anxiety; Balance Disorder; Dysarthria; Euphoric Mood; Hallucination; Muscle Twitching; Self-Injurious Ideation; Suicidal Ideation; Suicide Attempt | Cipralex<br>Propranolol<br>Zopiclone<br>Diazepam<br>Citalopram | S<br>C<br>C<br>C<br>C | Oral | 10 Mg Qd; Po | Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------|------|--------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2007              | 6356495       | EXPEDITED (15-DAY) | Y                  | LT              | GB-AVENTIS-200713346EU |                      | 56 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Hypotension; Intentional Overdose; Somnolence | Frusemide              |              |            | S           |              |                    |                 | Aventis      |
|                                                            | Bisoprolol             |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Amlodipine             |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Gtn Spray              |              |            | C           |              | Dose: 1-2 Puffs    |                 | Not Reported |
|                                                            | Nicorandil             |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Bendroflumethiazide    |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Ibersartan             |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Isosorbide Mononitrate |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Betahistine            |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Gabapentin             |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Dipyridamole Mr        |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Aspirin                |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Thiamine               |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Ranitidine             |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Rosuvastatin           |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Insulin Aspart         |              |            | C           |              | Dose: 58/28        |                 | Not Reported |
|                                                            | Hydralazine            |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Clopidogrel            |              |            | C           |              |                    |                 | Not Reported |
|                                                            | Zopiclone              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2007              | 6389181       | NON-EXPEDITED    | N                  |                 | 2007SP001372         |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |         |   |      |               |              |
|----------|---------|---|------|---------------|--------------|
| Insomnia | Lunesta | S | Oral | 2 Mg;Hs;Oral  | Not Reported |
|          | Lexapro | S | Oral | 10 Mg;Qd;Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2007              | 6329276       | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-02132-01     |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness Transient; Eye Haemorrhage | Escitalopram Oxalate |              |            | S           |              | 20 Mg Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2007              | 6353939       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02700-01     |                      | 55 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                           | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|-------------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Acute Generalised Exanthematous Pustulosis; Toxic Skin Eruption | Escitalopram Oxalate          |              |            | S           | Oral          | 10 Mg Bid Po       |                 | Not Reported |
|                                                                 | Loxapac (Loxapine Succinate)  |              |            | S           | Oral          | 50 Mg Qd Po        |                 | Not Reported |
|                                                                 | Loxapac (Loxapine Succinate)  |              |            | S           | Oral          | 100 Mg Qd Po       |                 | Not Reported |
|                                                                 | Loxapac (Loxapine Succinate)  |              |            | S           | Oral          | 150mg Qd Po        |                 | Not Reported |
|                                                                 | Loxapac (Loxapine Succinate)  |              |            | S           | Intramuscular | 100 Mg Qd Im       |                 | Not Reported |
|                                                                 | Trihexyphenidyl Hydrochloride |              |            | S           | Oral          | 5 Mg Bid Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2007              | 6361743       | DIRECT           | Y                  | CA              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autism Spectrum Disorder; Cleft Lip And Palate; Congenital Anomaly; Maternal Exposure During Pregnancy | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jul-2007                                                                                                                                                                  | 6366019                            | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-02902-01     |                      | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Blood Glucose Increased; Blood Potassium Decreased; Blood Pressure Increased; Dehydration; Hypophagia; Inappropriate Antidiuretic Hormone Secretion; Pain           | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                              | Lisinopril And Hydrochlorothiazide |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                              | Metoprolol                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                              | Glyburide                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                              | Ativan                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jul-2007                                                                                                                                                                  | 6366036                            | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-02997-01     |                      | 68 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                                                                                                                                                                 | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
|                                                                                                                                                                              | Sertraline                         |                    |                    | S               | Oral                 | 150 Mg Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                              | Clozapine                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                              | Valproate Sodium                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2007                                                                                                                                                                  | 6346699                            | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | L07-CAN-02608-01     |                      | 29 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Eye Pain; Insomnia; Intentional Overdose; Photophobia; Photosensitivity Reaction; Suicidal Ideation; Tearfulness; Vision Blurred; Visual Acuity Reduced | Cipralext                          |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                              | Cipralext                          |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                              | Zopiclone                          |                    |                    | S               | Oral                 | 7.5 Mg Qhs Po        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jul-2007                                                                     | 6367232                   | EXPEDITED (15-DAY) | Y                  | DS              | S07-NLD-03066-01                      |                      | 32 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Muscle Rigidity; Muscular Weakness; Pain In Extremity | Lexapro                   |                    |                    | S               | Oral                                  | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Lexapro                   |                    |                    | S               | Oral                                  | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                 | Lexapro                   |                    |                    | S               | Oral                                  | 5 Mg Qod Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2007                                                                     | 6374590                   | EXPEDITED (15-DAY) | Y                  | CA              | S07-USA-03018-02                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fallot'S Tetralogy; Maternal Exposure During Pregnancy                          | Lexapro                   |                    |                    | S               | Transdermal                           | 30 Mg Qd Transdermal |                 | Not Reported |                |
|                                                                                 | Risperdal                 |                    |                    | C               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2007                                                                     | 7021337                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20070703871                 |                      | 86 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Fall                                                  | Tavanic                   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                 | Zyprexa                   |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                 | Alprazolam                |                    |                    | S               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                 | Tropatepine Hydrochloride |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported |                |
|                                                                                 | Tramadol Hydrochloride    |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                                                                                 | Furosemide                |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                 | Forlax                    |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |
|                                                                                 | Paracetamol               |                    |                    | C               | Unknown                               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|-------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|-----------------|----------------|
| 25-Jul-2007              | 6306621           | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01615-01                      |                      | 15 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dehydration;             | Lexapro           |                    |                    | S               | Oral                                  | 5 Mg Qd Po           |                 | Not Reported    |                |
| Electroencephalogram     | Lexapro           |                    |                    | S               | Oral                                  | 5 Mg Qd Po           |                 | Not Reported    |                |
| Abnormal; Loss Of        | Lexapro           |                    |                    | S               | Oral                                  | 10 Mg Qd Po          |                 | Not Reported    |                |
| Consciousness; Petit Mal |                   |                    |                    |                 |                                       |                      |                 |                 |                |
| Epilepsy; Tremor         |                   |                    |                    |                 |                                       |                      |                 |                 |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Jul-2007              | 6309848           | EXPEDITED (15-DAY) | Y                  | HO              | B0470111A                             |                      | 71 YR           | Female          | AUT            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Extrapyramidal Disorder; | Lithium Carbonate |                    |                    | S               | Oral                                  |                      |                 | Glaxosmithkline |                |
| Mobility Decreased       | Risperdal         |                    |                    | S               | Oral                                  |                      | 25 DAY          | Not Reported    |                |
|                          | Cipralext         |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Aricept           |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Abilify           |                    |                    | C               | Oral                                  | 5mg Per Day          |                 | Not Reported    |                |
|                          | Cymbalta          |                    |                    | C               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Edronax           |                    |                    | C               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Rivotril          |                    |                    | C               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Cerebrolysin      |                    |                    | C               | Intravenous (not otherwise specified) | 1amp Per Day         | 10 DAY          | Not Reported    |                |
|                          | Nexium            |                    |                    | C               | Oral                                  | 20mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u> | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Jul-2007              | 6310402           | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-01719-01                      |                      | 59 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Asthenia; Dizziness;     | Lexapro           |                    |                    | S               | Oral                                  | 20 Mg Qd; Po         |                 | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |                     |   |      |               |              |
|-----------------------|---------------------|---|------|---------------|--------------|
| Hyperhidrosis;        | Lexapro             | S | Oral | 20 Mg, Qd; Po | Not Reported |
| Musculoskeletal Pain; | Protonix            | C |      |               | Not Reported |
| Pain; Splenic         | Synthroid           | C |      |               | Not Reported |
| Haemorrhage           | Benicar             | C |      |               | Not Reported |
|                       | Multivitamin (Nos)  | C |      |               | Not Reported |
|                       | Calcium + Vitamin D | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2007              | 6349822       | EXPEDITED (15-DAY) | Y                  | HO              | B0477676A            |                      | 71 YR      | Female     | AUT            |

| <u>Preferred Term</u>      | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------|-------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|-----------------|
| Drug Interaction;          | Lithium Carbonate |              |            | S           | Oral                                  |                    |                 | Glaxosmithkline |
| Dysstasia; Eating          | Cipralex          |              |            | S           | Oral                                  |                    |                 | Not Reported    |
| Disorder; Extrapramidal    | Nexium            |              |            | S           | Oral                                  | 20mg Per Day       |                 | Not Reported    |
| Disorder; Gait             | Risperdal         |              |            | S           | Oral                                  |                    |                 | Not Reported    |
| Disturbance; Loss Of       | Aricept           |              |            | S           | Oral                                  | 5mg Per Day        | 11 DAY          | Not Reported    |
| Personal Independence In   | Rivotril          |              |            | C           | Oral                                  | 1mg Per Day        |                 | Not Reported    |
| Daily Activities; Mobility | Rivotril          |              |            | C           | Oral                                  | 1.5mg Per Day      | 6 DAY           | Not Reported    |
| Decreased;                 | Rivotril          |              |            | C           | Oral                                  | 1.25mg Per Day     |                 | Not Reported    |
| Musculoskeletal Stiffness; | Rivotril          |              |            | C           | Oral                                  | 1mg Per Day        | 6 DAY           | Not Reported    |
| Parkinsonism; Salivary     | Rivotril          |              |            | C           | Oral                                  |                    |                 | Not Reported    |
| Hypersecretion             | Abilify           |              |            | C           | Oral                                  | 5mg Per Day        |                 | Not Reported    |
|                            | Cymbalta          |              |            | C           | Oral                                  |                    |                 | Not Reported    |
|                            | Edronax           |              |            | C           | Oral                                  |                    |                 | Not Reported    |
|                            | Cerebrolysin      |              |            | C           | Intravenous (not otherwise specified) | 1amp Per Day       | 10 DAY          | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2007              | 6369579       | EXPEDITED (15-DAY) | N                  | DE              | S07-USA-03081-01     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                          |         |   |      |             |              |
|----------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Completed Suicide;<br>Depressed Mood;<br>Depression; Drowning;<br>Drug Ineffective; Suicidal<br>Ideation | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|----------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2007              | 6371132       | EXPEDITED (15-DAY) | Y                  | OT              | S07-SWI-03109-01     |                      | 38 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia           | Cipralext       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Levomepromazine |              |            | S           | Oral         | 12 Drops Qd Po     |                 | Not Reported |
|                       | Valproic Acid   |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2007              | 6371140       | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-03110-01     |                      |            | Female     | IRL            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Self-Injurious Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2007              | 6329218       | EXPEDITED (15-DAY) | Y                  | DS, HO, LT      | S07-ITA-02143-01     |                      | 80 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Fall;<br>Haematoma; Humerus<br>Fracture; Hyponatraemia;<br>Loss Of Consciousness | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2007              | 6349416       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02663-01     |                      | 40 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                      |   |      |             |              |
|-----------------------------------|----------------------|---|------|-------------|--------------|
| Loss Of Consciousness;<br>Seizure | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|-----------------------------------|----------------------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2007              | 6303336       | EXPEDITED (15-DAY) | Y                  | DE              | S07-GER-01407-01     |                      | 75 YR      | Male       | DEU            |

  

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Fall | Escitalopram Oxalate |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |
|                         | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2007              | 6374166       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-03069-01     |                      | 29 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Change; Heart Rate Decreased; Hyperhidrosis; Palpitations; Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                       | Ativan         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2007              | 6375456       | DIRECT           | Y                  | LT, OT          |                      |                      | 58 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Withdrawal Syndrome; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Impaired Driving Ability; Impaired Work Ability; Medication Error; Muscular Weakness; Nausea; Paranoia; Product Dispensing Error; Product Dose Omission; Suicidal Ideation; Vomiting | Lexapro        |              |            | S           | Oral         | 20 Mg Qam Po       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jul-2007                                                                                                                                                     | 6375575              | DIRECT             | N                  | OT              |                      |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Cardiometabolic Syndrome; Hypertension; Insulin Resistance; Weight Decreased; Weight Loss Poor                                                       | Lexapro              |                    |                    | S               | Oral                 | 10mg Once Daily Po   |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2007                                                                                                                                                     | 6355058              | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02689-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Confusional State; Coordination Abnormal; Depression; Drug Ineffective; Drug Interaction; Extrapyrimal Disorder; Fall; Gait Disturbance; Mania; Tremor | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                 | Geodon               |                    |                    | S               |                      | 40 Mg Bid            |                 | Not Reported |                |
|                                                                                                                                                                 | Geodon               |                    |                    | S               |                      | 40 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                                 | Stelazine            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                 | Lamictal             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2007                                                                                                                                                     | 6365966              | EXPEDITED (15-DAY) | Y                  | HO              | S07-AUS-02906-01     |                      | 76 YR           | Female       | ZAF            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Status Epilepticus                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                 | Espiride (Sulpiride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2007                                                                                                                                                     | 6446315              | NON-EXPEDITED      | N                  | OT              | 233923               |                      | 33 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| White Blood Cell Count Decreased | Rituxan                |              |            | S           |              |                    |                 | Not Reported |
|                                  | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                  | Lexapro                |              |            | S           | Oral         | 10mg, Qd, Oral     |                 | Not Reported |
|                                  | Levaquin               |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 5787807       | EXPEDITED (15-DAY) | Y                  | HO              | S05-USA-01946-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| B-Cell Lymphoma; Blood Albumin Decreased; Central Nervous System Lymphoma; Confusional State; Drug Ineffective; Dyspnoea; Musculoskeletal Stiffness; Myoglobin Blood Increased; Neurotoxicity; Seizure; Somnolence; Unresponsive To Stimuli | Lexapro                |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                             | Ferrous Sulfate        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                             | Multivitamins          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                             | Calcium With Vitamin D |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 6219309       | EXPEDITED (15-DAY) | N                  | OT              | S06-USA-05450-01     |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Abnormal Dreams; Amnesia; Chest Discomfort; Colitis; Condition Aggravated; Depression; Obsessive-Compulsive Disorder | Lexapro            |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                          | Lexapro            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                          | Lexapro            |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                          | Lexapro            |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                          | Lexapro            |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                          | Imodium            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                          | Klonopin           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                          | Multivitamin (Nos) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 6376882       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-03096-01     |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiomyopathy        | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 6377305       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03196-01     |                      | 84 YR      | Female     | DNK            |

| <u>Preferred Term</u>              | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematoma; Major Depression; Wound | Escitalopram Oxalate               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                    | Seropram (Citalopram Hydrobromide) |              |            | S           |              |                    |                 | Not Reported |
|                                    | Alprazolam                         |              |            | C           |              |                    |                 | Not Reported |
|                                    | Athymil (Mianserin Hydrochloride)  |              |            | C           |              |                    |                 | Not Reported |
|                                    | Tranxene T-Tab                     |              |            | C           |              |                    |                 | Not Reported |
|                                    | Cyamemazine                        |              |            | C           |              |                    |                 | Not Reported |
|                                    | Orocal (Calcium Carbonate)         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 6377747       | DIRECT           | N                  | LT, RI          |                      |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Malaise; Osteoporosis; Pain; Product Quality Issue; Thoracic Vertebral Fracture | Lexapro        |              |            | S           | Oral         | 20mgs Daily Daily Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2007              | 6377758       | DIRECT           |                    | DE              |                      |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose              | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Aug-2007                                                                                                                                                                                                                                                                                                                                      | 6378769              | DIRECT             | Y                  | DS              |                      |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                                                                                                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10mg Qam Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                  | Hydroxyurea          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                  | Lorezapam            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2007                                                                                                                                                                                                                                                                                                                                      | 6378882              | DIRECT             | N                  | HO, OT          |                      |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Anorgasmia;<br>Anxiety; Chills; Condition<br>Aggravated; Crying;<br>Depression; Diarrhoea;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Furuncle; Hot Flush;<br>Hyperhidrosis; Irritability;<br>Libido Decreased;<br>Myalgia; Nausea; Restless<br>Legs Syndrome; Tremor;<br>Vision Blurred; Visual<br>Impairment; Weight<br>Increased | Lexapro              |                    |                    | S               | Oral                 | 10mg Once Daily Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2007                                                                                                                                                                                                                                                                                                                                      | 6379694              | EXPEDITED (15-DAY) | Y                  | DS              | S07-UKI-03234-01     |                      | 39 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Derealisation;                                                                                                                                                                                                                                                                                                                          | CipraleX             |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Dysgeusia; Insomnia;                                                                                                                                                                                                                                                                                                                             | CipraleX             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Movement Disorder; Panic<br>Attack; Suicidal Ideation;                                                                                                                                                                                                                                                                                           | CipraleX             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |               |   |              |
|-------------|---------------|---|--------------|
| Tearfulness | Amitriptyline | C | Not Reported |
|             | Diazepam      | C | Not Reported |
|             | Dosulepin     | C | Not Reported |
|             | Zopiclone     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2007              | 6321098       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-01882-01     |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Amnesia; | Lexapro        |              |            | S           | Oral         | 20 Mg Bid Po       |                 | Not Reported |
| Anion Gap Increased;                         | Lexapro        |              |            | S           | Oral         | 10 M G Qd Po       |                 | Not Reported |
| Aspartate                                    | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Aminotransferase Increased; Asthenia; Base   | Zocor          |              |            | S           |              | 40 Mg Qd           |                 | Not Reported |
| Excess Decreased; Blood                      | Zocor          |              |            | S           |              | 40 Mg Qd           |                 | Not Reported |
| Bicarbonate Decreased;                       | Coreg          |              |            | C           |              |                    |                 | Not Reported |
| Blood Chloride                               | Xanax          |              |            | C           |              |                    |                 | Not Reported |
| Decreased; Blood                             | Buspar         |              |            | C           |              |                    |                 | Not Reported |
| Creatinine Increased;                        | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
| Blood Glucose Increased;                     |                |              |            |             |              |                    |                 |              |
| Blood Osmolarity                             |                |              |            |             |              |                    |                 |              |
| Decreased; Blood                             |                |              |            |             |              |                    |                 |              |
| Pressure Systolic                            |                |              |            |             |              |                    |                 |              |
| Increased; Blood Thyroid                     |                |              |            |             |              |                    |                 |              |
| Stimulating Hormone                          |                |              |            |             |              |                    |                 |              |
| Decreased; Body                              |                |              |            |             |              |                    |                 |              |
| Temperature Decreased;                       |                |              |            |             |              |                    |                 |              |
| Carbon Dioxide                               |                |              |            |             |              |                    |                 |              |
| Decreased; Coma;                             |                |              |            |             |              |                    |                 |              |
| Confusional State;                           |                |              |            |             |              |                    |                 |              |
| Discomfort; Dizziness;                       |                |              |            |             |              |                    |                 |              |
| Fall; Feeling Abnormal;                      |                |              |            |             |              |                    |                 |              |
| Gliositis; Hyponatraemia;                    |                |              |            |             |              |                    |                 |              |
| Hypoxia; Loss Of                             |                |              |            |             |              |                    |                 |              |
| Consciousness;                               |                |              |            |             |              |                    |                 |              |
| Nightmare; Panic Attack;                     |                |              |            |             |              |                    |                 |              |
| Pco2 Decreased; Postictal                    |                |              |            |             |              |                    |                 |              |
| State; Road Traffic                          |                |              |            |             |              |                    |                 |              |
| Accident; Seizure; Speech                    |                |              |            |             |              |                    |                 |              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Syncope;  
Unevaluable Event;  
Unresponsive To Stimuli;  
Weight Decreased

| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 03-Aug-2007                 | 6380815        | DIRECT           | N                  | HO, LT          |                      |                      | 18 YR           | Female     | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Suicide Attempt | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Daily Po        | 3 WEEK          | Forest     |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Aug-2007                               | 6381035                 | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-03243-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Jittery;                          | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Intervertebral Disc Degeneration;         | Methadone Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Osteoporosis; Thoracic Vertebral Fracture | Provigil                |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>  | <u>Country</u> |
|----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-------------|----------------|
| 06-Aug-2007                                                          | 5825486                   | EXPEDITED (15-DAY) | Y                  | HO              | HQWYE032031MAY05     |                      | 68 YR           | Female      | AUT            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>  |                |
| Antidepressant Drug Level Increased; Drug Interaction; Hyponatraemia | Ciprallex                 |                    |                    | S               |                      |                      | 9 DAY           | Lundbeck    |                |
|                                                                      | Acetylsalicylic Acid      |                    |                    | C               | Oral                 |                      |                 | Unknown     |                |
|                                                                      | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 |                      | 3 DAY           | Wyeth       |                |
|                                                                      | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 |                      | 1 DAY           | Wyeth       |                |
|                                                                      | Selokeen                  |                    |                    | S               | Oral                 |                      |                 | Astrazeneca |                |
|                                                                      | Tegretol                  |                    |                    | S               | Oral                 |                      | 15 DAY          | Novartis    |                |
|                                                                      | Tegretol                  |                    |                    | S               | Oral                 |                      | 5 DAY           | Novartis    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 07-Aug-2007                                                      | 6321673                 | EXPEDITED (15-DAY)        | Y                           | DE                       | S07-UKI-02019-01              |                               |                          | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death                                                            | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Aug-2007                                                      | 6332546                 | EXPEDITED (15-DAY)        | Y                           | OT                       | FR-PFIZER INC-2007046766      |                               | 36 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Drug Interaction;<br>Ecchymosis                         | Champix                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                  | Doliprane               |                           |                             | C                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                  | Escitalopram Oxalate    |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Aug-2007                                                      | 6381281                 | DIRECT                    | Y                           | HO                       |                               |                               | 34 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Diarrhoea; Drug Withdrawal Syndrome; Hypophagia                  | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Daily Po                | 4 DAY                    | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Aug-2007                                                      | 6382290                 | EXPEDITED (15-DAY)        | Y                           | LT                       | GXKR2007GB06442               |                               | 56 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradycardia; Hypotension;<br>Intentional Overdose;<br>Somnolence | Amlodipine              |                           |                             | S                        |                               | 10 Mg,                        |                          | Not Reported        |                         |
|                                                                  | Bisoprolol Fumarate     |                           |                             | S                        |                               | 5 Mg,                         |                          | Not Reported        |                         |
|                                                                  | Furosemide              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                  | Escitalopram Oxalate    |                           |                             | S                        |                               | 20 Mg,                        |                          | Not Reported        |                         |
|                                                                  | Aspirin                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                           |   |              |
|--|-------------------------------------------|---|--------------|
|  | Bendroflumethiazide                       | C | Not Reported |
|  | (Bendroflumethiazide)                     |   |              |
|  | Betahistine (Betahistine)                 | C | Not Reported |
|  | Clopidogrel                               | C | Not Reported |
|  | Dipyridamole                              | C | Not Reported |
|  | Gabapentin                                | C | Not Reported |
|  | Glyceryl Trinitrate (Glyceryl Trinitrate) | C | Not Reported |
|  | Hydralazine Hydrochloride                 | C | Not Reported |
|  | Irbesartan                                | C | Not Reported |
|  | Isosorbide Mononitrate                    | C | Not Reported |
|  | Nicorandil (Nicorandil)                   | C | Not Reported |
|  | Novomix (Insulin Aspart)                  | C | Not Reported |
|  | Ranitidine                                | C | Not Reported |
|  | Rosuvastatin (Rosuvastatin)               | C | Not Reported |
|  | Thiamine (Thiamine)                       | C | Not Reported |
|  | Zopiclone (Zopiclone)                     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2007              | 6382835       | DIRECT           | Y                  | HO              |                      |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Parkinson'S Disease   | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po       | 3 MTH           | Not Reported |
|                       | Seroquel       |              |            | S           | Oral         | 25 Mg Twice Daily Po | 3 WEEK          | Not Reported |
|                       | Toprol XL      |              |            | C           |              |                      |                 | Not Reported |
|                       | Lipitor        |              |            | C           |              |                      |                 | Not Reported |
|                       | Aspirin        |              |            | C           |              |                      |                 | Not Reported |
|                       | Avapro         |              |            | C           |              |                      |                 | Not Reported |
|                       | Aricept        |              |            | C           |              |                      |                 | Not Reported |
|                       | Lexapro        |              |            | C           |              |                      |                 | Not Reported |
|                       | Seroquel       |              |            | C           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Aug-2007              | 6336957       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007047955 |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Drug Interaction; Fatigue; | Chantix        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |                         |   |              |
|-----------------------------------------|-------------------------|---|--------------|
| Nausea; Somnolence;<br>Weight Increased | Vytorin                 | C | Not Reported |
|                                         | Metformin Hydrochloride | C | Not Reported |
|                                         | Niacin                  | C | Not Reported |
|                                         | Lisinopril              | C | Not Reported |
|                                         | Chantix                 | S | Not Reported |
|                                         | Lexapro                 | S | Not Reported |

| <u>FDA Received Date</u>       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2007                    | 6317288        | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-01796-01     |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                | Seroquel       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Buspar         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Ambien         |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2007                                                                             | 6359910        | EXPEDITED (15-DAY) | N                  | DE              | S07-USA-02875-01     |                      | 73 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug<br>Ineffective; Gun Shot<br>Wound; Social Avoidant<br>Behaviour | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                         | Zocor          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                         | Avodart        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                         | Flomax         |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Aug-2007                | 6384905        | DIRECT           | N                  | HO, LT, OT      |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Suicidal Ideation | Zoloft 100mg   |                  |                    | S               | Oral                 | 100mg Daily Po       |                 | Not Reported |                |
|                            | Lexapro        |                  |                    | S               | Oral                 | 10mg Daily Po        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 09-Aug-2007                                                                                                  | 6393455                | DIRECT             | Y                  | OT              |                                                    |                      | 33 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Rubella Antibody Positive      | Escitalopram Oxalate   |                    |                    | S               | Oral                                               | 10 Mg Qd - Oral      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2007                                                                                                  | 6379885                | NON-EXPEDITED      | N                  |                 | A0644135A                                          |                      | 27 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Screen False<br>Positive                                                                                | Paxil                  |                    |                    | S               | Unknown                                            |                      |                 | Glaxosmithkline |                |
|                                                                                                              | Lexapro                |                    |                    | S               | Unknown                                            |                      |                 | Not Reported    |                |
|                                                                                                              | Unspecified Ingredient |                    |                    | C               |                                                    |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2007                                                                                                  | 6379969                | NON-EXPEDITED      | N                  |                 | A0651076A                                          |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams;<br>Diarrhoea; Dizziness;<br>Drug Withdrawal<br>Syndrome; Headache;<br>Hyperhidrosis; Nausea | Paxil                  |                    |                    | S               | Oral                                               |                      | 15 YR           | Glaxosmithkline |                |
|                                                                                                              | Lexapro                |                    |                    | S               |                                                    |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2007                                                                                                  | 6380696                | EXPEDITED (15-DAY) |                    | HO              | IN-ROXANE<br>LABORATORIES, INC-<br>2007-BP-18627RO |                      | 16 YR           | Female          | IND            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Urea Increased;<br>Catatonia; Dehydration;                                                             | Lithium Carbonate      |                    |                    | S               |                                                    |                      | 5 MTH           | Roxane          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                      |   |              |
|---------------------------------------------------------------------|----------------------|---|--------------|
| Mania; Toxicity To Various Agents; White Blood Cell Count Increased | Olanzapine           | S | Not Reported |
|                                                                     | Escitalopram Oxalate | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2007              | 6353188       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 157766ISR            |                      | 50 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of Consciousness;                                                              | Lamotrigine          |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Electrocardiogram Qt Prolonged; Intentional Overdose; Myoclonus; Pneumonia; Serotonin Syndrome | Zopiclone            |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                | Olanzapine           |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2007              | 6378154       | EXPEDITED (15-DAY) | Y                  | DE              | S07-FIN-03231-01     |                      | 73 YR      | Male       | FIN            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Ciprallex                   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Emconcor (Bisoprolol)       |              |            | C           |              |                    |                 | Not Reported |
|                       | Pravachol                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Warfarin Sodium             |              |            | C           |              |                    |                 | Not Reported |
|                       | Renitex (Enalapril Maleate) |              |            | C           |              |                    |                 | Not Reported |
|                       | Furosemide                  |              |            | C           |              |                    |                 | Not Reported |
|                       | Primperan                   |              |            | C           |              |                    |                 | Not Reported |
|                       | Nasacort                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2007              | 6387245       | EXPEDITED (15-DAY) | Y                  | LT              | 6036362              |                      | 56 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Hypotension; Intentional Overdose; Somnolence | Bisoprolol Fumarate |              |            | S           |              | (5 Mg)             |                 | Not Reported |
|                                                            | Amlodipine          |              |            | S           |              | (10 Mg)            |                 | Not Reported |

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|                                           |   |         |              |
|-------------------------------------------|---|---------|--------------|
| Escitalopram Oxalate                      | S | (20 Mg) | Not Reported |
| Frusemide                                 | S |         | Not Reported |
| Aspirin (Acetylsalicylic Acid)            | C |         | Not Reported |
| Bendroflumethiazide                       | C |         | Not Reported |
| (Bendroflumethiazide)                     |   |         |              |
| Betahistine (Betahistine)                 | C |         | Not Reported |
| Clopidogrel                               | C |         | Not Reported |
| Dipyridamole                              | C |         | Not Reported |
| Gabapentin (Gabapentin)                   | C |         | Not Reported |
| Glyceryl Trinitrate (Glyceryl Trinitrate) | C |         | Not Reported |
| Hydralazine (Hydralazine)                 | C |         | Not Reported |
| Irbesartan                                | C |         | Not Reported |
| Isosorbide Mononitrate                    | C |         | Not Reported |
| Nicorandil                                | C |         | Not Reported |
| Novomix (Insulin Aspart)                  | C |         | Not Reported |
| Ranitidine                                | C |         | Not Reported |
| Rosuvastatin (Rosuvastatin)               | C |         | Not Reported |
| Thiamine (Thiamine)                       | C |         | Not Reported |
| Zopiclone                                 | C |         | Not Reported |

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2007                                                         | 6388339              | DIRECT           | Y                  | OT              |                      |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10 Mg Qd - Oral      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Aug-2007                                                                 | 6388419        | DIRECT           | Y                  | HO, LT          |                      |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Stevens-Johnson Syndrome; Therapy Non-Responder; Toxic Epidermal Necrolysis | Dapsone        |                  |                    | S               | Oral                 | Dapsone Daily Po     |                 | Not Reported |                |
|                                                                             | Lexapro        |                  |                    | S               | Oral                 | Lexapro Daily Po     |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 16-Aug-2007                                                                                                                                                        | 6397764                  | DIRECT             | Y                  | HO              |                      |                      | 64 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Delusion; Hallucination,<br>Auditory; Loss Of<br>Employment; Major<br>Depression; Paranoia;<br>Psychotic Disorder | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg Od - Oral      |                 | Not Reported    |                |
|                                                                                                                                                                    | Glimepiride              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Quinapril                |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Carvedilol               |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 17-Aug-2007                                                                                                                                                        | 6339385                  | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-02438-01     |                      | 47 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                                                                                                                                  | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                    | Lodine                   |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Nasonex                  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Aug-2007                                                                                                                                                        | 6367750                  | EXPEDITED (15-DAY) | N                  | HO              | B0479582A            |                      | 55 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Epilepsy; Loss Of<br>Consciousness; Malaise;<br>Urinary Incontinence                                                                                               | Deroxat                  |                    |                    | S               | Oral                 | 20mg Per Day         | 3 MTH           | Glaxosmithkline |                |
|                                                                                                                                                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10mg Twice Per Day   | 1 YR            | Unknown         |                |
|                                                                                                                                                                    | Anafranil                |                    |                    | S               | Oral                 |                      | 3 YR            | Unknown         |                |
|                                                                                                                                                                    | Metformin Hydrochloride  |                    |                    | S               | Oral                 | 2000mg Per Day       | 5 MTH           | Unknown         |                |
|                                                                                                                                                                    | Cozaar                   |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Bisoprolol Fumarate      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Benfluorex Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                    | Tahor                    |                    |                    | C               |                      |                      |                 | Not Reported    |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Aug-2007                                                                                          | 6392202                | DIRECT             | Y                  | HO              |                      |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic Hormone Secretion                                                         | Lexapro                |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2007                                                                                          | 6393335                | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03456-01     |                      | 74 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                            | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2007                                                                                          | 6367682                | EXPEDITED (15-DAY) | Y                  | HO              | L07-GER-03072-01     |                      | 44 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                                                              | Escitalopram Oxalate   |                    |                    | S               |                      | 30 Mg Qd             |                 | Not Reported |                |
|                                                                                                      | Aripiprazole           |                    |                    | S               |                      | 15 Mg Qd             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2007                                                                                          | 6244259                | EXPEDITED (15-DAY) | N                  | HO              | S07-GER-00169-01     |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia;<br>Cognitive Disorder; Fluid Intake Reduced; Serotonin Syndrome; Speech Disorder | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                      | Antabuse               |                    |                    | S               |                      | 500 Mg Qd            |                 | Not Reported |                |
|                                                                                                      | Antabuse               |                    |                    | S               |                      | 100 Mg Qd            |                 | Not Reported |                |
|                                                                                                      | Elmendos (Lamotrigine) |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 23-Aug-2007                                                                                                                                                                                                                                                | 6367545                 | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-03039-01          |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Dysgeusia;<br>Headache; Panic Attack;<br>Seizure; Sensory<br>Disturbance                                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                      | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2007                                                                                                                                                                                                                                                | 6390782                 | EXPEDITED (15-DAY) | Y                  | CA              | CH-JNJFOC-<br>20070803424 |                      | 30 YR           | Unknown      | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Disease Congenital                                                                                                                                                                                                                                   | Concerta                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Cipralext               |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Zyprexa                 |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Methadone Hydrochloride |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Oxazepam                |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Valium                  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Valium                  |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2007                                                                                                                                                                                                                                                | 6405932                 | EXPEDITED (15-DAY) | N                  | HO, OT          | 2007SP016762              |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Condition Aggravated;<br>Dehydration; Depression;<br>Drug Ineffective; Dry<br>Mouth; Dysgeusia;<br>Headache; Influenza Like<br>Illness; Insomnia; Nausea;<br>Pneumonia; Seizure;<br>Vomiting; White Blood Cell<br>Count Decreased | Pegintron               |                    |                    | S               | Subcutaneous              | Sc                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Ribavirin               |                    |                    | S               | Oral                      | Po                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Lexapro                 |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Percodan                |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                            | Zoloft                  |                    |                    | C               |                           |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Aug-2007                                                                                                             | 6404761                                        | DIRECT             | N                  | OT              |                      |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Disorder;<br>Gastroesophageal Reflux<br>Disease                                                        | Lexapro                                        |                    |                    | S               | Oral                 | 10mg Once Daily Po   | 7 MTH           | Forest       |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2007                                                                                                             | 6295135                                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-01446-01     |                      | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Haemoconcentration;<br>Hyponatraemia; Loss Of<br>Consciousness;<br>Orthostatic Hypotension | Escitalopram Oxalate                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Bisoprolol Fumarate And<br>Hydrochlorothiazide |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                         | Moxonidine                                     |                    |                    | S               | Oral                 | 0.4 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                         | Olmotec                                        |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Lorazepam                                      |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                         | Lansoprazole                                   |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Plavix                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Fenofibrate                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Flecainide Acetate                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2007                                                                                                             | 6408240                                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03635-01     |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Loss Of<br>Consciousness; Malaise                                                                             | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                         | Paroxetine Hydrochloride                       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                         | Anafranil                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Metformin Hydrochloride                        |                    |                    | S               | Oral                 | 2000 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                                         | Cozaar                                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                         | Bisoprolol Fumarate                            |                    |                    | C               |                      |                      |                 | Not Reported |                |

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|                                                                                                            |                        | Mediator(Benfluorex Hydrochloride) |                    | C               |                      |                      |                 |              | Not Reported   |
|------------------------------------------------------------------------------------------------------------|------------------------|------------------------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                            |                        | Atorvastatin Calcium               |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>                   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2007                                                                                                | 6410314                | EXPEDITED (15-DAY)                 | Y                  | HO, OT          | S07-UKI-03633-01     |                      | 53 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>                       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Balance Disorder; Dizziness; Fatigue; Lethargy; Palpitations; Paraesthesia; Vision Blurred | Ciprallex              |                                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                            | Unspecified Ingredient |                                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>                   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2007                                                                                                | 6410539                | EXPEDITED (15-DAY)                 | N                  | OT              | S07-USA-03565-01     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>                       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea; Faeces Discoloured; Haematochezia; Nausea; Therapeutic Product Effect Decreased        | Lexapro                |                                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                            | Lexapro                |                                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Levothyroxine Sodium   |                                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>                   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2007                                                                                                | 6378036                | EXPEDITED (15-DAY)                 | N                  | OT              | S07-USA-03190-01     |                      | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>         | <u>Comp.</u>                       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cancer Pain; Confusional State; Drug Interaction; Dyspnoea; Lung Neoplasm Malignant                        | Lexapro                |                                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lortab                 |                                    |                    | S               |                      | 5 Mg Qd              |                 | Not Reported |                |
|                                                                                                            | Gemzar                 |                                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>          | <u>Case Type</u>                   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2007                                                                                                | 6394997                | NON-EXPEDITED                      | N                  |                 | A0643963A            |                      | 52 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Drug Ineffective; Drug Interaction                                                                                                                                                              | Wellbutrin XI        |                    |                    | S               | Oral                 | 300mg In The Morning |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 10mg At Night        |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Seroquel             |                    |                    | S               | Oral                 | 50mg At Night        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Aug-2007                                                                                                                                                                                     | 6395319              | NON-EXPEDITED      | N                  |                 | A0664339A            |                      | 58 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Gastric Disorder; Tremor                                                                                                                                                                        | Wellbutrin XI        |                    |                    | S               | Oral                 | 150mg Per Day        | 2 WEEK          | Glaxosmithkline |                |
|                                                                                                                                                                                                 | Lexapro              |                    |                    | S               |                      | 10mg Per Day         | 8               | Not Reported    |                |
|                                                                                                                                                                                                 | Norvasc              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Catapres-Tts         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Benicar              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Prempro              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Aciphex              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Potassium Chloride   |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                 | Lorazepam            |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Multivitamins        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Folic Acid           |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                 | Biaxin               |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 30-Aug-2007                                                                                                                                                                                     | 6395445              | EXPEDITED (15-DAY) | Y                  | HO, LT          | HQWYE756422AUG07     |                      | 76 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Gamma-Glutamyltransferase | Inipomp              |                    |                    | S               | Oral                 |                      | 102 DAY         | Wyeth           |                |
|                                                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1/Day 1 Df           |                 | Unknown         |                |
|                                                                                                                                                                                                 | Bactrim Forte        |                    |                    | S               | Oral                 | Df                   |                 | Roche           |                |
|                                                                                                                                                                                                 | Oroken               |                    |                    | S               | Oral                 | 1/Day 1 Df           |                 | Aventis         |                |
|                                                                                                                                                                                                 | Simvastatin          |                    |                    | C               | Oral                 | 1/Day 40 Mg          |                 | Unknown         |                |
|                                                                                                                                                                                                 | Fludex (Indapamide)  |                    |                    | C               | Oral                 | 1/Day 1.5 Mg         |                 | Not Reported    |                |

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|                                       |          |   |      |            |              |
|---------------------------------------|----------|---|------|------------|--------------|
| Increased; Serum Ferritin             | Ramipril | C | Oral | 1/Day 5 Mg | Not Reported |
| Increased; Toxic Epidermal Necrolysis | Hyperium | C | Oral | 1/Day 1 Df | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2007              | 6411305       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S07-FRA-03638-01     |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bedridden; Blood Chloride Decreased; Blood Osmolarity Decreased; Blood Potassium Decreased; Coma Scale Abnormal; Confusional State; Disorientation; Fall; General Physical Health Deterioration; Hyponatraemia; Malaise; Somnolence; Urine Osmolarity Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Fludex (Indapamide)  |              |            | S           |              | 1.5 Mg Qd          |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Mopral (Omeprazole)  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Plavix               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Cozaar               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Pravastatin          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Propranolol          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                 | Acetaminophen        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2007              | 6411312       | EXPEDITED (15-DAY) | Y                  | CA              | S07-SWI-03636-01     |                      | 30 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Induced; Heart Disease Congenital; Maternal Exposure During Pregnancy; Pregnancy | Cipralax       |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                           | Concerta       |              |            | S           | Oral         | 54 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Zyprexa        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                           | Methadone      |              |            | S           | Oral         | 25 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Oxazepam       |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Valium         |              |            | S           | Oral         | 5 Mg Bid Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2007              | 6412019       | EXPEDITED (15-DAY) | Y                  | CA              | S07-DEN-03637-02     |                      | 365 DAY    | Male       | DNK            |

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| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|--------------------------------|-------------------------|-----------------|--------------|----------------|
| Atrial Septal Defect;<br>Maternal Exposure During<br>Pregnancy | Ciprallex                         |                    |                    | S               | Transplacental                 | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                | Zyprexa                           |                    |                    | S               | Transplacental                 | 10 Mg Qd Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Aug-2007                                                    | 6747157                           | NON-EXPEDITED      | Y                  | OT              | 200713290US                    |                         | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Tremor                                          | Lasix                             |                    |                    | S               |                                |                         | 18 WEEK         | Not Reported |                |
|                                                                | Lasix                             |                    |                    | S               |                                |                         |                 | Not Reported |                |
|                                                                | Lasix                             |                    |                    | S               |                                | 20 Mg Qd                |                 | Not Reported |                |
|                                                                | Lexapro                           |                    |                    | S               | Oral                           | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                | Lexapro                           |                    |                    | S               | Oral                           | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                | Quinine                           |                    |                    | S               |                                |                         |                 | Not Reported |                |
|                                                                | Spironolactone                    |                    |                    | C               |                                |                         |                 | Not Reported |                |
|                                                                | Neomycin Sulfate                  |                    |                    | C               |                                |                         |                 | Not Reported |                |
|                                                                | Prevacid                          |                    |                    | C               |                                |                         |                 | Not Reported |                |
|                                                                | Magnesium                         |                    |                    | C               |                                |                         |                 | Not Reported |                |
|                                                                | Lactulose                         |                    |                    | C               |                                |                         |                 | Not Reported |                |
|                                                                | Oxazepam                          |                    |                    | C               |                                |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2007                                                    | 6405602                           | EXPEDITED (15-DAY) | Y                  | HO              | AU-ASTRAZENECA-<br>2007AP05360 |                         | 82 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse;<br>Hyponatraemia; Seizure                | Nexium                            |                    |                    | S               | Oral                           |                         | 4 DAY           | Astrazeneca  |                |
|                                                                | Escitalopram Oxalate              |                    |                    | S               | Oral                           |                         |                 | Not Reported |                |
|                                                                | Amiloride                         |                    |                    | S               | Oral                           |                         |                 | Not Reported |                |
|                                                                | Hydrochloride\Hydrochlorothiazide |                    |                    |                 |                                |                         |                 |              |                |
|                                                                | Carbamazepine                     |                    |                    | S               | Oral                           |                         |                 | Not Reported |                |
|                                                                | Lercanidipine Hydrochloride       |                    |                    | C               |                                |                         |                 | Not Reported |                |
| Prazosin Hydrochloride                                         |                                   |                    | C                  |                 |                                | Not Reported            |                 |              |                |

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|                        |   |              |
|------------------------|---|--------------|
| Isosorbide Mononitrate | C | Not Reported |
| Simvastatin            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2007              | 6391740       | EXPEDITED (15-DAY) | Y                  | HO              | S07-AUT-03434-01     |                      | 28 YR      | Female     | AUT            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotonia; Syncope;<br>Vertigo | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd; Po       |                 | Not Reported |
|                                | Ciprallex      |              |            | S           | Oral         | 15 Mg Qd; Po       |                 | Not Reported |
|                                | Lorazepam      |              |            | S           | Oral         | 1.25 Mg Qd; Po     |                 | Not Reported |
|                                | Lorazepam      |              |            | S           | Oral         | 2.5 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 500 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 600 Mgqd; Po       |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 500 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 400 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 350 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 300 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 200 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 100 Mg Qd;Po       |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 75 Mg Qd; Po       |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 100 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 150 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 300 Mg Qd; Po      |                 | Not Reported |
|                                | Seroquel       |              |            | S           | Oral         | 400mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 05-Sep-2007              | 6406398       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SOLVAY-00207033859 |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Blood Osmolarity Increased; Dehydration; | Perindopril Erbumine |              |            | S           | Oral         | Daily Dose: 4 Milligram(S) |                 | Not Reported |



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|                                                                    |                        |   |         |                             |              |
|--------------------------------------------------------------------|------------------------|---|---------|-----------------------------|--------------|
| General Physical Health Deterioration; Oral Fungal Infection; Scab | Escitalopram Oxalate   | S | Oral    | Daily Dose: 10 Milligram(S) | Not Reported |
|                                                                    | Fraxiparine            | C | Unknown | Daily Dose: Unknown         | Not Reported |
|                                                                    | Aerius (Desloratadine) | C | Unknown | Daily Dose: Unknown         | Not Reported |
|                                                                    | Levothyrox             | C | Unknown | Daily Dose: Unknown         | Not Reported |
|                                                                    | Speciafoldine          | C | Unknown | Daily Dose: Unknown         | Not Reported |

| <u>FDA Received Date</u>                                                         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Sep-2007                                                                      | 6413388        | DIRECT           |                    | CA              |                      |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Craniosynostosis; Maternal Exposure During Pregnancy; Seizure | Lexapro        |                  |                    | S               | Oral                 |                      | 2 WEEK          | Not Reported |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Sep-2007                                                                              | 6413389              | DIRECT           | Y                  | OT              |                      |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Maternal Exposure During Pregnancy; Pregnancy; Vaginal Haemorrhage | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10 Mg Qd - Oral      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 05-Sep-2007                                                          | 6418025              | EXPEDITED (15-DAY) | Y                  | HO              | DSM-2007-00619       |                                        | 76 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Systolic Increased;                                   | Olmotec              |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D), Oral           |                 | Not Reported |                |
| Haemoconcentration; Hyponatraemia; Malaise; Orthostatic Hypotension; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In 1 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Syncope                                                         |                      | Bisoprolol                   | S                  |                 |                      | D),Oral                                       |                 |            |                |
|-----------------------------------------------------------------|----------------------|------------------------------|--------------------|-----------------|----------------------|-----------------------------------------------|-----------------|------------|----------------|
|                                                                 |                      | Fumarate\Hydrochlorothiazide |                    |                 |                      | 5 Mg/6.25 Mg (1 Dosage Forms, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                                                 |                      | Moxonidine                   | S                  | Oral            |                      | 0.4 Mg (0.4 Mg, 1 In 1 D), Oral               |                 |            | Not Reported   |
|                                                                 |                      | Lorazepam                    | S                  | Oral            |                      | 1 Mg (1 Mg, 1 In 1 D),Oral                    |                 |            | Not Reported   |
|                                                                 |                      | Lansoprazole                 | S                  | Oral            |                      | 30 Mg (30 Mg, 1 In 1 D), Oral                 |                 |            | Not Reported   |
|                                                                 |                      | Plavix                       | C                  |                 |                      |                                               |                 |            | Not Reported   |
|                                                                 |                      | Lipanthyl (Fenofibrate)      | C                  |                 |                      |                                               |                 |            | Not Reported   |
|                                                                 |                      | (Fenofinbrate)               |                    |                 |                      |                                               |                 |            |                |
|                                                                 |                      | Flecainide Acetate           | C                  |                 |                      |                                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>             | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2007                                                     | 6338752              | EXPEDITED (15-DAY)           | Y                  | HO              | S07-USA-02401-01     |                                               | 64 YR           | Female     | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>                 | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Generalised Tonic-Clonic Seizure                                | Lexapro              |                              |                    | S               | Oral                 | 10 Mg Qd Po                                   |                 |            | Not Reported   |
|                                                                 | Prednisone           |                              |                    | C               |                      |                                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>             | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2007                                                     | 6393476              | EXPEDITED (15-DAY)           | Y                  | OT              | S07-USA-03374-01     |                                               |                 | Male       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>                 | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Fall; Feeling Hot; Seizure                                      | Lexapro              |                              |                    | S               | Oral                 | 10 Mg Qd Po                                   |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>             | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2007                                                     | 6419086              | EXPEDITED (15-DAY)           | Y                  | DS, HO          | S07-FRA-03711-01     |                                               | 28 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>                 | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Delirium; Emotional Distress; Hallucination, Auditory; | Escitalopram Oxalate |                              |                    | S               | Oral                 | 10 Mg Qd Po                                   |                 |            | Not Reported   |
|                                                                 | Zolpidem             |                              |                    | C               |                      |                                               |                 |            | Not Reported   |
|                                                                 | Bromazepam           |                              |                    | C               |                      |                                               |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Psychotic Disorder;  
Speech Disorder

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2007              | 6414701       | DIRECT           | Y                  | HO, LT          |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Amnesia; Apnoea; Cardiac<br>Disorder; Chest Pain;<br>Conversion Disorder;<br>Generalised Tonic-Clonic<br>Seizure; Headache;<br>Hepatic Enzyme<br>Increased; Hyperreflexia;<br>Hypersomnia; Insomnia;<br>Mania; Mental Status<br>Changes; Muscle Rigidity;<br>Muscle Tightness;<br>Serotonin Syndrome | Ultram         |              |            | S           | Oral         | 50mg Q4 Hours Prn Po |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                             | Lexapro        |              |            | S           | Oral         | 20mg Daily Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2007              | 6422753       | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-03726-01     |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Discomfort; Disturbance In<br>Attention; Dizziness; Drug<br>Withdrawal Syndrome;<br>Fatigue; Feeling<br>Abnormal; Hypoacusis;<br>Impaired Work Ability;<br>Memory Impairment;<br>Nightmare; Pain In<br>Extremity; Panic Attack;<br>Paraesthesia; Sleep | Ciprallex      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Suicidal  
Ideation; Visual Acuity  
Reduced

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2007              | 6425702       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03729-01     |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Osmolarity Increased; Blood Urea Increased; Dehydration; Eschar; Fungal Infection; General Physical Health Deterioration; Skin Disorder | Escitalopram Oxalate                         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                               | Perindopril Erbumine                         |              |            | S           | Oral         | 4 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                               | Fraxiparine (Heparin-Fraction, Calcium Salt) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Desloratadine                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Levothyroxine Sodium                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Speciafoldine (Folic Acid)                   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2007              | 6331537       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-ISR-02250-01     |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Head Injury; Loss Of Consciousness | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                          | Carbocisteine        |              |            | C           |              |                    |                 | Not Reported |
|                                          | Lorapid (Loperamide) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2007              | 6357648       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-02818-01     |                      | 12 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Platelet Count Decreased | Lexapro                   |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                     | Adderall Xr (Amphetamine) |              |            | C           |              |                    |                 | Not Reported |
|                                     | Strattera                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Sep-2007              | 6360219       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-02899-01     |                      | 55 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>             | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide; Gun Shot Wound | Lexapro                                      |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                   | Xanax                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Lescol XI                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Altace                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2007                       | 6382174                                      | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03321-01     |                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>             | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Face Oedema; Lip Oedema           | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                   | Inipomp                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Inipomp                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Celectol                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Fludex (Indapamide)                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Simvastatin                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2007                       | 6412352                                      | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03626-01     |                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>             | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Face Oedema; Lip Oedema           | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                   | Inipomp                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                   | Celiprolol                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Indapamide                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Simvastatin                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Di-Gesic                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2007                       | 6382229                                      | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-TUN-03345-01     |                      | 61 YR           | Male         | TUN            |
| <u>Preferred Term</u>             | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                      |   |      |             |              |
|----------------------------------------------------------------------|----------------------|---|------|-------------|--------------|
| Cardiac Disorder; Chest Pain; Discomfort; Dyspnoea; Malaise; Vertigo | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|----------------------------------------------------------------------|----------------------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Sep-2007              | 6415602       | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2006UW16035 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Screen Positive  | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Vistaril       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Sep-2007              | 6415926       | NON-EXPEDITED    | Y                  | OT              | US-ASTRAZENECA-2006UW20293 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaphylactic Reaction | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2007              | 6417360       | EXPEDITED (15-DAY) | Y                  | OT              | B0482701A            |                      | 40 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Aggression; Anxiety; Dizziness; Drug Withdrawal Syndrome;                | Paroxetine     |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
| Eye Disorder; Headache;                                                  | Paroxetine     |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
| Intentional Overdose;                                                    | Fluoxetine     |              |            | S           |              |                    |                 | Not Reported    |
| Irritability; Migraine; Mood                                             | Ciprallex      |              |            | S           |              |                    |                 | Not Reported    |
| Altered; Nausea; Self-Injurious Ideation; Suicidal Ideation; Tearfulness | Sertraline     |              |            | S           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 19-Sep-2007                                            | 6419136        | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2007UW06123 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Interaction;<br>Muscle Twitching; Tremor | Seroquel       |                  |                    | S               | Oral                       |                      | 0 MTH           | Zeneca       |                |
|                                                        | Lexapro        |                  |                    | S               | Oral                       |                      | 0 YR            | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               | Oral                       |                      | 0 YR            | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               | Oral                       |                      | 0 MTH           | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               | Oral                       |                      | 0 MTH           | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                            |                      | 1 YR            | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                            |                      | 1 YR            | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                            |                      |                 | Not Reported |                |
|                                                        | Risperdal      |                  |                    | C               |                            |                      | 0 YR            | Not Reported |                |
|                                                        | Benicar        |                  |                    | C               |                            |                      |                 | Not Reported |                |
|                                                        | Ativan         |                  |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 19-Sep-2007                     | 6419313        | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2007UW07636 |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error;<br>Somnolence | Seroquel       |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                 | Lexapro        |                  |                    | S               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 19-Sep-2007                                     | 6419317        | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2007UW07432 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dry Eye;<br>Dysphagia; Tremor | Seroquel       |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                 | Lexapro        |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Klonopin       |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|                                                          | Depakote       |                    | S                  | Oral            |                            |                        |                 | Not Reported |                |
|----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|------------------------|-----------------|--------------|----------------|
|                                                          | Topamax        |                    | S                  | Oral            |                            |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2007                                              | 6420728        | NON-EXPEDITED      | Y                  |                 | US-ASTRAZENECA-2007UW13125 |                        | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Muscle Spasms; Nightmare; Somnambulism | Seroquel       |                    |                    | S               | Oral                       |                        | 2 WEEK          | Zeneca       |                |
|                                                          | Lexapro        |                    |                    | S               |                            |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2007                                              | 6420769        | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2007UW13713 |                        | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Feeling Cold; Sleep Disorder          | Seroquel       |                    |                    | S               |                            | 1-1 1/2 50 Mg Po Daily |                 | Zeneca       |                |
|                                                          | Seroquel       |                    |                    | S               |                            | 1-1 1/2 50 Mg Po Daily |                 | Zeneca       |                |
|                                                          | Lexapro        |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Dilaudid       |                    |                    | C               |                            |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2007                                              | 6420937        | EXPEDITED (15-DAY) | Y                  | OT              | NO-ASTRAZENECA-2007SE04515 |                        | 41 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Maternal Exposure During Pregnancy | Seroquel       |                    |                    | S               | Oral                       |                        |                 | Zeneca       |                |
|                                                          | Seroquel       |                    |                    | S               | Oral                       |                        |                 | Zeneca       |                |
|                                                          | Cipralext      |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Cipralext      |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Cipralext      |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Cipralext      |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Lamictal       |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Lamictal       |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Lamictal       |                    |                    | S               |                            |                        |                 | Not Reported |                |
|                                                          | Lamictal       |                    |                    | S               |                            |                        |                 | Not Reported |                |



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|  |          |   |      |              |
|--|----------|---|------|--------------|
|  | Lyrica   | S | Oral | Not Reported |
|  | Lyrica   | S | Oral | Not Reported |
|  | Diazepam | S |      | Not Reported |
|  | Diazepam | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2007              | 6429618       | DIRECT           | Y                  | OT              |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Chills; Condition Aggravated; Fatigue; Muscle Contractions Involuntary; Muscle Spasms; Paraesthesia; Restless Legs Syndrome; Somnolence; Spinal Disorder; Tenderness; Tooth Disorder; Tremor | Lexapro        |              |            | S           | Oral         | 20 Mg Once A Day Po | 3 YR            | Forest       |
|                                                                                                                                                                                              | Nexium         |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                                                                              | Bupropion      |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2007              | 6431849       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 100#08#2007-03421    |                      | 31 YR      | Male       | TUR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Aspartate Aminotransferase Increased; Blood Chloride Decreased; Blood Creatine Phosphokinase Mb Increased; Blood Lactate Dehydrogenase Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Cerebellar Syndrome; Depression; Disease Recurrence; Electrolyte Imbalance; Lymphocyte Percentage Decreased; | Lithium                                 |              |            | S           |              | 1200 Mg; 4 Months + 3 Months In Remission | 4 MTH           | Not Reported |
|                                                                                                                                                                                                                                                                                                                      | Escitalopram Oxalate                    |              |            | S           |              | 10 Mg; 4 Months + 3 Months In Remission   | 4 MTH           | Not Reported |
|                                                                                                                                                                                                                                                                                                                      | Lamotrigine (Lamotrigine) (Lamotrigine) |              |            | C           |              |                                           |                 | Not Reported |

# FDA Adverse Event Reporting System

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Nausea; Neurotoxicity;  
Neutrophil Percentage  
Increased; Pneumonia;  
Pyrexia; Red Blood Cell  
Sedimentation Rate  
Increased; Toxicity To  
Various Agents; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2007              | 6132299       | EXPEDITED (15-DAY) | Y                  | OT              | S06-ITA-03395-01     |                      | 75 YR      | Male       | ITA            |

| <u>Preferred Term</u>                                       | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gravitational Oedema;<br>Renal Failure; Weight<br>Increased | Cipraxel                              |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                             | Carvedilol                            |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Amiodar (Amiodarone<br>Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Glurenor (Gliquidone)                 |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Omeprazole                            |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Ziloryc (Allopurinol) (Allopurinol)   |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Sodium Bicarbonate                    |              |            | C           |              |                    |                 | Not Reported |
|                                                             | Lasix                                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2007              | 6204423       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-04734-01     |                      | 77 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation;<br>Condition Aggravated;<br>Depression; Paraesthesia;<br>Skin Burning Sensation | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd; Po       |                 | Not Reported |
|                                                                                                    | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg Qd; Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2007              | 6353937       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-02701-01     |                      | 35 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Steatosis;    | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |

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| Hepatitis                                             | Abilify                 | S                         | Oral                        | 10 Mg Qd Po              | Not Reported                  |                               |                          |                     |                         |
|-------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
|                                                       | Noctran                 | C                         |                             |                          | Not Reported                  |                               |                          |                     |                         |
|                                                       | Cyamemazine             | C                         |                             |                          | Not Reported                  |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                           | 6432672                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03843-01              |                               | 16 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Seizure; Suicide Attempt                    | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                           | 6433155                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03851-01              |                               | 45 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Respiratory Depression; Tachycardia; Tremor | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                           | 6433187                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03844-01              |                               | 26 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arrhythmia; Overdose; Suicide Attempt                 | Escitalopram Oxalate    |                           |                             | S                        |                               | 10 Tablet Once                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                           | 6433192                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03845-01              |                               | 13 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Seizure                                     | Escitalopram Oxalate    |                           |                             | S                        |                               | 60 Mg Once                    |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Sep-2007                                                                                                    | 6433198                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03846-01              |                               | 15 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Haematemesis; Overdose;<br>Suicide Attempt; Vomiting                                                           | Escitalopram Oxalate    |                           |                             | S                        |                               | 100 Mg Once                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                                                                                    | 6433203                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03847-01              |                               | 18 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Irritability;<br>Lethargy; Overdose;<br>Pneumonitis; Somnolence;<br>Tachycardia                     | Escitalopram Oxalate    |                           |                             | S                        |                               | 18 Tablet Once                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                                                                                    | 6433212                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03840-01              |                               | 53 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Acidosis; Agitation;<br>Delusion; Hallucination;<br>Irritability; Overdose;<br>Suicide Attempt;<br>Tachycardia | Escitalopram Oxalate    |                           |                             | S                        |                               | 110 Mg Once                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2007                                                                                                    | 6433222                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03841-01              |                               | 29 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lethargy; Overdose;<br>Seizure; Somnolence;<br>Suicide Attempt                                                 | Escitalopram Oxalate    |                           |                             | S                        |                               | 250 Mg Once                   |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Sep-2007                                                                     | 6433298                | EXPEDITED (15-DAY) | N                  | OT              | L07-USA-03852-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hyperventilation; Irritability; Nausea; Overdose; Tachypnoea; Tremor | Escitalopram Oxalate   |                    |                    | S               |                      | 1 Tablet Once        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2007                                                                     | 6433314                | EXPEDITED (15-DAY) | N                  | OT              | L07-USA-03848-01     |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Overdose; Respiratory Depression; Suicide Attempt            | Escitalopram Oxalate   |                    |                    | S               |                      | 15 Mg Once           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2007                                                                     | 6433340                | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-05060-01     |                      | 77 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion  | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                 | Polyethylene Glycols   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Aspirin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                 | Veratran (Clotiazepam) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2007                                                                     | 6433550                | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-UKI-05054-01     |                      | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Foot Fracture; Generalised Tonic-Clonic Seizure;             | Cipralext              |                    |                    | S               | Oral                 | 20 Mg Qd; Po         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Legal Problem; Petit Mal  
Epilepsy

| <a href="#">FDA Received Date</a>                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Sep-2007                                                 | 6433650                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03842-01              |                               | 37 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Pain;<br>Arrhythmia; Overdose;<br>Suicide Attempt | Escitalopram Oxalate    |                           |                             | S                        |                               | 30 Tablet Once                |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Sep-2007                                                                      | 6433933                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03850-01              |                               | 30 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lethargy; Overdose;<br>Respiratory Depression;<br>Somnolence; Suicide<br>Attempt | Escitalopram Oxalate    |                           |                             | S                        |                               | 12 Tablet Once                |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Sep-2007                                                        | 6433970                 | EXPEDITED (15-DAY)        | N                           | OT                       | L07-USA-03849-01              |                               | 19 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyperventilation; Lethargy;<br>Overdose; Somnolence;<br>Tachypnoea | Escitalopram Oxalate    |                           |                             | S                        |                               | 36 Tablet Once                |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Sep-2007                                | 6382226                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S07-JPN-03322-01              |                               | 42 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alcohol Use; Blood<br>Potassium Decreased; | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| Blood Sodium Decreased;                    | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

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|                             |                              |   |      |             |              |
|-----------------------------|------------------------------|---|------|-------------|--------------|
| Bundle Branch Block;        | Escitalopram Oxalate         | S | Oral | 20 Mg Qd Po | Not Reported |
| Condition Aggravated;       | Escitalopram Oxalate         | S | Oral | 20 Mg Qd Po | Not Reported |
| Electrocardiogram St-T      | Escitalopram Oxalate         | S | Oral | 10 Mg Qd Po | Not Reported |
| Change; Fatigue; Hepatitis  | Lasix                        | S | Oral | 20 Mg Qd Po | Not Reported |
| Acute; Hepatitis Alcoholic; | Lasix                        | S | Oral | 20 Mg Qd Po | Not Reported |
| Major Depression;           | Lasix                        | S | Oral | 20 Mg Qd Po | Not Reported |
| Malaise; Oedema             | Lasix                        | S | Oral | 20 Mg Qd Po | Not Reported |
| Peripheral; Somnolence;     | Lasix                        | S | Oral | 20 Mg Qd Po | Not Reported |
| Stomatitis; Therapeutic     | Lasix                        | S | Oral | 40 Mg Qd Po | Not Reported |
| Product Effect Decreased;   | Alcohol                      | S |      |             | Not Reported |
| Vomiting                    | Alprazolam                   | C |      |             | Not Reported |
|                             | Rohypnol (Flunitrazepam)     | C |      |             | Not Reported |
|                             | Gasmotin (Mosapride Citrate) | C |      |             | Not Reported |
|                             | Gaster                       | C |      |             | Not Reported |
|                             | Levothyroxine Sodium         | C |      |             | Not Reported |
|                             | Allopurinol                  | C |      |             | Not Reported |
|                             | Bisacodyl                    | C |      |             | Not Reported |
|                             | Nauzelin                     | C |      |             | Not Reported |
|                             | Alesion (Epinastine          | C |      |             | Not Reported |
|                             | Hydrochloride)               |   |      |             |              |
|                             | Medicon (Dextromethorphan    | C |      |             | Not Reported |
|                             | Hydrobromide)                |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2007              | 6432537       | DIRECT           |                    |                 |                      |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Medication Error; Product | Lipitor        |              |            | S           |              | Tablet             |                 | Pfizer     |
| Dispensing Error          | Lexapro        |              |            | S           |              | Tablet             |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2007              | 6433664       | DIRECT           |                    |                 |                      |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Medication Error      | Lexapro        |              |            | S           |              | Tablet             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Sep-2007                                                               | 6435298                                | EXPEDITED (15-DAY) | Y                  | HO, LT          | S07-FRA-05055-01     |                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse;<br>Dehydration; Hepatitis;<br>Hepatitis Cholestatic | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Unspecified Ingredient                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2007                                                               | 6435358                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-UKI-05053-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;<br>Supraventricular<br>Tachycardia                   | Ciprallex                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Ciprallex                              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Unspecified Ingredient                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2007                                                               | 6435116                                | EXPEDITED (15-DAY) | Y                  | DE, LT          | S07-TUN-05059-01     |                      | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus; Renal<br>Failure                                       | Escitalopram Oxalate                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                           | Levothyroxin (Levothyroxine<br>Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Insulin Nos                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Metformin Hydrochloride                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Gliclazide                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2007                                                               | 6321682                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-BEL-02020-01     |                      | 23 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Renal Failure;<br>Rhabdomyolysis;                                         | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |



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|                                |                                            |   |      |             |  |  |  |  |              |
|--------------------------------|--------------------------------------------|---|------|-------------|--|--|--|--|--------------|
| Serotonin Syndrome;<br>Syncope | Escitalopram Oxalate                       | S | Oral | 10 Mg Qd Po |  |  |  |  | Not Reported |
|                                | Spasmomen (Otilonium Bromide)              | C |      |             |  |  |  |  | Not Reported |
|                                | Perenterol Forte (Saccharomyces Boulardii) | C |      |             |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2007              | 6509487       | DIRECT           | N                  | DE              |                      |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide;<br>Irritability | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2007              | 6672213       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05138-01     |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Alcohol Interaction; Amnesia; Anxiety; Blood Alcohol Increased; Confusional State; Hallucination | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                             | Loprazolam           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                             | Alprazolam           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                             | Alcohol              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2007              | 6427903       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-BRISTOL-MYERS SQUIBB COMPANY-13916515 |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Stevens-Johnson Syndrome | Aripiprazole         |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Lamotrigine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2007              | 6428065       | EXPEDITED (15-DAY) | Y                  | DS, OT          | AU-PFIZER INC-2007071079 |                      | 61 YR      | Male       | AUS            |

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| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Blood Creatine Phosphokinase Increased; Chromaturia; Depression; Liver Function Test Abnormal; Muscular Weakness; Myalgia; Rhabdomyolysis | Lipitor                |                    |                    | S               | Oral                 |                             |                 | Not Reported |                |
|                                                                                                                                           | Lexapro                |                    |                    | S               | Oral                 |                             |                 | Not Reported |                |
|                                                                                                                                           | Unspecified Ingredient |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                           | Allopurinol            |                    |                    | C               | Oral                 | Daily Dose:100mg-Freq:Daily |                 | Not Reported |                |
|                                                                                                                                           | Allopurinol            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                           | Cartia Xt              |                    |                    | C               | Oral                 | Daily Dose:100mg-Freq:Daily |                 | Not Reported |                |
|                                                                                                                                           | Metoprolol             |                    |                    | C               | Oral                 | Daily Dose:25mg-Freq:Daily  |                 | Not Reported |                |
|                                                                                                                                           | Ramipril               |                    |                    | C               | Oral                 | Daily Dose:2.5mg-Freq:Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2007                                                                                                                               | 6434924                | DIRECT             | Y                  | HO              |                      |                             | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Mental Status Changes; Rhabdomyolysis                                                                                                     | Lexapro                |                    |                    | S               | Oral                 | Po                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2007                                                                                                                               | 6438376                | EXPEDITED (15-DAY) | Y                  | CA              |                      | S07-USA-05043-02            |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Disease Congenital; Maternal Exposure During Pregnancy; Trisomy 18                                                                  | Lexapro                |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental     |                 | Not Reported |                |
|                                                                                                                                           | Lexapro                |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental     |                 | Not Reported |                |
|                                                                                                                                           | Lexapro                |                    |                    | S               | Transplacental       | 5 Mg Qd Transplacental      |                 | Not Reported |                |
|                                                                                                                                           | Lexapro                |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental     |                 | Not Reported |                |
|                                                                                                                                           | Prenatabs Fa           |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <a href="#">FDA Received Date</a>                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Sep-2007                                                                                                                | 6439046                 | EXPEDITED (15-DAY)        | N                           | OT                       | S07-USA-05170-01              |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lung Neoplasm                                                                                                              | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                            | Klonopin                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Sep-2007                                                                                                                | 6439424                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S07-CAN-05150-01              |                               | 18 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Crying; Drug Withdrawal Syndrome; Fear; Hallucination; Nervousness; Nightmare; Suicidal Behaviour                          | Cipralex                |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Sep-2007                                                                                                                | 7302117                 | DIRECT                    | Y                           | OT                       |                               |                               | 49 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatic Fibrosis; Hepatic Necrosis; Hepatitis C; Hepatitis C Rna Positive; Hepatotoxicity; Liver Injury; Suicidal Ideation | Levaquin                |                           |                             | S                        |                               | 500mg/Day                     |                          | Not Reported        |                         |
|                                                                                                                            | Lexapro                 |                           |                             | S                        |                               | 20mg/Day                      |                          | Not Reported        |                         |
|                                                                                                                            | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                            | Vicodin                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Oct-2007                                                                                                                | 6360277                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S07-USA-02803-01              |                               | 56 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Muscle Spasms; Neck Pain; Odynophagia; Rheumatoid Arthritis                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                    |   |      |             |              |
|--|------------------------------------|---|------|-------------|--------------|
|  | Lexapro                            | S | Oral | 10 Mg Qd Po | Not Reported |
|  | Lopresor                           | C |      |             | Not Reported |
|  | Nasonex                            | C |      |             | Not Reported |
|  | Zocor                              | C |      |             | Not Reported |
|  | Loratadine\Pseudoephedrine Sulfate | C |      |             | Not Reported |
|  | Hydrochlorothiazide                | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2007              | 6410604       | EXPEDITED (15-DAY) | Y                  | OT              | S07-PRT-03624-01     |                      | 88 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Transient Ischaemic Attack | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2007              | 6426565       | EXPEDITED (15-DAY) | Y                  | DS              | S07-SWI-03793-01     |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Photophobia;<br>Xerophthalmia | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2007              | 6432430       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007080103 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Abdominal Discomfort;<br>Anxiety; Crying;<br>Depression; Emotional Distress;<br>Gastroesophageal Reflux Disease; Irritability;<br>Suicidal Ideation | Chantix<br>Celexa<br>Lexapro |              |            | S<br>S<br>S |              | Text:Every Day     |                 | Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2007              | 6440794       | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-05277-01     |                      |            | Female     | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neutropenia           | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2007              | 5846815       | EXPEDITED (15-DAY) | Y                  | HO, LT          | A044-002-005675      |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Bradycardia; Essential<br>Tremor; Torsade De<br>Pointes | Aricept                  |              |            | S           | Oral         | 10 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                                                      | Inderal                  |              |            | S           | Oral         | 80 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                                                      | Escitalopram Oxalate     |              |            | S           | Oral         | 10 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                                                      | Prochlorperazine Maleate |              |            | C           |              |                       |                 | Not Reported |
|                                                                                      | Omeprazole               |              |            | C           |              |                       |                 | Not Reported |
|                                                                                      | Ferrous Sulfate          |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2007              | 6352981       | EXPEDITED (15-DAY) | Y                  | HO              | S07-CZE-02734-01     |                      | 74 YR      | Female     | CZE            |

| <u>Preferred Term</u>            | <u>Product</u>                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-----------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angina Pectoris; Panic<br>Attack | Ciprallex                                                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                  | Monotab (Isosorbide<br>Mononitrate) (Isosorbide<br>Mononitrate) |              |            | C           |              |                    |                 | Not Reported |
|                                  | Simcalmed (Simvastatin)                                         |              |            | C           |              |                    |                 | Not Reported |
|                                  | Trenaxum (Rilmenidine)                                          |              |            | C           |              |                    |                 | Not Reported |
|                                  | Hydrochlorothiazide                                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Oct-2007              | 6415097       | EXPEDITED (15-DAY) | Y                  | OT              | B0487285A            |                      | 41 YR      | Female     | NOR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |           |   |         |                   |                 |
|-----------------------|-----------|---|---------|-------------------|-----------------|
| Abortion Spontaneous; | Lamictal  | S | Oral    |                   | Glaxosmithkline |
| Foetal Heart Rate     | Lyrica    | S | Oral    | 300mg Per Day     | Not Reported    |
| Abnormal              | Seroquel  | S | Oral    | 100mg Per Day     | Not Reported    |
|                       | Cipralext | S | Unknown | 10mg Per Day      | Not Reported    |
|                       | Diazepam  | S | Unknown | 100mg As Required | Glaxosmithkline |

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------|----------------|
| 02-Oct-2007                                                                                                                                                          | 6438434        | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 50 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Akathisia; Confusional State; Depression; Dry Mouth; Gait Disturbance; Impaired Self-Care; Musculoskeletal Stiffness; Paresis; Rhabdomyolysis; Therapy Non-Responder | Abilify        |                  |                    | S               | Oral                 | 30 Mg 1/Day Po       | 8 MTH           | Bristol Myers Squibb |                |
|                                                                                                                                                                      | Lexapro        |                  |                    | S               | Oral                 | 10 Mg 1/Day Po       | 4 DAY           | Forest               |                |

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Oct-2007                                                                                                                                 | 6328172                    | EXPEDITED (15-DAY) | Y                  | HO              | S07-IRL-02108-01     |                      | 74 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Arthralgia; Decreased Appetite; Depression; Lower Respiratory Tract Infection; Meningitis; Serotonin Syndrome; Weight Decreased | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                             | Claforan                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Digoxin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Lanoprazole (Lansoprazole) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Metoprolol                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Doxazosin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Ferrous Fumarate           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Singulair                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Warfarin Sodium            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Rohypnol (Flunitrazepam)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Levothyroxine Sodium       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                             | Oxycontin                  |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 03-Oct-2007               | 6433660                  | EXPEDITED (15-DAY) | Y                  | HO              | US-RB-008168-07            |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Bruxism; Fall;   | Buprenorphine            |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Flushing; Incoherent;     | Buprenorphine            |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Insomnia; Muscle          | Buprenorphine            |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Tightness; Muscle         | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Twitching; Mydriasis;     | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Myoclonus; Paraesthesia;  | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Restlessness; Serotonin   | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Syndrome; Status          | Aripiprazole             |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| Epilepticus; Tremor       | Mirtazapine              |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2007               | 6434340                  | EXPEDITED (15-DAY) | Y                  | HO              | GB-ASTRAZENECA-2007AC01870 |                      | 76 YR           | Female       | GBR            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Torsade | Omeprazole               |                    |                    | S               |                            |                      |                 | Not Reported |                |
| De Pointes                | Propranolol              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                           | Propranolol              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                           | Donepezil Hydrochloride  |                    |                    | S               |                            |                      | 2 YR            | Not Reported |                |
|                           | Escitalopram Oxalate     |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2007               | 6434407                  | EXPEDITED (15-DAY) | Y                  | OT              | GB-PFIZER INC-2007079996   |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;      | Sertraline Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |
| Dizziness; Drug           | Escitalopram Oxalate     |                    |                    | S               |                            |                      |                 | Not Reported |                |
| Withdrawal Syndrome;      | Fluoxetine               |                    |                    | S               |                            |                      |                 | Not Reported |                |
| Eye Disorder; Headache;   | Paroxetine Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| Intentional Overdose;     |                          |                    |                    |                 |                            |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Irritability; Migraine; Mood  
Altered; Nausea; Self-  
Injurious Ideation; Suicidal  
Ideation; Tearfulness

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2007              | 6442484       | EXPEDITED (15-DAY) | Y                  | LT              | GXKR2007GB08305      |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure | Omeprazole              |              |            | S           |              | 20 Mg              |                 | Not Reported |
| Increased; Drug         | Propranolol             |              |            | S           |              | 80 Mg              |                 | Not Reported |
| Interaction;            | Donepezil Hydrochloride |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Electrocardiogram Qt    | Escitalopram Oxalate    |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Prolonged; Essential    |                         |              |            |             |              |                    |                 |              |
| Tremor; Sinus           |                         |              |            |             |              |                    |                 |              |
| Bradycardia; Syncope;   |                         |              |            |             |              |                    |                 |              |
| Torsade De Pointes      |                         |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2007              | 6442650       | EXPEDITED (15-DAY) | Y                  | OT              | 6027066              |                      | 38 YR      | Male       | TUR            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Extrapyramidal Disorder; | Sertraline              |              |            | S           |              | 50,000 Mg                  |                 | Not Reported |
| Major Depression;        | Escitalopram Oxalate    |              |            | S           |              |                            |                 | Not Reported |
| Parkinsonism;            | Tianeptine              |              |            | S           |              | 12,5000 Mg (12,5 Mg,       |                 | Not Reported |
| Restlessness; Tremor     |                         |              |            |             |              | Titrated Up To 37.5 Mg);   |                 |              |
|                          |                         |              |            |             |              | 37,5000 Mg (37,5 1 In 1 D) |                 |              |
|                          | Biperiden Hydrochloride |              |            | C           |              |                            |                 | Not Reported |
|                          | Lorazepam               |              |            | C           |              |                            |                 | Not Reported |
|                          | Bupropion Hydrochloride |              |            | C           |              |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2007              | 6366786       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-03006-01     |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                                                    |                       |      |             |              |
|----------------------------------------------------------------------------|----------------------------------------------------|-----------------------|------|-------------|--------------|
| Completed Suicide; Drug Intolerance; Gun Shot Wound; Hypersomnia; Sedation | Lexapro<br>Xanax<br>Zyprexa<br>Temazepam<br>Prozac | S<br>C<br>C<br>C<br>C | Oral | 10 Mg Qd Po | Not Reported |
|----------------------------------------------------------------------------|----------------------------------------------------|-----------------------|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2007              | 6412348       | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-03645-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haematemesis          | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2007              | 6442872       | EXPEDITED (15-DAY) | Y                  | DE              | S07-FRA-05252-01     |                      | 43 YR      | Male       | FRA            |

| <u>Preferred Term</u>                        | <u>Product</u>                                                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|----------------------------------------------|-------------------------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Hyperthermia Malignant; Toxic Shock Syndrome | Escitalopram Oxalate<br>Neoral<br>Tramadol Hydrochloride<br>Durogesxc (Prntanyl)<br>Xanax |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2007              | 6453769       | EXPEDITED (15-DAY) | Y                  | OT              | 2007RR-10221         |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|------------------|--------------|--------------------|-----------------|--------------------------------------------------------------|
| Drug Intolerance; Drug Withdrawal Syndrome; Dystonia; Eye Disorder; Inappropriate Schedule Of Product Administration; Intentional Overdose; Reaction To Excipient; Self-Injurious Ideation; Suicidal Ideation | Paroxetine<br>Fluoxetine<br>Sertraline<br>Ciprallex |              |            | S<br>S<br>S<br>S | Oral         | Oral               |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 05-Oct-2007                                                         | 6346703                          | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-CAN-02602-01                         |                      | 62 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Immune Thrombocytopenic Purpura; Immune Thrombocytopenic Purpura    | Ciprallex                        |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported         |                |
|                                                                     | Ciprallex                        |                    |                    | S               | Oral                                     | 5 Mg Qd Po           |                 | Not Reported         |                |
|                                                                     | Celexa                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Metoprolol                       |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Altace                           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Crestor                          |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Asaphen (Acetylsalicylic Acid)   |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Inexium (Esomeprazole)           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Oct-2007                                                         | 6410503                          | EXPEDITED (15-DAY) | Y                  | HO              | ES-BRISTOL-MYERS SQUIBB COMPANY-13901236 |                      | 75 YR           | Female               | ESP            |
| <u>Preferred Term</u>                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Inappropriate Antidiuretic Hormone Secretion; Restlessness | Coaprovel Tabs 300mg/12.5mg      |                    |                    | S               | Oral                                     |                      |                 | Bristol Myers Squibb |                |
|                                                                     | Deprax (Trazodone Hydrochloride) |                    |                    | S               | Oral                                     |                      |                 | Apothecon            |                |
|                                                                     | Risperidone                      |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                     | Escitalopram Oxalate             |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                     | Tegretol                         |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
|                                                                     | Duphalac                         |                    |                    | C               | Oral                                     |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 05-Oct-2007                                                         | 6436287                          | EXPEDITED (15-DAY) | Y                  | OT              | DE-JNJFOC-20070904459                    |                      |                 | Male                 | DEU            |
| <u>Preferred Term</u>                                               | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Apraxia; Maternal Exposure During Pregnancy                         | Topamax                          |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Ciprallex                        |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                     | Levothyroxine                    |                    |                    | S               |                                          |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Sodium\Potassium Iodide |   |              |
| Singulair               | S | Not Reported |
| Berotec                 | S | Not Reported |
| Symbicort               | S | Not Reported |
| Ibuprofen               | S | Not Reported |
| Methyldopa              | S | Not Reported |
| Folic Acid              | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 05-Oct-2007              | 6436477       | EXPEDITED (15-DAY) | Y                  | HO              | TR-ASTRAZENECA-2007AC01882 |                      | 76 YR      | Male       | TUR            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                              | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                              | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2007              | 6442660       | DIRECT           | Y                  | HO              |                      |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Presyncope; Serotonin Syndrome; Syncope | Lexapro        |              |            | S           | Oral         | 10mg Bid Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 08-Oct-2007              | 6437689       | EXPEDITED (15-DAY) |                    | HO              | GB-ROXANE LABORATORIES, INC-2007-BP-21949RO |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Interaction;     | Propranolol    |              |            | S           |              |                    | 5 DAY           | Roxane     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                         |   |       |              |
|--------------------------------------------------------------------------------|-------------------------|---|-------|--------------|
| Electrocardiogram Qt Prolonged; Sinus Bradycardia; Syncope; Torsade De Pointes | Propranolol             | S | 5 DAY | Roxane       |
|                                                                                | Escitalopram Oxalate    | S |       | Not Reported |
|                                                                                | Donepezil Hydrochloride | S | 2 YR  | Not Reported |
|                                                                                | Omeprazole              | S |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2007              | 6331554       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-CAN-02227-01     |                      | 34 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness | Cipralext              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                         | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2007              | 6354627       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-02683-01     |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Cardiotoxicity; Myocardial Infarction; Sudden Death | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                 | Neurontin      |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Tenormin       |              |            | C           |              |                    |                 | Not Reported |
|                                                                 | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2007              | 6445215       | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-05283-01     |                      | 85 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Cipralext          |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Cipralext          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Cipralext          |              |            | S           |              |                    |                 | Not Reported |
|                       | Prednisolone       |              |            | C           |              |                    |                 | Not Reported |
|                       | Calcimagon-D3      |              |            | C           |              |                    |                 | Not Reported |
|                       | Carvedilol         |              |            | C           |              |                    |                 | Not Reported |
|                       | Lorzaar Plus       |              |            | C           |              |                    |                 | Not Reported |
|                       | Pravastatin Sodium |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                                                   |                    |                    |                 |                      |                      |                 |                              |                |
|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Allopurinol                                                                                                      |                                                   |                    | C                  |                 |                      | Not Reported         |                 |                              |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Oct-2007                                                                                                      | 6445219                                           | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-05317-01     |                      | 45 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dissociation; Disturbance<br>In Attention; Dizziness                                                             | Escitalopram Oxalate                              |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Oct-2007                                                                                                      | 6445220                                           | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-05318-01     |                      | 19 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depersonalisation/Dereali<br>sation Disorder;<br>Dissociation; Disturbance<br>In Attention; Dizziness            | Escitalopram Oxalate<br>Several Unspecified Drugs |                    |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Oct-2007                                                                                                      | 6445225                                           | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-05316-01     |                      | 65 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Confusional State;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Dissociation; Disturbance<br>In Attention | Escitalopram Oxalate                              |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Oct-2007                                                                                                      | 6445497                                           | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05272-01     |                      | 18 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Alcohol Use; Drug<br>Withdrawal Syndrome;<br>Dysphoria; Psychotic                                                | Lexapro<br>Alcohol                                |                    |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Treatment  
Noncompliance

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Oct-2007                       | 6201912                 | EXPEDITED (15-DAY)        | Y                           | OT                       | T06-GER-05026-01              |                               | 40 YR                    | Female              | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Vaginal Haemorrhage               | Cipralext               |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Cipralext               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Oct-2007                       | 6429573                 | EXPEDITED (15-DAY)        | Y                           | LT                       | S07-FRA-02864-01              |                               | 24 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Angioedema                        | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Oct-2007                             | 6438854                   | EXPEDITED (15-DAY)        | Y                           | HO                       | GB-WYE-H00482507              |                               | 76 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Torsade<br>De Pointes | Escitalopram Oxalate      |                           |                             | S                        | Unknown                       | 10 Mg                         |                          | Unknown             |                         |
|                                         | Omeprazole                |                           |                             | S                        | Unknown                       | 20 Mg                         |                          | Unknown             |                         |
|                                         | Propranolol Hydrochloride |                           |                             | S                        | Unknown                       | 80 Mg                         |                          | Wyeth               |                         |
|                                         | Propranolol Hydrochloride |                           |                             | S                        |                               |                               |                          | Wyeth               |                         |
|                                         | Donepezil Hydrochloride   |                           |                             | S                        | Unknown                       | 10 Mg                         |                          | Unknown             |                         |

| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Oct-2007                                       | 6440625                 | EXPEDITED (15-DAY)        | Y                           | HO                       | S07-TUN-05202-01              |                               | 53 YR                    | Male                | TUN                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Diabetic Ketoacidosis;<br>Treatment Noncompliance | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                   | Insulin Nos             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Oct-2007                                                      | 6376618                 | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-03135-01     |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                      | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                  | Lunesta                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                  | Effexor                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                  | Zyrtec                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2007                                                      | 6445401                 | DIRECT             | Y                  | OT              |                      |                      | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Skin; Skin Fissures; Skin Irritation                         | Lexapro                 |                    |                    | S               | Oral                 | 1po Qd               |                 | Not Reported |                |
|                                                                  |                         |                    |                    |                 | Oral                 | 1po Qd               |                 |              |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2007                                                      | 6446097                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | 162066ISR            |                      | 76 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Sinus Bradycardia; Syncope; Torsade De Pointes | Propranolol             |                    |                    | S               |                      | (80 Mg)              | 2 YR            | Not Reported |                |
|                                                                  | Donepezil Hydrochloride |                    |                    | S               |                      | (10 Mg)              |                 | Not Reported |                |
|                                                                  | Escitalopram Oxalate    |                    |                    | S               |                      | (10 Mg)              |                 | Not Reported |                |
|                                                                  | Omeprazole              |                    |                    | S               |                      | (20 Mg)              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                      | 4061564                 | NON-EXPEDITED      |                    | OT              | S03-USA-02642-01     |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Adverse Drug Reaction;                          | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                    |         |   |      |             |              |
|--------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------------|
| Anxiety; Burning Sensation; Dry Mouth; Feeling Abnormal; Night Sweats; Suicidal Ideation; Tremor; Weight Decreased | Lexapro | S | Oral | 5 Mg Qd Po  | Not Reported |
|                                                                                                                    | Lexapro | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                                                                                    | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                                    | Lexapro | S |      |             | Not Reported |
|                                                                                                                    | Effexor | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 5884742       | NON-EXPEDITED    |                    | HO              | S05-USA-02813-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Decreased Appetite; Headache; Hypersensitivity; Lethargy; Nausea | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                           | Lantus         |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Glipizide      |              |            | C           |              |                    |                 | Not Reported |
|                                                                           | Diovan         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6207108       | NON-EXPEDITED    | Y                  | HO, OT          | S06-USA-04715-01     |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lithium        |              |            | S           | Oral         | 300 Mg Qd Po       |                 | Not Reported |
|                       | Lithium        |              |            | S           | Oral         | 1200 Mg Qd Po      |                 | Not Reported |
|                       | Lithium        |              |            | S           |              |                    |                 | Not Reported |
|                       | Wellbutrin XL  |              |            | C           |              |                    |                 | Not Reported |
|                       | Geodon         |              |            | C           |              |                    |                 | Not Reported |
|                       | Atenolol       |              |            | C           |              |                    |                 | Not Reported |
|                       | Lipitor        |              |            | C           |              |                    |                 | Not Reported |
|                       | Maxalt         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6474932       | NON-EXPEDITED    | Y                  |                 | 2007SP002530         |                      |            | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Ineffective; Insomnia                                                                        | Lunesta        |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                   | Lexapro        |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                       | 6478476        | NON-EXPEDITED    |                    | OT              | S07-USA-00190-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Accidental Overdose;<br>Confusional State;<br>Hyperhidrosis; Nausea;<br>Thirst | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                   | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                   | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                   | Morphine       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                       | 6478524        | NON-EXPEDITED    |                    | OT              | S07-USA-00185-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective; Emotional Disorder; Myocardial Infarction                           | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                   | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                       | 6478547        | NON-EXPEDITED    |                    | OT              | S07-USA-00011-01     |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                                                                  | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Once Po        |                 | Not Reported |                |
|                                                                                                   | Aleve          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                       | 6478560        | NON-EXPEDITED    | Y                  | OT              | S06-USA-05394-01     |                      | 18 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Suicidal Ideation                                                                                                        | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Lexapro             |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                              | 6478611             | NON-EXPEDITED    | Y                  | OT              | S06-USA-05167-01     |                      | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyperhidrosis; Impatience;<br>Psychomotor<br>Hyperactivity; Suicidal<br>Ideation                   | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Protonix            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Diovan              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Coreg               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Singulair           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                          | Lamisil             |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                              | 6478613             | NON-EXPEDITED    | Y                  | OT              | S06-USA-05225-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;<br>Loss Of Consciousness;<br>Mydriasis; Personality<br>Change; Visual<br>Impairment                 | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Lexapro             |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                          | Birth Control Pills |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                              | 6478617             | NON-EXPEDITED    | N                  | HO              | S06-USA-05109-01     |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Bradycardia; Disturbance<br>In Attention; Headache;<br>Loss Of Consciousness;<br>Supraventricular | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                          | Lexapro             |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Tachycardia; Tachycardia;  
Vision Blurred

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478872       | NON-EXPEDITED    | Y                  | OT              | S07-USA-01044-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Delusion; Hallucination;<br>Auditory; Libido Increased;<br>Musculoskeletal Stiffness;<br>Suicidal Ideation | Lexapro<br>Lithium |              |            | S<br>C      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478874       | NON-EXPEDITED    |                    | OT              | S07-USA-00820-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Hot Flush;<br>Intentional Overdose; Loss<br>Of Consciousness | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478882       | NON-EXPEDITED    |                    | OT              | S07-USA-00821-01     |                      | 45 YR      | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|----------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Disorientation; Panic<br>Attack; Suicidal Ideation | Lexapro<br>Bupropion<br>Alcohol |              |            | S<br>S<br>C |              | 150 Mg Bid         |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478894       | NON-EXPEDITED    |                    | OT              | S07-USA-00667-01     |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dry Mouth; Dyspnoea;<br>Insomnia; Paraesthesia; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |          |   |      |             |              |
|------------------------------------------------|----------|---|------|-------------|--------------|
| Sinusitis; Suicidal Ideation; Weight Increased | Lexapro  | S | Oral | 20 Mg Qd Po | Not Reported |
|                                                | Lexapro  | S | Oral | 30 Mg Qd Po | Not Reported |
|                                                | Klonopin | C |      |             | Not Reported |
|                                                | Seroquel | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478905       | NON-EXPEDITED    |                    | OT              | S07-USA-00669-01     |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Insomnia; Irritability; Mood Altered; Panic Attack; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                           | Ambien         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                           | Klonopin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478912       | NON-EXPEDITED    | N                  | OT              | S07-USA-01632-01     |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Coordination Abnormal; Decreased Appetite; Depression; Disturbance In Attention; Fatigue; Nausea; Suicidal Ideation; Weight Decreased | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                 | Clonazepam     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478913       | NON-EXPEDITED    | Y                  | OT              | S07-USA-01605-01     |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                       | Lithium        |              |            | C           |              |                    |                 | Not Reported |
|                       | Synthroid      |              |            | C           |              |                    |                 | Not Reported |
|                       | Pepcid         |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------|-------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 15-Oct-2007              | 6478914                       | NON-EXPEDITED    | Y                  | HO              | S07-USA-01588-01     |                      |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Overdose                 | Lexapro<br>Lexapro            |                  |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Oct-2007              | 6478919                       | NON-EXPEDITED    | Y                  | HO              | S07-USA-00511-01     |                      | 44 YR           | Female                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Syncope                  | Lexapro                       |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported                                 |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Oct-2007              | 6478921                       | NON-EXPEDITED    | Y                  | HO              | S07-USA-01527-01     |                      | 32 YR           | Male                                         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Pulmonary Embolism       | Lexapro<br>Diamox Sequels     |                  |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Oct-2007              | 6478922                       | NON-EXPEDITED    | N                  |                 | S07-USA-01521-01     |                      | 44 YR           | Female                                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Suicidal Ideation        | Lexapro<br>Klonopin<br>Elavil |                  |                    | S<br>C<br>C     | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Oct-2007              | 6478930                       | NON-EXPEDITED    |                    | OT              | S07-USA-00489-01     |                      | 51 YR           | Male                                         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                        |   |      |             |              |
|--------------------------|------------------------|---|------|-------------|--------------|
| Blood Glucose Increased; | Lexapro                | S | Oral | 10 Mg Qd Po | Not Reported |
| Dry Mouth; Nausea        | Lexapro                | S | Oral | 5 Mg Qd Po  | Not Reported |
|                          | Lexapro                | S | Oral | 10 Mg Qd Po | Not Reported |
|                          | Insulin Nos            | C |      |             | Not Reported |
|                          | Singulair              | C |      |             | Not Reported |
|                          | Unspecified Ingredient | C |      |             | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Oct-2007                       | 6478932                | NON-EXPEDITED             |                             | OT                       | S07-USA-00482-01              |                               | 17 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Abdominal Pain;                | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
| Dizziness; Orthostatic         | Topamax                 |                       |                     | C                    |                       |                             |                          | Not Reported        |
| Hypotension                    |                         |                       |                     |                      |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Oct-2007                       | 6478938                | NON-EXPEDITED             | N                           | OT                       | S07-USA-03272-01              |                               | 64 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Contusion; Dizziness; Fall;    | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
| Hyperhidrosis; Loss Of         |                         |                       |                     |                      |                       |                             |                          |                     |
| Consciousness                  |                         |                       |                     |                      |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Oct-2007                       | 6478939                | NON-EXPEDITED             | N                           | OT                       | S07-USA-03200-01              |                               | 80 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Fall; Upper Limb Fracture      | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Unspecified Ingredient  |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 15-Oct-2007                       | 6478941                | NON-EXPEDITED             | Y                           | HO                       | S07-USA-01394-01              |                               | 57 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |               |   |      |             |              |
|---------------------------|---------------|---|------|-------------|--------------|
| Aggression; Cardiac       | Lexapro       | S | Oral | 10 Mg Qd Po | Not Reported |
| Murmur; Decreased         | Wellbutrin XL | S |      | 300 Mg Qd   | Not Reported |
| Appetite; Dehydration;    | Alcohol       | S |      |             | Not Reported |
| Depression; Mania;        | Lotrel        | C |      |             | Not Reported |
| Suicidal Ideation; Tremor |               |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478944       | NON-EXPEDITED    | Y                  | OT              | S07-USA-01351-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Mania                 | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po             |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po             |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po,20 Mg Qd Po |                 | Not Reported |
|                       |                |              |            |             | Oral         | 10 Mg Qd Po,20 Mg Qd Po |                 |              |
|                       | Effexor        |              |            | C           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478947       | NON-EXPEDITED    | Y                  | HO              | S07-USA-01156-01     |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrointestinal      | Lexapro             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Haemorrhage           | Zanaflex            |              |            | C           |              |                    |                 | Not Reported |
|                       | Norvasc             |              |            | C           |              |                    |                 | Not Reported |
|                       | Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6478950       | NON-EXPEDITED    | N                  | OT              | S07-USA-01051-01     |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Diarrhoea; Dizziness;     | Lexapro        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Feeling Hot; Headache;    | Avapro         |              |            | C           |              |                    |                 | Not Reported |
| Insomnia; Peripheral      |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Coldness; Restlessness;  
Tachycardia; Tremor

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 15-Oct-2007                       | 6479006                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02246-02              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastrointestinal<br>Haemorrhage   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                       | 6479008                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02246-03              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastrointestinal<br>Haemorrhage   | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                       | 6479011                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02247-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                       | 6479013                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02252-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Sodium Decreased            | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                       | 6479017                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02252-02              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



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|                                                                                           |                        |                  |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Sodium Decreased                                                                    |                        | Lexapro          |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                               | 6479021                | NON-EXPEDITED    |                    | OT              | S07-USA-02239-01     |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anger;<br>Anxiety; Paranoia                                                   | Lexapro                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                           | Coumadin               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Nexium (Esomeprazole)  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Lovastatin             |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                               | 6479022                | NON-EXPEDITED    |                    | OT              | S07-USA-02220-01     |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Flat Affect; Impulse-<br>Control Disorder; Mental<br>Status Changes; Suicidal<br>Ideation | Lexapro                |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                           | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                           | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                           | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |
|                                                                                           | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                           | Pletal                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Hydrocodone            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Unspecified Ingredient |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                               | 6479026                | NON-EXPEDITED    | N                  | OT              | S07-USA-02197-01     |                      | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Dizziness; Fall;<br>Nausea; Syncope                                            | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                           | Amaryl                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Plavix                 |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Zetia (Ezetimibe)      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                           | Prevacid               |                  |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-----------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                                                                                   | 6479028                                 | NON-EXPEDITED    | N                  | OT              | S07-USA-02166-01     |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Vomiting                                                             | Lexapro                                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Lexapro                                 |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                   | 6479031                                 | NON-EXPEDITED    | N                  | OT              | S07-USA-02115-01     |                      | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Suicidal<br>Ideation                                                              | Lexapro                                 |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                               | Xanax                                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                   | 6479080                                 | NON-EXPEDITED    | Y                  | OT              | S07-USA-02267-01     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Accidental Overdose;<br>Chest Pain; Dyspnoea;<br>Fatigue; Nausea; Vomiting | Lexapro                                 |                  |                    | S               | Oral                 | 70 Mg Once Po        |                 | Not Reported |                |
|                                                                                               | Wellbutrin (Bupropion<br>Hydrochloride) |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                               | Synthroid                               |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Hormones (Nos)                          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                   | 6479081                                 | NON-EXPEDITED    |                    |                 | S07-USA-02246-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal<br>Haemorrhage                                                               | Lexapro                                 |                  |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                                                                                                           | 6479160        | NON-EXPEDITED    | N                  | OT              | S07-USA-01427-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anger;<br>Insomnia; Psychomotor<br>Hyperactivity                                                          | Lexapro        |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Lexapro        |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Paxil          |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                           | 6479306        | NON-EXPEDITED    | Y                  | HO              | S07-USA-02435-01     |                      | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Hypoaesthesia;<br>Hypoaesthesia; Insomnia;<br>Nausea; Suicidal Ideation;<br>Thinking Abnormal | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Risperdal      |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Ativan         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Lamictal       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                           | 6479388        | NON-EXPEDITED    |                    | OT              | S07-USA-00672-01     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Erectile<br>Dysfunction; Suicidal<br>Ideation                                                      | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                       | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                       | Metoprolol     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                       | Clonidine      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                           | 6479473        | NON-EXPEDITED    | N                  | OT              | S06-USA-03505-01     |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity                                                                                                      | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Once Po         |                 | Not Reported |                |

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|                                                     |                                 |                  |                    |                 |                              |                      |                 |              |                |
|-----------------------------------------------------|---------------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Ceftin [Cefuroxime Axetil]<br>Nasarel (Flunisolide) |                                 |                  | S<br>C             |                 | Not Reported<br>Not Reported |                      |                 |              |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                         | 6479476                         | NON-EXPEDITED    |                    | HO              | S06-USA-03507-01             |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion     | Lexapro                         |                  |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                         | 6479488                         | NON-EXPEDITED    |                    | OT              | S06-USA-03508-01             |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mood Swings                                         | Lexapro                         |                  |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Pegasys (Peginterferon Alfa-2a) |                  |                    | S               | Subcutaneous                 | 180 Mcg Qw Sc        |                 | Not Reported |                |
|                                                     | Ambien                          |                  |                    | S               |                              | 10 Mg Qhs            |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                         | 6479498                         | NON-EXPEDITED    | Y                  | HO              | S06-USA-03512-01             |                      | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Orthostatic Hypotension;<br>Urine Output Decreased  | Lexapro                         |                  |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                         | 6479500                         | NON-EXPEDITED    |                    | OT              | S06-USA-03228-01             |                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia                                         | Lexapro                         |                  |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                                                              | 6479502        | NON-EXPEDITED    | N                  | HO, LT          | S06-USA-03513-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                          | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Lexapro        |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Seroquel       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Cogentin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Vistaril       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                              | 6479503        | NON-EXPEDITED    |                    | OT              | S06-USA-03417-01     |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Abilify        |                  |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                              | 6479516        | NON-EXPEDITED    |                    |                 | S06-USA-01165-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                                      | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                          | Actos          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Benicar        |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                          | Coumadin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                              | 6479518        | NON-EXPEDITED    | Y                  | OT              | S06-USA-03231-01     |                      | 52 YR           | Male         | USA            |

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| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Depression; Suicidal Ideation                                             | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                           | Pegintron               |                  |                    | S               |                      |                         | Not Reported    |              |                |
|                                                                           | Ribavirin               |                  |                    | S               |                      |                         | Not Reported    |              |                |
|                                                                           | Xanax                   |                  |                    | C               |                      |                         | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                               | 6479520                 | NON-EXPEDITED    | Y                  | OT              | S06-USA-02748-02     |                         |                 | Male         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation Neonatal; Hypoglycaemia; Hypotonia                              | Lexapro                 |                  |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                           | Geodon                  |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Trileptal               |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Macrodantin             |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Flagyl                  |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Fes04 (Ferrous Sulfate) |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Epidural (Nos)          |                  |                    | C               |                      |                         | Not Reported    |              |                |
|                                                                           | Terazol 7 (Terconazole) |                  |                    | C               |                      |                         | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                               | 6479576                 | NON-EXPEDITED    |                    | OT              | S07-USA-03344-01     |                         |                 | Male         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression; Hostility; Hyperhidrosis; Mania; Thinking Abnormal | Lexapro                 |                  |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                           | Trazodone Hydrochloride |                  |                    | S               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                               | 6479581                 | NON-EXPEDITED    |                    | OT              | S07-USA-03340-01     |                         |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                           | Lexapro                 |                  |                    | S               |                      |                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>            | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 15-Oct-2007                         | 6479583                    | NON-EXPEDITED    |                    | OT              | S07-USA-03340-02     |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>               | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicide Attempt                     | Lexapro                    |                  |                    | S               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                         | 6479585                    | NON-EXPEDITED    |                    | OT              | S07-USA-03328-01     |                      |                 | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation                   | Lexapro                    |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                         | 6479682                    | NON-EXPEDITED    |                    | OT              | S06-USA-04031-01     |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation                   | Lexapro                    |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 |            | Not Reported   |
|                                     | Multiple Medications (Nos) |                  |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                         | 6479700                    | NON-EXPEDITED    |                    | OT              | S06-USA-03740-01     |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Suicidal Ideation | Lexapro                    |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                     | Lexapro                    |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                     | Xanax                      |                  |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                         | 6479707                    | NON-EXPEDITED    | N                  | OT              | S06-USA-03685-01     |                      | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                    |         |   |      |             |              |
|------------------------------------|---------|---|------|-------------|--------------|
| Weight Increased; Weight Loss Poor | Lexapro | S | Oral | 30 Mg Qd Po | Not Reported |
|                                    | Ativan  | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479713       | NON-EXPEDITED    | N                  | OT              | S06-USA-03638-01     |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Aggression; Anger; Contusion; Cough; Discomfort; Drug Interaction; Dysphagia; Hyperhidrosis; Mental Impairment; Muscle Rigidity; Pain In Extremity; Panic Attack; Paranoia; Suicidal Ideation | Lexapro                                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                | Namenda                                        |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                                                                                                                                                | Acetaminophen\Dextromethorphan\Pseudoephedrine |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                | Sular                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                | Diovan                                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                | Aricept                                        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479727       | NON-EXPEDITED    | Y                  | OT              | S06-USA-03547-01     |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Dizziness; Fatigue; Hyperhidrosis; Insomnia; Nausea; Syncope; Tremor; Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479728       | NON-EXPEDITED    | Y                  | OT              | S06-USA-03503-01     |                      |            | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysphoria; Suicidal Ideation | Lexapro        |              |            | S           |              |                    |                 | Not Reported |



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| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
|-----------------------------------------------------------|--------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|----------------------------------------------|-------------------------|
| 15-Oct-2007                                               | 6479744                        | NON-EXPEDITED             | Y                           | OT                       | S06-USA-04372-01              |                               |                          | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Mania                                                     | Lexapro<br>Risperdal<br>Zoloft |                           |                             | S<br>C<br>C              |                               |                               |                          | Not Reported<br>Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 15-Oct-2007                                               | 6479746                        | NON-EXPEDITED             | Y                           | OT                       | S06-USA-04368-01              |                               |                          | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Gastroenteritis Viral;<br>Gastrointestinal<br>Haemorrhage | Lexapro                        |                           |                             | S                        |                               |                               |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 15-Oct-2007                                               | 6479754                        | NON-EXPEDITED             | Y                           | OT                       | S06-USA-04331-01              |                               | 47 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Serotonin Syndrome                                        | Lexapro                        |                           |                             | S                        | Oral                          | 10 Mg Once Po                 |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 15-Oct-2007                                               | 6479921                        | NON-EXPEDITED             | N                           | OT                       | S06-USA-04255-01              |                               | 41 YR                    | Male                                         | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |
| Anxiety; Hypersensitivity                                 | Lexapro                        |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported                                 |                         |
| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>                          | <a href="#">Country</a> |
| 15-Oct-2007                                               | 6479923                        | NON-EXPEDITED             |                             | OT                       | S06-USA-04219-01              |                               | 21 YR                    | Female                                       | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>                          |                         |

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|                            |          |   |      |             |              |
|----------------------------|----------|---|------|-------------|--------------|
| Anxiety; Drug Ineffective; | Lexapro  | S | Oral | 20 Mg Qd Po | Not Reported |
| Insomnia; Palpitations;    | Lexapro  | S | Oral | 20 Mg Qd Po | Not Reported |
| Suicidal Ideation; Tremor  | Lexapro  | S |      |             | Not Reported |
|                            | Seroquel | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479925       | NON-EXPEDITED    |                    | OT              | S06-USA-04179-01     |                      | 66 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Erectile      | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Dysfunction; Feeling Hot; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Hypersomnia; Mania;       |                |              |            | C           |              |                    |                 | Not Reported |
| Mouth Breathing; Suicidal | Minoxidil      |              |            | C           |              |                    |                 | Not Reported |
| Ideation; Tremor; Yawning | Propranolol    |              |            | C           |              |                    |                 | Not Reported |
|                           | Gemfibrozil    |              |            | C           |              |                    |                 | Not Reported |
|                           | Aspirin        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479927       | NON-EXPEDITED    |                    |                 | S07-USA-02103-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Withdrawal       | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Syndrome              | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6479928       | NON-EXPEDITED    | N                  | OT              | S07-USA-02092-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Constipation;    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Contusion; Dizziness; Fall; | Lexapro        |              |            | S           | Oral         | 10 Mg Qod Po       |                 | Not Reported |
| Flight Of Ideas; Headache;  |                |              |            | C           |              |                    |                 | Not Reported |
| Nausea; Tinnitus;           | Prevacid       |              |            |             |              |                    |                 | Not Reported |
| Vascular Headache; Wrist    |                |              |            |             |              |                    |                 | Not Reported |
| Fracture                    |                |              |            |             |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|-----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                                             | 6479930                     | NON-EXPEDITED    | Y                  | HO              | S07-USA-02047-01     |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Burning Sensation; Flushing; Headache; Nausea | Lexapro                     |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Cardizem                    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Lisinopril                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Tricor                      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Metformin Hydrochloride     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Glucotrol                   |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Cialis                      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Lortabs                     |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | (Acetaminophen/Hydrocodone) |                  |                    |                 |                      |                      |                 |              |                |
|                                                         | Nexium (Esomeprazole)       |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                         | Aspirin                     |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                             | 6479934                     | NON-EXPEDITED    |                    | OT              | S07-USA-01997-01     |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased                                | Lexapro                     |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Advair                      |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                             | 6479943                     | NON-EXPEDITED    | Y                  | HO              | S07-USA-01981-01     |                      | 84 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased                                  | Lexapro                     |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                         | Avalide                     |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                         | Atenolol                    |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                             | 6479945                     | NON-EXPEDITED    | Y                  | HO              | S07-USA-01981-02     |                      |                 | Female       | USA            |

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| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Blood Sodium Decreased                                                                                                         | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                                                                                                                    | 6479948                 | NON-EXPEDITED             |                             | OT                       | S07-USA-01823-01              |                               | 24 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Intentional Overdose;<br>Suicidal Ideation                                                                                     | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 40 Mg Once Po                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                                                                                                                    | 6479950                 | NON-EXPEDITED             | Y                           | LT                       | S06-USA-04052-01              |                               | 58 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Pain Upper;<br>Asthenia; Depression;<br>Drug Ineffective; Drug<br>Interaction; Malaise;<br>Nausea; Suicidal Ideation | Lexapro                 |                           |                             | S                        | Oral                          | 0 Mg Qd Po                    |                          | Not Reported        |                         |
|                                                                                                                                | Combunox                |                           |                             | S                        | Oral                          | 5 Mg Tid Po                   |                          | Not Reported        |                         |
|                                                                                                                                | Synthroid               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                | Cortef                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                | Lisinopril              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                | Albuterol               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                                                                                                                    | 6479957                 | NON-EXPEDITED             | Y                           | OT                       | S07-USA-01728-01              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Serotonin Syndrome                                                                                                             | Lexapro                 |                           |                             | S                        | Oral                          | 40 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                | Cymbalta                |                           |                             | S                        |                               | 120 Mg Qd                     |                          | Not Reported        |                         |
|                                                                                                                                | Cymbalta                |                           |                             | S                        |                               | 60 Mg Qd                      |                          | Not Reported        |                         |
|                                                                                                                                | Cymbalta                |                           |                             | S                        |                               | 60 Mg Qd                      |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                      | 6479964                | NON-EXPEDITED    |                    | OT              | S07-USA-01650-01     |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Syncope               | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                  | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |
|                                  | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                      | 6480295                | NON-EXPEDITED    | Y                  | OT              | S06-USA-05039-01     |                      | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness            | Lexapro                |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                  | Alcohol                |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                      | 6480298                | NON-EXPEDITED    | N                  | OT              | S06-USA-05000-01     |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| White Blood Cell Count Decreased | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                  | Unspecified Ingredient |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Rituxan                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Levaquin               |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                      | 6480300                | NON-EXPEDITED    | Y                  | HO              | S06-USA-04993-01     |                      | 90 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hip Fracture               | Lexapro                |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Xanax                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                  | Unspecified Ingredient |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                 | 6480301                 | NON-EXPEDITED    | Y                  | HO, OT          | S06-USA-04854-01     |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Headache;     | Lexapro                 |                  |                    | S               | Oral                 | 50 Mg Qd Po          |                 | Not Reported |                |
| Hypertension;               | Aleve                   |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Nephrolithiasis; Renal      | Excedrin                |                  |                    | S               |                      |                      |                 | Not Reported |                |
| Failure; Sinusitis          | Buspar                  |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Trazodone Hydrochloride |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6480302                 | NON-EXPEDITED    | N                  | OT              | S06-USA-04828-01     |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure              | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Decreased                   | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6480314                 | NON-EXPEDITED    | N                  | OT              | S06-USA-04626-01     |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Apathy;            | Lexapro                 |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Depersonalisation/Dereali   | Lexapro                 |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| sation Disorder; Dizziness; |                         |                  |                    |                 |                      |                      |                 |              |                |
| Drug Ineffective; Insomnia; |                         |                  |                    |                 |                      |                      |                 |              |                |
| Loss Of Libido; Mood        |                         |                  |                    |                 |                      |                      |                 |              |                |
| Swings; Nausea; Neck        |                         |                  |                    |                 |                      |                      |                 |              |                |
| Pain; Nightmare; Thinking   |                         |                  |                    |                 |                      |                      |                 |              |                |
| Abnormal                    |                         |                  |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6480326                 | NON-EXPEDITED    | Y                  | OT              | S06-USA-04598-01     |                      | 14 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Suicide Attempt                                               | Lexapro             |                  |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                               | Ibuprofen           |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Benadryl            |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                   | 6480801             | NON-EXPEDITED    | Y                  | HO              | S06-USA-03545-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Flushing; Hypertension                                        | Lexapro             |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                               | Remeron             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Tenormin            |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                   | 6491676             | NON-EXPEDITED    |                    | OT              | S07-USA-00680-01     |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased                                      | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                               | Atenolol            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Hydrochlorothiazide |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                   | 6491682             | NON-EXPEDITED    | N                  | OT              | S06-USA-05313-01     |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Dizziness; Hypotension; Loss Of Consciousness | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                               | Reglan              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                               | Clorazepate         |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                   | 6491683             | NON-EXPEDITED    | Y                  | HO              | S06-USA-05235-01     |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                             |                |                  |                    |                 |                      |                      |                 |              |                |
|-----------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Overdose; Suicide Attempt   | Lexapro        |                  | S                  | Oral            | 20 Mg Qd Po          |                      | Not Reported    |              |                |
|                             | Trileptal      |                  | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6491691        | NON-EXPEDITED    | Y                  | OT              | S06-USA-05051-01     |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                     | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Lunesta        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6491712        | NON-EXPEDITED    | Y                  | OT              | S06-USA-04506-01     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation           | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                             | Effexor Xr     |                  |                    | S               |                      | 150 Mg Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6491760        | NON-EXPEDITED    | N                  | OT              | S06-USA-04698-01     |                      | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness;        | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Muscle Spasms; Nausea;      | Aspirin        |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Pain In Extremity; Suicidal | Prinivil       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| Ideation                    | Hydroxyzine    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Famotidne      |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Prednisone     |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                 | 6491793        | NON-EXPEDITED    |                    | OT              | S06-USA-03272-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|                              |                            |                  |                    |                 |                      |                      |                    |                 |                |
|------------------------------|----------------------------|------------------|--------------------|-----------------|----------------------|----------------------|--------------------|-----------------|----------------|
| Liver Function Test Abnormal | Lexapro                    |                  | S                  |                 |                      |                      |                    |                 | Not Reported   |
|                              | Multiple Medications (Nos) |                  | C                  |                 |                      |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 15-Oct-2007                  | 6492134                    | NON-EXPEDITED    | Y                  | HO              | S07-USA-02007-01     |                      |                    | Male            | USA            |
| <u>Preferred Term</u>        | <u>Product</u>             |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hyponatraemia                | Lexapro                    |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
|                              | Hydrochlorothiazide        |                  |                    |                 | S                    |                      |                    |                 | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 15-Oct-2007                  | 6494030                    | NON-EXPEDITED    | Y                  | HO              | S06-USA-04005-01     |                      | 88 YR              | Female          | USA            |
| <u>Preferred Term</u>        | <u>Product</u>             |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Confusional State; Fall;     | Lexapro                    |                  |                    |                 | S                    | Oral                 | 20 Mg Qd Po        |                 | Not Reported   |
| Hip Fracture; Listless       | Lexapro                    |                  |                    |                 | S                    | Oral                 | 20 Mg Qd Po        |                 | Not Reported   |
|                              | Lexapro                    |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 15-Oct-2007                  | 6494032                    | NON-EXPEDITED    | Y                  | HO              | S06-USA-03960-01     |                      | 40 YR              | Female          | USA            |
| <u>Preferred Term</u>        | <u>Product</u>             |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Blood Pressure Increased;    | Lexapro                    |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |
| Dizziness; Flight Of Ideas;  | Alcohol                    |                  |                    |                 | C                    |                      |                    |                 | Not Reported   |
| Palpitations; Syncope;       |                            |                  |                    |                 |                      |                      |                    |                 |                |
| Weight Decreased             |                            |                  |                    |                 |                      |                      |                    |                 |                |
| <u>FDA Received Date</u>     | <u>Case #</u>              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 15-Oct-2007                  | 6494034                    | NON-EXPEDITED    | Y                  | OT              | S06-USA-04260-01     |                      | 87 YR              | Female          | USA            |
| <u>Preferred Term</u>        | <u>Product</u>             |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>          | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Blood Sodium Decreased       | Lexapro                    |                  |                    |                 | S                    | Oral                 | 10 Mg Qd Po        |                 | Not Reported   |

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Stalevo (Levodopa/Carbidopa)  
Diovan  
Ibuprofen  
Excedrin Migraine  
(Acetaminophen/Aspirin/Caffeine  
)

C  
C  
C  
C

Not Reported  
Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6494035       | NON-EXPEDITED    | Y                  | OT              | S06-USA-04489-01     |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |
|                       | Ambien                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6496620       | NON-EXPEDITED    | Y                  |                 | S07-USA-03318-01     |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Intentional Overdose; Suicide Attempt | Lexapro          |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                   | Unisom SleepTabs |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6496623       | NON-EXPEDITED    | Y                  | HO              | S07-USA-03167-01     |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Jittery; Heart Rate Increased; Hypoaesthesia; Syncope; Tension Headache | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Xanax          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2007              | 6496624       | NON-EXPEDITED    | Y                  | HO              | S07-USA-03176-01     |                      | 79 YR      | Female     | USA            |

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| <a href="#">Preferred Term</a>       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Hyponatraemia                        | Lexapro                    |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                          | 6496625                    | NON-EXPEDITED             | Y                           |                          | S07-USA-02978-01              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Loss Of Consciousness                | Lexapro                    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                          | 6496626                    | NON-EXPEDITED             | Y                           | HO                       | S07-USA-02955-01              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hyponatraemia                        | Lexapro                    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                      | Numerous Medications (Nos) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                          | 6496628                    | NON-EXPEDITED             | Y                           | OT                       | S07-USA-02837-01              |                               | 15 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicidal Ideation; Thinking Abnormal | Lexapro                    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                      | Lithium                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                      | Depakote                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                      | Zyprexa                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                      | Risperdal                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2007                          | 6496629                    | NON-EXPEDITED             | Y                           | HO                       | S07-USA-02661-01              |                               | 73 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depression                           | Lexapro                    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2007                     | 6497547             | NON-EXPEDITED    | Y                  | OT              | S07-USA-03187-01     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation               | Lexapro             |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                     | 6497562             | NON-EXPEDITED    | N                  | OT              | S07-USA-02565-01     |                      | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Loss Of Consciousness | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                 | Birth Control Pills |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                     | 6497563             | NON-EXPEDITED    | N                  |                 | S07-USA-02542-01     |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity; Nausea        | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                 | Aleve               |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Advil               |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                     | 6497564             | NON-EXPEDITED    | Y                  | OT              | S07-USA-02489-01     |                      | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoglycaemia                   | Lexapro             |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                 | Lexapro             |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                 | Humalog             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Lantus              |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Glucophage          |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Benicar             |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Pravachol           |                  |                    | C               |                      |                      |                 | Not Reported |                |

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| Inhalers (Nos)                                                                   |                        |                  | C                  |                 |                      |                      | Not Reported    |            |                |
|----------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                                                                      | 6497565                | NON-EXPEDITED    | N                  | HO              | S07-USA-02462-01     |                      | 19 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue; Pancreatitis                                                            | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                  | Alcohol                |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                                                                                  | Unspecified Ingredient |                  |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                                                                      | 6497566                | NON-EXPEDITED    | N                  | OT              | S07-USA-02430-01     |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthenia; Depression; Fatigue; Intervertebral Disc Protrusion; Suicidal Ideation | Lexapro                |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                  | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                  | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 |            | Not Reported   |
|                                                                                  | Lexapro                |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 |            | Not Reported   |
|                                                                                  | Vivelle                |                  |                    | C               |                      |                      |                 |            | Not Reported   |
|                                                                                  | Xanax                  |                  |                    | C               |                      |                      |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                                                                      | 6497568                | NON-EXPEDITED    | N                  | OT              | S07-USA-02417-01     |                      | 64 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Insomnia; Restlessness; Suicidal Ideation                                        | Lexapro                |                  |                    | S               | Oral                 | 5 Mg Qd Po           |                 |            | Not Reported   |
|                                                                                  | Lexapro                |                  |                    | S               | Oral                 | 2.5mg Qd Po          |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2007                                                                      | 6506662                | NON-EXPEDITED    | Y                  | DE              | S06-USA-03741-01     |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                                                                                              |                |                  |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Death                                                                                                        | Lexapro        |                  |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                  | 6506744        | NON-EXPEDITED    | Y                  | HO              | S06-USA-04330-01     |                      | 14 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharospasm; Loss Of Consciousness; Tremor                                                                 | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Lamictal       |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                              | Lamictal       |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                  | 6507069        | NON-EXPEDITED    |                    | HO              | S06-USA-02840-01     |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression; Intentional Overdose; Speech Disorder; Suicidal Ideation; Tremor                      | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                  | 6507116        | NON-EXPEDITED    |                    | OT              | S06-USA-01889-01     |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disturbance In Attention; Dizziness; Flatulence; Middle Insomnia; Suicidal Ideation; Vision Blurred | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Klonopin       |                  |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2007                                                                                                  | 6507239        | NON-EXPEDITED    |                    | HO              | S07-USA-02571-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                   |         |   |      |             |              |
|-------------------|---------|---|------|-------------|--------------|
| Drug Ineffective; | Lexapro | S | Oral | 10 Mg Qd Po | Not Reported |
| Hypersensitivity  | Lexapro | S | Oral | 20 Mg Qd Po | Not Reported |
|                   | Prozac  | C |      |             | Not Reported |
|                   | Effexor | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2007              | 6398009       | EXPEDITED (15-DAY) | Y                  | DE              | S07-IRL-03519-01     |                      | 58 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Completed Suicide; Condition Aggravated; Contusion; Craniocerebral Injury; Gun Shot Wound; Incorrect Dose Administered; Skull Fracture | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                   | Xanax          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2007              | 6448610       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-05347-01     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cholelithiasis; Hereditary Motor And Sensory Neuropathy; Hypokalaemia; Overdose; Road Traffic Accident; Seizure; Thrombosis; Toxicity To Various Agents | Lexapro               |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                         | Potassium Replacement |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Oct-2007              | 6346198       | EXPEDITED (15-DAY) | Y                  | DE              | S07-FRA-02578-01     |                      | 28 YR      | Female     | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed Suicide | Escitalopram Oxalate   |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                             | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |                                                          | Risperidone              |                    | C                |                      |                      |                 |                                                              | Not Reported   |
|---------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------|--------------------|------------------|----------------------|----------------------|-----------------|--------------------------------------------------------------|----------------|
|                                                                                 |                                                          | Clonazepam               |                    | C                |                      |                      |                 |                                                              | Not Reported   |
|                                                                                 |                                                          | Noctamide (Lormetazepam) |                    | C                |                      |                      |                 |                                                              | Not Reported   |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Oct-2007                                                                     | 6411603                                                  | EXPEDITED (15-DAY)       | N                  | OT               | 2007AP000908         |                      |                 | Male                                                         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Agitation; Depression;<br>Hostility; Hyperhidrosis;<br>Mania; Thinking Abnormal | Trazodone Hydrochloride<br>Escitalopram Oxalate          |                          |                    | S<br>S           |                      |                      |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Oct-2007                                                                     | 6443958                                                  | NON-EXPEDITED            | N                  |                  | A0619823A            |                      | 41 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Dyspnoea;<br>Hypersensitivity; Throat<br>Tightness; Urticaria                   | Ceftin<br>Lexapro<br>Nasarel                             |                          |                    | S<br>S<br>C      | Unknown<br>Oral      | 5mg Per Day          | 6 DAY<br>1 DAY  | Glaxosmithkline<br>Not Reported<br>Not Reported              |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Oct-2007                                                                     | 6454494                                                  | EXPEDITED (15-DAY)       | Y                  | DE               | S07-IRL-05115        |                      | 65 YR           | Male                                                         | IRL            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Completed Suicide;<br>Intentional Overdose                                      | Lexapro<br>Paraquat<br>Pravastatin Sodium<br>Mirtazapine |                          |                    | S<br>S<br>C<br>C | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Oct-2007                                                                     | 6455685                                                  | EXPEDITED (15-DAY)       | Y                  | LT               | S07-FRA-05460-01     |                      | 52 YR           | Male                                                         | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                                                                      |                  |      |             |                                                              |
|---------------------------------------------------------------|----------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|
| Gastrointestinal Erosion;<br>Phlebitis; Pulmonary<br>Embolism | Escitalopram Oxalate<br>Urbanyl<br>Trimeprazine Tartrate<br>Prazepam | S<br>C<br>C<br>C | Oral | 20 Mg Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------|----------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2007              | 6365178       | EXPEDITED (15-DAY) | Y                  | DS              | S07-IRL-02863-01     |                      | 45 YR      | Female     | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Vaginal Haemorrhage   | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Amoxicillin    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2007              | 6426831       | EXPEDITED (15-DAY) | Y                  | HO              | S07-ESP-03797-01     |                      | 75 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Cortisol<br>Increased; Drug<br>Interaction; Inappropriate<br>Antidiuretic Hormone<br>Secretion; Restlessness | Escitalopram Oxalate  |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                                                                                                         | Risperidone           |              |            | S           | Oral         | 2 Mg Qd Po         |                 | Not Reported |
|                                                                                                                         | Durphalac (Lactulose) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2007              | 6445693       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-<br>2007086029 |                      | 95 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Aggression; Delirium;<br>Drug Ineffective; Drug<br>Interaction | Zoloft               |              |            | S           |              |                                    |                 | Not Reported |
|                                                                | Aricept              |              |            | S           |              | Daily Dose:10mg-<br>Freq:Every Day |                 | Not Reported |
|                                                                | Escitalopram Oxalate |              |            | S           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2007              | 5905961       | EXPEDITED (15-DAY) | Y                  | OT              | PHFR2005GB03379      |                      | 49 YR      | Male       | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Hypersomnia; Overdose;<br>Sedation | Clozaril       |              |            | S           | Oral         | 450 Mg/Day               |                 | Novartis     |
|                                    | Cipralext      |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                    | Clozaril       |              |            | S           | Oral         | 1700 Mg Overdose         |                 | Novartis     |
|                                    | Clozaril       |              |            | S           | Oral         | Overdose - 3 Days Supply |                 | Novartis     |
|                                    | Abilify        |              |            | S           | Unknown      | Overdose - 3 Days Supply |                 | Not Reported |
|                                    | Mirtazapine    |              |            | S           | Unknown      | Overdose - 3 Days Supply |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2007              | 6455918       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-05505-01     |                      | 79 YR      | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dehydration; Diarrhoea;<br>Nausea | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                   | Plavix         |              |            | C           |              |                    |                 | Not Reported |
|                                   | Imdur          |              |            | C           |              |                    |                 | Not Reported |
|                                   | Lopresor       |              |            | C           |              |                    |                 | Not Reported |
|                                   | Protonix       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2007              | 6455922       | EXPEDITED (15-DAY) | Y                  | OT              | US021474             |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Seizure | Provigil                                  |              |            | S           | Oral         | 100 Mg Bid Oral    |                 | Not Reported |
|                           | Provigil                                  |              |            | S           | Oral         | 100 Mg Qd Oral     |                 | Not Reported |
|                           | Lexapro                                   |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |
|                           | Lorazepam                                 |              |            | C           |              |                    |                 | Not Reported |
|                           | Zyrtec                                    |              |            | C           |              |                    |                 | Not Reported |
|                           | Hormone Replacement Therapy (Unspecified) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2007              | 6456777       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05526-01     |                      | 75 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Chorea                                                                    | Escitalopram Oxalate   |                    |                    | S               | Oral                  | 20 Mg Qd Po                                   |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate   |                    |                    | S               | Oral                  | 10 Mg Qd Po                                   |                 | Not Reported |                |
|                                                                           | Sinemet                |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                           | Depakote               |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                           | Unspecified Ingredient |                    |                    | C               |                       |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2007                                                               | 6457948                | DIRECT             | N                  | DE, OT          |                       |                                               | 76 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                         | Lexapro                |                    |                    | S               | Oral                  | 1 Per Day Po                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2007                                                               | 6313300                | EXPEDITED (15-DAY) | N                  | OT              | US-BAYER-200711492BCC |                                               | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Diarrhoea; Dizziness; Dyspnoea; Loss Of Consciousness; Vomiting | Aleve                  |                    |                    | S               | Oral                  | Total Daily Dose: 220 Mg<br>Unit Dose: 220 Mg | 1 DAY           | Bayer        |                |
|                                                                           | Rebif                  |                    |                    | S               | Subcutaneous          | Unit Dose: 44 Mg                              |                 | Not Reported |                |
|                                                                           | Lexapro                |                    |                    | S               | Oral                  | Total Daily Dose: 10 Mg<br>Unit Dose: 10 Mg   |                 | Not Reported |                |
|                                                                           | Femhrt                 |                    |                    | C               |                       | Total Daily Dose: 1 Mg<br>Unit Dose: 1 Mg     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2007                                                               | 6457744                | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-05540-01      |                                               | 77 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Sleep Disorder; Tremor                              | Escitalopram Oxalate   |                    |                    | S               | Oral                  | 20 Mg Qd Po                                   |                 | Not Reported |                |
|                                                                           | Mysoline (Primidone)   |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                           | Unspecified Ingredient |                    |                    | C               |                       |                                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2007              | 6459512       | DIRECT           | Y                  | OT              |                      |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Headache; Therapy Non-Responder | Lexapro                 |              |            | S           |              |                    |                 | Forest       |
|                                                          | Relpax                  |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Phenergan               |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Excedrin                |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Calcium                 |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Magnesium               |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Amoxicillin             |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Nasarel                 |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Hydrocodone             |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Ibuprofen               |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Vicodin                 |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Naprosyn                |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Asa                     |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Midrin                  |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Fish Oil                |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Zoloft                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2007              | 6392488       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-03425-01     |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcoholism            | Lexapro                       |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                       | Lexapro                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                       | Acetaminophen\Diphenhydramine |              |            | C           |              |                    |                 | Not Reported |
|                       | Celebrex                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2007              | 6459259       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05456-01     |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |                                 |   |      |             |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---|------|-------------|--------------|
| Dizziness; Drug Interaction; Dyspnoea; Feeling Abnormal; Intervertebral Disc Degeneration; Serotonin Syndrome; Sinusitis; Swollen Tongue; Tinnitus | Lexapro                         | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                                                                    | Delsym                          | S |      |             | Not Reported |
|                                                                                                                                                    | Levothyroxine                   | C |      |             | Not Reported |
|                                                                                                                                                    | Atacand (Candesartan Cilexetil) | C |      |             | Not Reported |
|                                                                                                                                                    | Hydrochlorothiazide             | C |      |             | Not Reported |
|                                                                                                                                                    | Vytorin                         | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2007              | 6460994       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-05565-01     |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder; Diplopia; General Physical Health Deterioration; Toxicity To Various Agents; Weight Decreased | Escitalopram Oxalate                         |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                 | Prazepam                                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                 | Prazepam                                     |              |            | S           | Oral         | 0.5 Tid Po         |                 | Not Reported |
|                                                                                                                 | Propoxyphene Hydrochloride And Acetaminophen |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2007              | 6496095       | NON-EXPEDITED    | Y                  | OT              | 2007US002014         |                      | 83 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|------------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Vaprisol       |              |            | S           | Intravenous drip | Iv Drip            |                 | Not Reported |
|                       | Lexapro        |              |            | S           |                  |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2007              | 6453724       | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-526271      |                      | 35 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Completed Suicide     | Clonazepam                |              |            | S           | Oral         | Acute On Chronic. Route: Ingestion. |                 | Roche        |
|                       | Escitalopram Oxalate      |              |            | S           | Oral         | Acute On Chronic. Route: Ingestion. |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           | Oral         | Drug Reported As                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Venlafaxine (Long Acting).  
Acute On Chronic. Route:  
Ingestion.

Unspecified Ingredient

S

Unknown

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2007              | 6433342       | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-05056-01     |                      | 69 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                                                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|--------------------|-----------------|----------------------------------------------------------------------------------------------|
| High Density Lipoprotein Decreased; Left Ventricular Dysfunction; Stress Cardiomyopathy; Troponin Increased; Vascular Pseudoaneurysm | Cipralext<br>Ramipril<br>Sortis (Atorvastatin)<br>Concor 5 Plus (Biselect)<br>Allopurinol<br>Tavor (Lorazepam) |              |            | S<br>S<br>C<br>C<br>C<br>C | Oral         | 5 Mg Qd Po         |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2007              | 6461859       | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-05552-01     |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Arrhythmia; Drug Level Above Therapeutic | Lexapro<br>Fentanyl<br>Hydrocodone |              |            | S<br>C<br>C | Oral         | 10 Mg Bid Po       |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Oct-2007              | 6462124       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 100#03#2007-04173    |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u>            | <u>Mfr</u>                                                   |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------|------------|------------------|--------------|----------------------------------|----------------------------|--------------------------------------------------------------|
| Anxiety; Blood Pressure Increased; Depressive Symptom; Drug Interaction; Essential Tremor; Sinus Bradycardia; Syncope; | Omeprazole<br>Propranolol<br>Donepezil<br>Escitalopram Oxalate |              |            | S<br>S<br>S<br>S |              | 20 Mg<br>80 Mg<br>10 Mg<br>10 Mg | <br>5 DAY<br>2 YR<br>5 DAY | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                    |             |   |              |
|--------------------|-------------|---|--------------|
| Torsade De Pointes | Mirtazapine | C | Not Reported |
|--------------------|-------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2007              | 6462186       | EXPEDITED (15-DAY) | Y                  | HO, LT          | DSA_30787_2007       |                      | 31 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                              | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Mydriasis; Somnolence;<br>Suicide Attempt | Tavor /00273201/ (Lorazepam) |              |            | S           | Oral         | Not The Prescribed Amount, Oral |                 | Not Reported |
|                                                                    | Alcohol                      |              |            | S           | Oral         | Not The Prescribed Amount, Oral |                 | Not Reported |
|                                                                    | Cipralex                     |              |            | S           | Oral         | Not The Prescribed Amount, Oral |                 | Not Reported |
|                                                                    | Risperdal                    |              |            | S           | Oral         | Not The Prescribed Amount, Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2007              | 6462331       | EXPEDITED (15-DAY) | Y                  | OT              | 2007S1010664         |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes; Ventricular<br>Tachycardia | Omeprazole              |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                           | Donepezil Hydrochloride |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                           | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                           | Propranolol             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2007              | 6462372       | DIRECT           |                    | HO              |                      |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Suicide Attempt | Escitalopram Oxalate |              |            | S           | Oral         | Po                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2007              | 6462741       | EXPEDITED (15-DAY) | Y                  | HO              | 2007RL000477         |                      | 76 YR      | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Off Label Use;<br>Sinus Bradycardia;<br>Syncope; Torsade De<br>Pointes                                            | Propranolol Hydrochloride |                    |                    | S               |                      | 80 Mg                |                 | Not Reported |                |
|                                                                                                                                                                           | Donepezil Hydrochloride   |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                           | Escitalopram Oxalate      |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                           | Omeprazole                |                    |                    | S               |                      | 20 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2007                                                                                                                                                               | 6464416                   | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-05653-01     |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Conversion Disorder;<br>Infection; Seizure; Tremor                                                                                                                        | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                           | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                           | Zyrtec                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2007                                                                                                                                                               | 6464802                   | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05623-01     |                      | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hostility;<br>Irritability; Mental Disorder;<br>Speech Disorder                                                                                                | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                           | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2007                                                                                                                                                               | 6464917                   | DIRECT             | Y                  |                 |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Dissociation;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Headache; Inappropriate<br>Schedule Of Product<br>Administration; Influenza<br>Like Illness; Initial | Lexapro                   |                    |                    | S               | Oral                 | 20mg Every Day Po    |                 | Not Reported |                |
|                                                                                                                                                                           | Loestrin 1.5/30 21 Day    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                           | Singulair                 |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Insomnia; Lethargy;  
Middle Insomnia; Myalgia;  
Nausea; Sleep Disorder;  
Vomiting

| <u>FDA Received Date</u>                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Nov-2007                                 | 6466166                 | DIRECT             | N                  | HO, OT          |                      |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Suicide Attempt | Trazodone Hydrochloride |                    |                    | S               |                      | 100 Mg 1 X Ea Day    |                 | Not Reported |                |
|                                             | Lexapro                 |                    |                    | S               |                      | 10 Mg 1x Ea Day      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2007                                 | 6363219                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-UKI-02929-01     |                      | 50 YR           | Female       | GBR            |
| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine                              | Cipralax                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Phosphokinase Increased;                    | Lamotrigine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Depressed Level Of                          | Zyprexa                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Consciousness;                              | Zopiclone               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Electrocardiogram Qt                        |                         |                    |                    |                 |                      |                      |                 |              |                |
| Prolonged; Intentional                      |                         |                    |                    |                 |                      |                      |                 |              |                |
| Overdose; Myoclonus;                        |                         |                    |                    |                 |                      |                      |                 |              |                |
| Pneumonia; Serotonin                        |                         |                    |                    |                 |                      |                      |                 |              |                |
| Syndrome; Toxicity To                       |                         |                    |                    |                 |                      |                      |                 |              |                |
| Various Agents                              |                         |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2007                                 | 6468101                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05692-01     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block;                     | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Blood Pressure                              | Lamictal                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Decreased; Dizziness;                       | Seroquel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Syncope                                     |                         |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Nov-2007                                    | 6468627                                        | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-05775-01     |                      |                 | Female       | IRL            |
| <u>Preferred Term</u>                          | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage                                    | Lexapro                                        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2007                                    | 6468986                                        | DIRECT             | Y                  |                 |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Feeling Hot; Hyperhidrosis; Tremor | Lexapro                                        |                    |                    | S               | Oral                 | 20mg 1qd Po          |                 | Not Reported |                |
|                                                | Bupropion                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                | Prevacid                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2007                                    | 6469479                                        | EXPEDITED (15-DAY) | Y                  | DE              | S07-FRA-05782-01     |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Urea Increased; Haematoma;               | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Haemorrhagic Stroke; Hyperkalaemia;            | Aspirin Lysine                                 |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 | Not Reported |                |
| Hyperthermia;                                  | Zaldiar (Paracetamol/Tramadol)                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hyponatraemia; Increased                       | Acetaminophen                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Bronchial Secretion;                           | Movicol                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Intraventricular Haemorrhage; Meningorrhagia   | Densical D3 (Calcium Carbonate/Colecalciferol) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2007                                    | 6469480                                        | EXPEDITED (15-DAY) | Y                  | HO, LT          | S07-GER-05781-01     |                      | 40 YR           | Female       | DEU            |
| <u>Preferred Term</u>                          | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                           |                                |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Fall; Hypoglycaemia; Loss Of Consciousness                                | Ciprallex                      |                    | S                  | Oral            | 20 Mg Qd Po          |                      | Not Reported    |              |                |
|                                                                           | L-Thyroxin (Levothyroxine)     |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2007                                                               | 6440810                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-AUS-05208-01     |                      | 64 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysuria; Feeling Of Body Temperature Change; Vision Blurred               | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg Qd;Po          |                 | Not Reported |                |
|                                                                           | Unspecified Ingredient         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2007                                                               | 6443594                        | EXPEDITED (15-DAY) | Y                  | DS              | S07-KOR-05265-01     |                      | 69 YR           | Male         | KOR            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Infarction; Cerebrovascular Accident                             | Lexapro                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                           | Aspirin (Acetylsalicylic Acid) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Clopidogrel                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Nicorandil                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                           | Thioctic Acid                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2007                                                               | 6466267                        | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05658-01     |                      | 32 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cutaneous Vasculitis; Lymphocytosis; Skin Toxicity; Therapy Non-Responder | Escitalopram Oxalate           |                    |                    | S               | Ophthalmic           | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2007                                                               | 6472745                        | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05785-01     |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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| Colitis                                                                                             | Escitalopram Oxalate                   | S                  | Oral               | 20 Mg Qd Po     | Not Reported         |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                     | Inipomp                                | C                  |                    |                 | Not Reported         |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2007                                                                                         | 6465732                                | EXPEDITED (15-DAY) | Y                  | OT              | S07-NLD-05680-01     |                      | 64 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hypoglycaemia                                                                  | Lexapro                                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Insulin Aspart                         |                    |                    | S               | Intramuscular        | 100 lu, Im           |                 | Not Reported |                |
|                                                                                                     | Oxazepam                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Acetylsalicylic Acid                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Nebivolol                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Simvastatin                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Ramipril                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2007                                                                                         | 6472700                                | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-05816-01     |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chorioretinal Disorder                                                                              | Lexapro                                |                    |                    | S               | Oral                 | 20 Mg Qd;Po          |                 | Not Reported |                |
|                                                                                                     | Prednisone                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Tylenol #3 (Acetaminophen And Codeine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Methotrexate                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Xanax                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Orencia (Abatacept)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2007                                                                                         | 6472787                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05753-01     |                      | 73 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Cataract Operation; Heart<br>Rate Decreased;<br>Procedural Complication | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                     | Pentothal                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | 70/30 Nph / Regular Insulin            |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Nov-2007                                                                                                    | 6472799                           | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-05821-01     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure                                                                                      | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                | Provigil                          |                    |                    | S               |                      | 100 Mg Bid           |                 | Not Reported |                |
|                                                                                                                | Provigil                          |                    |                    | S               |                      | 100 Mg Qd            |                 | Not Reported |                |
|                                                                                                                | Hormone Replacement Therapy (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Lorazepam                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                | Zyrtec                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Nov-2007                                                                                                    | 6474943                           | EXPEDITED (15-DAY) | Y                  | CA              | S07-USA-05717-02     |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Craniosynostosis; Maternal Exposure During Pregnancy; Post Procedural Complication; Seizure | Lexapro                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2007                                                                                                    | 6408469                           | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-03602-01     |                      | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejaculation Delayed; Hypothyroidism                                                                            | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                | Lexapro                           |                    |                    | S               |                      | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                | Chantix                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2007                                                                                                    | 6461427                           | EXPEDITED (15-DAY) | Y                  | HO              | 2007S1010361         |                      | 76 YR           | Female       | GBR            |

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| <u>Preferred Term</u>                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction; Sinus Bradycardia; Syncope; Torsade De Pointes                 | Propranolol                   |                    |                    | S               |                                             | 80 Mg;               |                 | Not Reported |                |
|                                                                                  | Donepezil Hydrochloride       |                    |                    | S               |                                             | 10 Mg;               |                 | Not Reported |                |
|                                                                                  | Escitalopram Oxalate          |                    |                    | S               |                                             | 10 Mg;               |                 | Not Reported |                |
|                                                                                  | Omeprazole                    |                    |                    | S               |                                             | 20 Mg;               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2007                                                                      | 6468198                       | EXPEDITED (15-DAY) | N                  | HO              | US-ABBOTT-07P-163-0423493-00                |                      | 9 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                                                                            | Lexapro                       |                    |                    | S               | Oral                                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2007                                                                      | 6468450                       | EXPEDITED (15-DAY) |                    | OT              | US-ROXANE LABORATORIES, INC-2007-BP-24224RO |                      | 71 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adrenal Insufficiency; Blood Thyroid Stimulating Hormone Decreased; Hypogonadism | Megestrol Acetate             |                    |                    | S               | Oral                                        |                      |                 | Roxane       |                |
|                                                                                  | Oxycodone                     |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Escitalopram Oxalate          |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Levothyroxine                 |                    |                    | S               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Fludrocortisone Acetate       |                    |                    | S               | Topical                                     |                      |                 | Not Reported |                |
|                                                                                  | Testosterone                  |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Paclitaxel                    |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Carboplatin                   |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Capecitabine                  |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Dexamethasone                 |                    |                    | C               |                                             |                      |                 | Not Reported |                |
|                                                                                  | Methylphenidate Hydrochloride |                    |                    | C               |                                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2007                                                                      | 6476259                       | EXPEDITED (15-DAY) | Y                  | OT              | S07-ESP-05885-01                            |                      |                 | Female       | ESP            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                                                                                             |                          |                      |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hypertensive Crisis                                                                                                                                                                         |                          | Escitalopram Oxalate |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             |                          | Almogran             |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2007                                                                                                                                                                                 | 6459822                  | EXPEDITED (15-DAY)   | Y                  | OT              | S07-SWI-05567-01     |                      | 54 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Dehydration;<br>Dizziness; Heart Rate<br>Decreased; Nausea;<br>Orthostatic Hypotension;<br>Parosmia; Respiratory<br>Rate Decreased; Sleep<br>Disorder; Vision Blurred;<br>Vomiting | Cipralext                |                      |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                                                                                                             | Ritalin                  |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Clorazepate Dipotassium  |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Melatonin                |                      |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2007                                                                                                                                                                                 | 6468631                  | EXPEDITED (15-DAY)   | Y                  | DS, HO          | S07-NOR-05759-01     |                      | 56 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness; Dizziness;<br>Influenza; Nausea;<br>Syncope; Vomiting                                                                                                                             | Cipralext                |                      |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                             | Cipralext                |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                             | Adalat Oros (Nifedipine) |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Irbesartan               |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Lipitor                  |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Furosemide               |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                             | Levothyroxine Sodium     |                      |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Nov-2007                                                                                                                                                                                 | 6475945                  | EXPEDITED (15-DAY)   | Y                  | OT              | S07-SWE-05951-01     |                      |                 | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lip Swelling; Oedema<br>Peripheral; Proteinuria                                                                                                                                             | Escitalopram Oxalate     |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                             | Concerta                 |                      |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 15-Nov-2007                                                                                                                             | 6509523                 | DIRECT             | Y                  | HO, RI          |                            |                      | 80 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphagia; Dystonia; Ill-Defined Disorder; Jaw Disorder; Mental Status Changes; Respiratory Disorder; Trismus; Vital Functions Abnormal | Lexapro                 |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Quinidine Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2007                                                                                                                             | 6462873                 | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | CZ-ASTRAZENECA-2007SE05938 |                      | 17 YR           | Female       | CZE            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Suicide Attempt                                                                                                   | Quetiapine              |                    |                    | S               | Oral                       |                      | 107 DAY         | Zeneca       |                |
|                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               |                            |                      | 87 DAY          | Not Reported |                |
|                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               |                            |                      | 1 DAY           | Not Reported |                |
|                                                                                                                                         | Lamotrigine             |                    |                    | S               | Oral                       |                      | 36 DAY          | Not Reported |                |
|                                                                                                                                         | Rivotril                |                    |                    | S               | Oral                       |                      | 36 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2007                                                                                                                             | 6470632                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20071105221      |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Gait Disturbance; Hallucination                                                                                                   | Risperdal               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                         | Modopar                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                         | Ditropan                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                         | Discotrine              |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Pantoprazole Sodium     |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                         | Levothyrox              |                    |                    | C               |                            |                      |                 | Not Reported |                |



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|  |                   |   |              |
|--|-------------------|---|--------------|
|  | Praxinor          | C | Not Reported |
|  | Calcium Carbonate | C | Not Reported |
|  | Structum          | C | Not Reported |
|  | Stilnox           | C | Not Reported |
|  | Tanakan           | C | Not Reported |
|  | Vastarel          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2007              | 6476772       | DIRECT           |                    |                 |                      |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Coronary Artery Occlusion; Medication Error; Product Dispensing Error | Lexapro        |              |            | S           |              | Tablet             |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2007              | 6477060       | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-05869-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia; Feeling Cold; Muscle Twitching; Panic Reaction; Seizure; Serotonin Syndrome | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                         | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                         | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2007              | 6478337       | DIRECT           | Y                  | HO, LT, RI, OT  |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation; Alopecia; Amnesia; Anxiety; Back Injury; Chills; Confusional State; Depression; Drug Interaction; Hyperhidrosis; Hypoglycaemia; Impaired | Lexapro        |              |            | S           | Oral         | One Tab Daily Po   |                 | Not Reported |
|                                                                                                                                                                 | Toprol XL      |              |            | S           | Oral         | One Tab Dailt Po   |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Driving Ability; Impaired  
Work Ability; Injury; Loss  
Of Consciousness;  
Malnutrition; Nausea;  
Overdose; Road Traffic  
Accident; Syncope;  
Tremor; Unresponsive To  
Stimuli; Vomiting;  
Withdrawal Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Nov-2007              | 6360192       | EXPEDITED (15-DAY) | Y                  | OT              | PHNU2007DE02415      |                      | 57 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug<br>Level Increased; Lethargy;<br>Salivary Hypersecretion;<br>Somnolence | Leponex        |              |            | S           | Oral         | 325mg/Day          | 89 DAY          | Novartis     |
|                                                                                                | Cipralext      |              |            | S           | Oral         | 15 Mg/Day          |                 | Not Reported |
|                                                                                                | Amisulpride    |              |            | C           | Oral         | 200 Mg/Day         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2007              | 6377285       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-03165-01     |                      | 55 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic<br>Seizure | Escitalopram Oxalate                   |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                                     | Anafranil                              |              |            | S           | Oral         | 25 Mg Qd Po        |                 | Not Reported |
|                                     | Paroxetine Hydrochloride               |              |            | C           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                     | Metformin Hydrochloride                |              |            | C           | Oral         | 2000 Mg Qd Po      |                 | Not Reported |
|                                     | Cozaar                                 |              |            | C           |              |                    |                 | Not Reported |
|                                     | Cardensiel (Bisoprolol)                |              |            | C           |              |                    |                 | Not Reported |
|                                     | Mediator (Benfluorex<br>Hydrochloride) |              |            | C           |              |                    |                 | Not Reported |
|                                     | Atorvastatin Calcium                   |              |            | C           |              |                    |                 | Not Reported |
|                                     | Losartan Potassium                     |              |            | C           |              |                    |                 | Not Reported |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2007              | 6436517       | EXPEDITED (15-DAY) | Y                  | LT              | S07-FRA-05130-01     |                      | 75 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Coronary Syndrome; Anoxia; Arrhythmia; Bundle Branch Block Right; Cardiac Arrest; Coma; Drug Level Increased; Electrocardiogram Qrs Complex Prolonged; Hypertension; Hypertrophic Cardiomyopathy; Hypokalaemia; Malaise; Mydriasis; Toxicity To Various Agents | Escitalopram Oxalate     |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                      | Noctamide (Lormetazepam) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                      | Bisoprolol               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                      | Hyzaar                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                      | Aspirin                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2007              | 6480209       | EXPEDITED (15-DAY) | Y                  | HO              | 071004637            |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased; Drug Interaction; Dyspnoea; Feeling Abnormal; Hypotension; Intervertebral Disc Degeneration; Intervertebral Disc Protrusion; Meniere'S Disease; Serotonin Syndrome; Sinusitis; Swollen Tongue | Lexapro                         |              |            | S           | Oral         | 10mg, Qd, Oral     |                 | Not Reported |
|                                                                                                                                                                                                                        | Delsym                          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | Levothyroxine Sodium            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | Atacand (Candesartan Cilexetil) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | Hydrochlorothiazide             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | (Hydrochlorothiazide) Vytarin   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2007              | 6454414       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-05417-01     |                      | 42 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                   | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|-----------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Dysarthria; Impaired Driving Ability; Lethargy; Psychomotor Skills Impaired; Somnolence | Lexapro<br>Lisinopril<br>Naproxen |              |            | S<br>C<br>C | Oral         | 10 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2007              | 6475793       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2007-04652           |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u>                                                                                                                                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                | <u>Route</u> | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|----------------------------|--------------|----------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------|
| Bladder Discomfort; Depression; Device Related Sepsis; Diabetes Mellitus; Dysuria; Escherichia Sepsis; Escherichia Urinary Tract Infection; Failure To Thrive; Gastritis; Hyperlipidaemia; Hypertension; Incisional Hernia; Inguinal Mass; Intestinal Stenosis; Malaise; Nausea; Oedema Peripheral; Osteopenia; Osteoporosis; Postoperative Adhesion; Prostate Cancer; Prostatitis; Pubic Pain; Sepsis; Urge Incontinence; Urinary Tract Infection Fungal; Weight Increased | Prednisone<br>Prednisone<br>Zyprexa<br>Lexapro<br>Pentasa "Pharmacia" (Mesalazine)<br>Loperamide Hydrochloride<br>Multivitamins (Retinol, Riboflaving, Nicotinamide, Panthenol)<br>Fish Oil (Fish Oil) |              |            | S<br>S<br>C<br>C<br>C<br>C | Oral<br>Oral | 5 Mg, Daily (Long Taper), Oral<br>10-40 Mg, Daily Taper To 5mg, Oral |                 | Watson<br>Watson<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2007              | 6483606       | EXPEDITED (15-DAY) | Y                  | HO              | T07-TUN-05611-01     |                      | 21 YR      | Female     | TUN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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| Hypotension                      | Escitalopram Oxalate   |                    |                    | S               |                            | 10 Mg Qd                |                 | Not Reported |                |
|----------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|--------------|----------------|
|                                  | Amisulpride            |                    |                    | C               |                            |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2007                      | 6529196                | NON-EXPEDITED      | N                  | OT              | US-JNJFOC-20070206475      |                         | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| White Blood Cell Count Decreased | Levaquin               |                    |                    | S               |                            |                         |                 | Not Reported |                |
|                                  | Lexapro                |                    |                    | S               | Oral                       | 10 Mg, 1 In 1 Day, Oral |                 | Not Reported |                |
|                                  | Unspecified Ingredient |                    |                    | S               |                            |                         |                 | Not Reported |                |
|                                  | Rituxan                |                    |                    | S               |                            |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2007                      | 6474737                | EXPEDITED (15-DAY) | Y                  | HO              | DE-ASTRAZENECA-2007PK02369 |                         | 24 YR           | Male         | DEU            |
| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased         | Seroquel               |                    |                    | S               | Oral                       |                         | 13 DAY          | Zeneca       |                |
|                                  | Seroquel               |                    |                    | S               | Oral                       |                         | 14 DAY          | Zeneca       |                |
|                                  | Seroquel               |                    |                    | S               | Oral                       |                         | 19 DAY          | Zeneca       |                |
|                                  | Cipralexx              |                    |                    | S               | Oral                       |                         | 5 DAY           | Not Reported |                |
|                                  | Cipralexx              |                    |                    | S               | Oral                       |                         | 3 DAY           | Not Reported |                |
|                                  | Cipralexx              |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                  | Valproic Acid          |                    |                    | S               | Oral                       |                         | 3 DAY           | Not Reported |                |
|                                  | Valproic Acid          |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                  | Zopiclone              |                    |                    | C               | Oral                       |                         |                 | Not Reported |                |
|                                  | Diazepam               |                    |                    | C               | Oral                       |                         | 8 DAY           | Not Reported |                |
|                                  | Diazepam               |                    |                    | C               | Oral                       |                         | 15 DAY          | Not Reported |                |
|                                  | Diazepam               |                    |                    | C               | Oral                       |                         | 9 DAY           | Not Reported |                |
|                                  | Diazepam               |                    |                    | C               | Oral                       |                         | 7 DAY           | Not Reported |                |
|                                  | Diazepam               |                    |                    | C               | Oral                       |                         | 7 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Nov-2007                            | 6480836              | DIRECT             | N                  |                 |                      |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder; Ill-Defined Disorder | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Daily Po       | 1 MTH           | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2007                            | 6468197              | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-05608-01     |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Headache; Muscle Spasms    | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qod Po         |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 7.5 Mg Qd Po         |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 7.5 Mg Qod Po        |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 2.5 Mg Qod Po        |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 5 Mg Qod Po          |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 2.5 Mg Qd Po         |                 | Not Reported |                |
|                                        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2007                            | 6490510              | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06092-01     |                      | 61 YR           | Male         | DNK            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonic Epilepsy                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2007                            | 6490539              | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-06055-01     |                      | 60 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Disease Recurrence;<br>Disorientation;<br>Hyponatraemia; Partial<br>Seizures; Seizure;<br>Syncope                                                                                                                                                                                     | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Torsemide                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Spironolactone                         |                    |                    | S               | Oral                 | 50 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Zyprexa                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Asa (Acetylsalicylic Acid)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Pantozol (Pantoprazole Sodium)         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Prednisolone                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Allopurinol                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Cipramil Filmtabletten<br>(Citalopram) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                              | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2007                                                                                                                                                                                                                                                                           | 6490553                                | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-06057-01     |                      | 70 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Cerebral Atrophy;<br>Cerebral Ischaemia;<br>Condition Aggravated;<br>Depression; Gait<br>Disturbance; General<br>Physical Health<br>Deterioration;<br>Psychomotor Retardation;<br>Reduced Facial<br>Expression; Stupor;<br>Transient Ischaemic<br>Attack; Tremor | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Mirtazapine                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Tavor (Lorazepam)                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Zyprexa                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Enalapril                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                       | Amlodipine                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                              | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2007                                                                                                                                                                                                                                                                           | 6336985                                | EXPEDITED (15-DAY) | Y                  | DE              | S07-SWI-02387-01     |                      | 76 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                 | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|                                       |                                            |   |      |               |              |
|---------------------------------------|--------------------------------------------|---|------|---------------|--------------|
| Asphyxia; Completed Suicide; Overdose | Ciprallex                                  | S | Oral | 35 Mg Qd Po   | Not Reported |
|                                       | Remeron                                    | S | Oral | 45 Mg Qd Po   | Not Reported |
|                                       | Bromazepam                                 | S | Oral | 3.75 Mg Qd Po | Not Reported |
|                                       | Losartan Potassium And Hydrochlorothiazide | C |      |               | Not Reported |
|                                       | Pantoprazole Sodium                        | C |      |               | Not Reported |
|                                       | Perenterol (Yeast Dried)                   | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2007              | 6366160       | EXPEDITED (15-DAY) | Y                  | CA, OT          | S07-USA-02894-02     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Congenital Ovarian Anomaly; Maternal Exposure During Pregnancy; Ovarian Cyst | Lexapro           |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
|                                                                              | Prenatal Vitamins |              |            | C           |                |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2007              | 6445216       | EXPEDITED (15-DAY) | Y                  | DE              | S07-GRC-05340-01     |                      | 75 YR      | Male       | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coronary Artery Disease; Myocardial Infarction | Ciprallex         |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                | Remeron           |              |            | C           |              |                    |                 | Not Reported |
|                                                | Stedon (Diazepam) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2007              | 6471726       | EXPEDITED (15-DAY) | N                  | OT              | S07-USA-05799-01     |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Groin Pain; Hernia    | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2007              | 6477169       | NON-EXPEDITED    | N                  | OT              | A0639042A            |                      | 45 YR      | Male       | USA            |



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| <u>Preferred Term</u>                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Disorientation; Panic Attack; Suicidal Ideation      | Wellbutrin Sr                        |                    |                    | S               | Oral                 | 150mg Twice Per Day  | 1 DAY           | Glaxosmithkline |                |
|                                                      | Lexapro                              |                    |                    | S               |                      |                      | 3 MTH           | Not Reported    |                |
|                                                      | Alcohol                              |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Nov-2007                                          | 6477177                              | NON-EXPEDITED      | N                  |                 | A0641774A            |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Behaviour; Alcohol Use; Hostility; Overdose | Wellbutrin Sr                        |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                                      | Phentermine                          |                    |                    | S               |                      |                      |                 | Glaxosmithkline |                |
|                                                      | Lexapro                              |                    |                    | S               | Oral                 |                      |                 | Not Reported    |                |
|                                                      | Alcohol                              |                    |                    | S               |                      |                      |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Nov-2007                                          | 6495665                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06077-01     |                      | 65 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Epilepsy                                             | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                      | Antiepileptics (Nos)                 |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Nov-2007                                          | 6495670                              | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06073-01     |                      | 53 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Subileus                           | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                      | Escitalopram Oxalate                 |                    |                    | S               |                      | 10 Mg Once Po        |                 | Not Reported    |                |
|                                                      | Botulinum Toxin Type A               |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                      | Lexomil (Bromazepam)                 |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                      | Herbals With Minerals/Vitamins (Nos) |                    |                    | C               |                      |                      |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Nov-2007                                                         | 6500628                            | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06076-01     |                      | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                            | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                     | Antiepileptics (Nos)               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2007                                                         | 6503531                            | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06081-01     |                      | 83 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder;<br>Coronary Artery Disease                        | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg Qd;Po          |                 | Not Reported |                |
|                                                                     | Previscan (Fluindione)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Kardegic (Acetylsalicylate Lysine) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Perindopril Erbumine               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Atenolol                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Inergy (Ezetimibe/Simvastatin)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2007                                                         | 6287894                            | NON-EXPEDITED      | Y                  | CA              | HQWYE138110APR07     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Foetal Growth Restriction; Foetal Hypokinesia; Trisomy 21 | Effexor Xr                         |                    |                    | S               | Transplacental       | See Image            |                 | Not Reported |                |
|                                                                     |                                    |                    |                    |                 | Transplacental       | See Image            |                 |              |                |
|                                                                     |                                    |                    |                    |                 | Transplacental       | See Image            |                 |              |                |
|                                                                     | Cortef                             |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                     | Cytomel                            |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                     | Lexapro                            |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                     | Synthroid                          |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                     | Wellbutrin                         |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Dec-2007               | 6291355                      | EXPEDITED (15-DAY) | Y                  |                 | S07-ITA-00163-01     |                      | 33 YR           | Female       | ITA            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate                 | Cipralelex                   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Aminotransferase          | Cipralelex                   |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Increased; Blood          | Cipralelex                   |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| Potassium Increased;      | Cipralelex                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Caesarean Section;        | Cipralelex                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| Haematocrit Increased;    | Cipralelex                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Hypertension; Maternal    | Sedatol                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Exposure During           |                              |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Pregnancy; Mean Cell      |                              |                    |                    |                 |                      |                      |                 |              |                |
| Haemoglobin               |                              |                    |                    |                 |                      |                      |                 |              |                |
| Concentration Increased;  |                              |                    |                    |                 |                      |                      |                 |              |                |
| Mean Cell Volume          |                              |                    |                    |                 |                      |                      |                 |              |                |
| Abnormal; Perinatal       |                              |                    |                    |                 |                      |                      |                 |              |                |
| Depression; Pregnancy;    |                              |                    |                    |                 |                      |                      |                 |              |                |
| Presyncope                |                              |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2007               | 6468632                      | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-05779-01     |                      | 67 YR           | Male         | DEU            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Basal | Cipralelex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| Cell Carcinoma;           |                              |                    |                    |                 | Oral                 | 10 Mg Qd Po          |                 |              |                |
| Hyperhidrosis; Pruritus;  | Cipralelex                   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
| Psoriasis; Vision Blurred | Cipralelex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                           | Escitalopram Oxalate         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Concor (Bisoprolol Fumarate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Dec-2007               | 6499981                      | DIRECT             | N                  | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                       |         |   |                                          |                        |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------------------------------------------|------------------------|--------------|
| Alopecia; Asthenia;<br>Confusional State;<br>Decreased Activity;<br>Fibromyalgia;<br>Hypoaesthesia; Influenza<br>Like Illness; Muscle<br>Spasms; Muscular<br>Weakness | Celexa  | S | Intravenous (not<br>otherwise specified) | 1 Tablet Once A Day Iv | Not Reported |
|                                                                                                                                                                       | Lexapro | S | Intravenous (not<br>otherwise specified) | 1 Tablet Na Iv         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2007              | 6500630       | DIRECT           | Y                  |                 |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysphemia; Metabolic<br>Acidosis; Serotonin<br>Syndrome; Tremor;<br>Urinary Tract Infection | Linezolid            |              |            | S           | Oral         | 600 Mg Bid Po      |                 | Not Reported |
|                                                                                             | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2007              | 6507524       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-05783-01     |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Interaction;<br>Confusional State | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                           | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                           | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                           | Disulfiram           |              |            | S           | Oral         | 1 Tablet Qd Po     |                 | Not Reported |
|                                           | Alcohol              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2007              | 6569926       | NON-EXPEDITED    | Y                  | OT              | HQWYE482124OCT06     |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Seizure               | Effexor Xr     |              |            | S           | Oral         | 37.5 Mg 1x Per 1 Day,<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                    |                        |                    |                    |                 |                          |                      |                 |              |                |
|----------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                            |                        |                    | S                  |                 | 20 Mg 1x Per 1 Day       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2007                                        | 6506076                | DIRECT             | N                  |                 |                          |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error                                   | Lipitor                |                    |                    | S               |                          | Tablet               |                 | Pfizer       |                |
|                                                    | Lexapro                |                    |                    | S               |                          | Tablet               |                 | Forest       |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2007                                        | 6483563                | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2007100003 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;                                  | Lyrica                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Impaired Work Ability;                             | Unspecified Ingredient |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Nausea; Thinking Abnormal                          | Lexapro                |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2007                                        | 6570890                | NON-EXPEDITED      | Y                  | OT              | 2007056549               |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                   | Viagra                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                    | Lexapro                |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2007                                        | 6434530                | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PFIZER INC-2007081030 |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;                                    | Geodon                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Electrocardiogram Qt Prolonged; Respiratory Arrest | Lexapro                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                    | Lexapro                |                    |                    | S               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |            |   |                  |              |
|--|------------|---|------------------|--------------|
|  | Lyrica     | C | Daily Dose:150mg | Not Reported |
|  | Glucophage | C | Daily Dose:200mg | Not Reported |
|  | Esgic      | C |                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6443577       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-05263-01     |                      | 54 YR      | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anterograde Amnesia;      | Escitalopram Oxalate       |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
| Brain Neoplasm;           | Escitalopram Oxalate       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Confusional State;        | Victan (Ethyl Loflazepate) |              |            | C           |              |                    |                 | Not Reported |
| Decreased Appetite;       |                            |              |            |             |              |                    |                 |              |
| Depressed Mood;           |                            |              |            |             |              |                    |                 |              |
| Depression; Disturbance   |                            |              |            |             |              |                    |                 |              |
| In Attention; Psychomotor |                            |              |            |             |              |                    |                 |              |
| Retardation; Weight       |                            |              |            |             |              |                    |                 |              |
| Decreased                 |                            |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6487286       | EXPEDITED (15-DAY) | Y                  | OT              | A0697996A            |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Live Birth; Maternal     | Wellbutrin        |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
| Exposure During          | Lexapro           |              |            | S           |              | 10mg Per Day       |                 | Not Reported    |
| Pregnancy;               | Tylenol           |              |            | C           |              |                    |                 | Glaxosmithkline |
| Nephrolithiasis; Urinary | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported    |
| Tract Infection          | Vicodin           |              |            | C           |              |                    |                 | Not Reported    |
|                          | Pyridium          |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6501292       | EXPEDITED (15-DAY) | Y                  | OT              | S07-NOR-06074-01     |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bipolar Disorder;      | Cipralext      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Depression; Dizziness; |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |           |   |      |             |              |
|-----------------------------|-----------|---|------|-------------|--------------|
| Drug Interaction;           | Cipralext | S | Oral | 20 Mg Qd Po | Not Reported |
| Headache; Mania;            | Strattera | S |      | 60 Mg Qd    | Not Reported |
| Personality Disorder;       | Antabuse  | C |      |             | Not Reported |
| Seizure; Suicidal Ideation; |           |   |      |             |              |
| Vomiting                    |           |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6510460       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06171-01     |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Immunoglobulin A Increased; Drug Interaction; Hypersensitivity Vasculitis | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Oxazepam                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Zolpidem Tartrate       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Diamicron (Gliclazide)  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Tenstaten (Cicletanine) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Bisoprolol Fumarate     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Trimeprazine Tartrate   |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6511690       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S07-FRA-05254-01     |                      | 49 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Anxiety; Asphyxia; Impulsive Behaviour; Skin Laceration; Suicidal Ideation; Suicide Attempt | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                      | Inipomp                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Havlane (Loprazolam Mesilate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Lexomil (Bromazepam)          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2007              | 6512323       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05253-01     |                      | 67 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                               | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Cognitive Disorder; Confusional State; Dementia; Disorientation; Disturbance In Attention; | Escitalopram Oxalate              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                     | Selokeen                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                     | Pravastatin                       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hallucination, Auditory;  
Memory Impairment;  
Psychomotor Retardation;  
Sleep Disorder

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 11-Dec-2007                                                                                                                                                                                                                  | 6511913        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06106-03     |                              |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                                                                      | Lexapro        |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Lexapro        |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                                                  | 6511918        | DIRECT             | N                  | HO, LT, OT      |                      |                              | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Amnesia; Contusion; Drug<br>Abuse; Hallucinations,<br>Mixed; Head Injury;<br>Imprisonment; Poisoning;<br>Psychotic Disorder;<br>Screaming; Seizure;<br>Swelling Face; Thinking<br>Abnormal; Toothache | Lexapro        |                    |                    | S               | Oral                 | 60 Mg All At Once, Am Po     |                 | Forest       |                |
|                                                                                                                                                                                                                              | Wellbutrin     |                    |                    | S               | Oral                 | 450 Mg All At Once, Am<br>Po |                 | Teva         |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                                                  | 6511932        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06106-02     |                              |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                                                                      | Lexapro        |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Lexapro        |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                                                  | 6511940        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06106-01     |                              |                 | Unknown      | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|------------------------------|----------------|
| Seizure                                                                                                                                                                                          | Lexapro<br>Lexapro           |                    |                    | S<br>S          |                      |                                   |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                      | 6513804                      | DIRECT             | Y                  | HO, LT, OT      |                      |                                   | 50 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abdominal Pain; Alcoholic;<br>Antinuclear Antibody<br>Positive; Diarrhoea;<br>Hypertension; Insomnia;<br>Nerve Injury; Palpitations;<br>Panic Attack; Serotonin<br>Syndrome; Tremor;<br>Vomiting | Lexapro                      |                    |                    | S               |                      | 1 Daily                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Zoloft                       |                    |                    | S               |                      | 1; Then 4 Then Back To 1<br>Daily |                 | Not Reported                 |                |
|                                                                                                                                                                                                  |                              |                    |                    |                 |                      |                                   |                 |                              |                |
|                                                                                                                                                                                                  |                              |                    |                    |                 |                      |                                   |                 |                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                      | 6513968                      | DIRECT             | Y                  | HO              |                      |                                   | 64 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Behaviour;<br>Major Depression                                                                                                                                                          | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 10 Mg Od - Oral                   |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Glimepiride                  |                    |                    | C               |                      |                                   |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Quinapril                    |                    |                    | C               |                      |                                   |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Carvedilol                   |                    |                    | C               |                      |                                   |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 11-Dec-2007                                                                                                                                                                                      | 6513976                      | EXPEDITED (15-DAY) | Y                  | HO              | DSA_30950_2007       |                                   | 29 YR           | Female                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>                   |                |
| Intentional Overdose;<br>Suicide Attempt;<br>Tachycardia                                                                                                                                         | Tavor /00273201/ (Lorazepam) |                    |                    | S               | Oral                 | 5 Mg 1x .Oral                     |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Tablet                       |                    |                    |                 |                      |                                   |                 |                              |                |
|                                                                                                                                                                                                  | Aspirin                      |                    |                    | S               | Oral                 | 15 G 1x . Oral                    |                 | Not Reported                 |                |
|                                                                                                                                                                                                  | Ciprallex                    |                    |                    | S               | Oral                 | 6 Df 1x Oral                      |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |      |                   |              |
|---------------|---|------|-------------------|--------------|
| Acetaminophen | S | Oral | Oral              | Not Reported |
| Mirtazapine   | S | Oral | 1050 Mg 1x . Oral | Not Reported |
| Seroquel      | S | Oral | 20 G 1x . Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2007              | 6150301       | EXPEDITED (15-DAY) | Y                  | HO              | S06-FRA-04081-01     |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Apathy; Asthenia; Fall;<br>Hyponatraemia; Loss Of<br>Consciousness;<br>Orthostatic Hypotension;<br>Urinary Incontinence;<br>Urinary Tract Infection | Escitalopram Oxalate       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                     | Exelon                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                     | Basdene (Benzylthiouracil) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2007              | 6436465       | EXPEDITED (15-DAY) | N                  | OT              | A0697996B            |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Infection; Maternal<br>Exposure During<br>Pregnancy; Pulmonary<br>Hypertension | Wellbutrin        |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                | Lexapro           |              |            | S           |              | 10mg Per Day       |                 | Not Reported    |
|                                                                                | Tylenol           |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                                                | Prenatal Vitamins |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                | Vicodin           |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                | Pyridium          |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2007              | 6509949       | DIRECT           | N                  | CA              |                      |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Dizziness; Loss Of<br>Consciousness; Maternal<br>Exposure During<br>Pregnancy; Mitral Valve<br>Disease; Pregnancy; | Lexapro        |              |            | S           | Oral         | 10 Mg 1tab Daily By<br>Mouth |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syncopal

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Dec-2007                                                                                    | 6513703              | DIRECT             | N                  | OT              |                      |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Fatigue; Fear; Lethargy;<br>Thinking Abnormal | Lexapro              |                    |                    | S               | Oral                 | 10mg 1 Day Po        | 2 WEEK          | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2007                                                                                    | 6514251              | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-06141-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                              | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2007                                                                                    | 6516995              | DIRECT             | Y                  | HO              |                      |                      | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Bilirubin Increased;                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Od - Oral      |                 | Not Reported |                |
| Conduction Disorder;                                                                           | Metoclopramide       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Mitral Valve                                                                                   | Levothyroxine Sodium |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Incompetence; Nausea;                                                                          | Saw Palmetto         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Non-Cardiac Chest Pain;                                                                        | Acetylsalicylic Acid |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Pulmonary Valve                                                                                | Niacin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Incompetence; Qrs Axis                                                                         | Fish Oil             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Abnormal; Sinus                                                                                | Ginkgo Biloba        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Arrhythmia; Tricuspid                                                                          |                      |                    |                    |                 |                      |                      |                 | Not Reported |                |
| Valve Incompetence                                                                             |                      |                    |                    |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2007                                                                                    | 6517770              | DIRECT             | Y                  | OT              |                      |                      | 51 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|-----------------|----------------|
| Abnormal Behaviour;<br>Anxiety; Confusional<br>State; Fear; Restlessness;<br>Suicidal Ideation                                                                  | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Tablet Once A Day<br>Po |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Dec-2007                                                                                                                                                     | 6515089        | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-06211-01     |                               | 25 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Aggression; Agitation;<br>Alcohol Abuse; Mania;<br>Suicidal Ideation; Weight<br>Increased                                                                       | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po                   |                 | Not Reported    |                |
|                                                                                                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 30 Mg Qd Po                   |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Dec-2007                                                                                                                                                     | 6452807        | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-05457-01     |                               | 17 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Behaviour;<br>Amnesia; Dissociation;<br>Haemorrhage; Intentional<br>Self-Injury; Intentional<br>Self-Injury; Skin<br>Laceration; Suicidal<br>Behaviour | Lexapro        |                    |                    | S               | Oral                 | 20 Mg Qd Po                   |                 | Not Reported    |                |
|                                                                                                                                                                 | Lamictal       |                    |                    | C               |                      |                               |                 | Not Reported    |                |
|                                                                                                                                                                 | Depakote       |                    |                    | C               |                      |                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Dec-2007                                                                                                                                                     | 6501387        | EXPEDITED (15-DAY) | Y                  | OT              | A0698825A            |                               | 42 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Blood Pressure<br>Increased; Drug<br>Ineffective; Headache                                                                                             | Imitrex        |                    |                    | S               | Oral                 | 100mg Single Dose             | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                                                                 | Lexapro        |                    |                    | S               | Oral                 | 10mg Per Day                  |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Dec-2007                                                                                | 6516273               | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06246-01     |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                    | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2007                                                                                | 6517634               | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06186-01     |                      | 30 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Contact;<br>Disorientation; Drug<br>Interaction; Rash; Road<br>Traffic Accident | Lexapro               |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                            | Benadryl              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2007                                                                                | 6590158               | NON-EXPEDITED      | Y                  | OT              | 2006152713           |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction                                                                       | Doxazosin             |                    |                    | S               |                      | 2 Mg (1 D)           |                 | Not Reported |                |
|                                                                                            | Escitalopram Oxalate  |                    |                    | S               |                      | 10 Mg (1 D)          |                 | Not Reported |                |
|                                                                                            | Cozaar                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Remeron               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Norvasc (Norvasc)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2007                                                                                | 6472751               | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-05784-01     |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accommodation Disorder;<br>Back Pain; Dysuria;<br>Fatigue; Muscle<br>Contracture; Pyrexia; | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                            | Fenofibrate           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                            | Fosinopril Sodium And |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                     |                        |                     |                    |                 |                      |                      |                 |                 |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Torticollis                                                                                                                                                                         |                        | Hydrochlorothiazide |                    | C               |                      | Not Reported         |                 |                 |                |
| Xanax                                                                                                                                                                               |                        |                     |                    |                 |                      |                      |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>          | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 18-Dec-2007                                                                                                                                                                         | 6508006                | EXPEDITED (15-DAY)  | Y                  | OT              | A0699323A            |                      | 43 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>         | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Demyelinating<br>Polyneuropathy;<br>Intracranial Mass                                                                                                                               | Wellbutrin XL          |                     |                    | S               | Oral                 | 300mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                                                                                                     | Effexor Xr             |                     |                    | S               | Oral                 | 75mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                                                     | Lexapro                |                     |                    | S               |                      | 20mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                                                                     | Unspecified Ingredient |                     |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>          | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 18-Dec-2007                                                                                                                                                                         | 6516931                | EXPEDITED (15-DAY)  | Y                  | OT              | S07-ESP-06274-01     |                      | 60 YR           | Male            | ESP            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>         | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Lung Infiltration; Pyrexia;<br>Rash                                                                                                                                                 | Ciprallex              |                     |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                     | Idalprem (Lorazepam)   |                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                     | Diltiazem              |                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                     | Edemox (Acetazolamide) |                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                     | Haloperidol            |                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                     | Vitamin B12            |                     |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                     | Folic Acid             |                     |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>          | <u>Case Type</u>    | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 18-Dec-2007                                                                                                                                                                         | 6517336                | EXPEDITED (15-DAY)  | Y                  | HO              | S07-FRA-06253-01     |                      | 60 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>         | <u>Comp.</u>        | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Confusional<br>State; Csf Protein<br>Increased; Dyskinesia;<br>Fall; Gait Disturbance;<br>General Physical Health<br>Deterioration; Generalised<br>Tonic-Clonic Seizure; | Escitalopram Oxalate   |                     |                    | S               | Oral                 | 2 Unk Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                     | Escitalopram Oxalate   |                     |                    | S               | Oral                 | 2 Unk Unk Po         |                 | Not Reported    |                |
|                                                                                                                                                                                     | Acepromazine           |                     |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                                                                                                     | Maleate\Clorazepate    |                     |                    |                 |                      |                      |                 |                 |                |
|                                                                                                                                                                                     | Dipotassium            |                     |                    | S               |                      |                      |                 |                 | Not Reported   |
| Acepromazine                                                                                                                                                                        |                        |                     |                    |                 |                      |                      |                 |                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                                                                                                        |                  |      |             |                                                              |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|
| Hallucination;<br>Hyponatraemia;<br>Persecutory Delusion;<br>Post-Traumatic Amnestic<br>Disorder; Therapy Change | Maleate\Clorazepate<br>Dipotassium<br>Aceprometazine\Meprobamate<br>Zolpidem<br>Zocor<br>Levothyroxine | S<br>C<br>C<br>C | Oral | 2 Unk Qd Po | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------|------|-------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2007              | 6518209       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06324        |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>                   |
|----------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------------------------|
| Rash Erythematous; Rash<br>Macular; Rash<br>Morbilloform; Toxic Skin<br>Eruption | Escitalopram Oxalate<br>Allopurinol |              |            | S<br>S      | Oral<br>Oral | 20 Mg Qd Po<br>300 Mg Qd Po |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2007              | 6689512       | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWI-06242-01     |                      | 80 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Amnesia; Dizziness;<br>Feeling Abnormal;<br>Intentional Product<br>Misuse; Nausea;<br>Neurological Examination<br>Abnormal; Syncope;<br>Tremor; Ventricular<br>Hypokinesia | Cipralax<br>Flupentixol\Melitracen<br>Zocor<br>Symfona N (Gingko Biloba<br>Extract)<br>Lorazepam |              |            | S<br>S<br>C<br>C<br>C | Oral         | 10 Mg Once Po      |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2007              | 6454454       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-05438-01     |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|----------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Blood Cholesterol<br>Increased; Generalised<br>Tonic-Clonic Seizure; | Lexapro<br>Unknown Hypertension<br>Medication (Nos) |              |            | S<br>C      | Oral         | 30 Mg Qd Po        |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Haemorrhagic Stroke;  
Overdose; Weight  
Increased

| <u>FDA Received Date</u>                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|----------------------|----------------|
| 19-Dec-2007                                                           | 6471062              | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13982640 |                                                                                                                 | 66 YR           | Female               | DEU            |
| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>           |                |
| Hospitalisation; Serotonin<br>Syndrome                                | Abilify              |                    |                    | S               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
|                                                                       | Cipralext            |                    |                    | S               | Oral                                            | Daily Dosage:From 18-Jul-<br>07 To 23-Jul-07 Is 5 Mg                                                            |                 | Not Reported         |                |
|                                                                       | Lamotrigine          |                    |                    | C               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
|                                                                       | Trileptal            |                    |                    | C               | Oral                                            | Unk/06 To 17/Jul/07 -<br>300mg/D,18/Jul To 29/Jul<br>- 450mg, 30/Jul To 31/Jul -<br>600mg, 01/Aug/07 -<br>900mg |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Dec-2007                                                           | 6509052              | EXPEDITED (15-DAY) | Y                  | HO              | ES-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14017818 |                                                                                                                 | 72 YR           | Female               | ESP            |
| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>           |                |
| Aggression; Delirium;<br>Disorientation;<br>Psychomotor Hyperactivity | Sinemet              |                    |                    | S               | Oral                                            | 1 Dosage Form =<br>25/100mg Tablet.                                                                             | 25 DAY          | Bristol Myers Squibb |                |
|                                                                       | Stalevo              |                    |                    | S               | Oral                                            | 1 Dosage Form= 2 Fixed<br>Dose<br>(25mg+200mg+100mg<br>Tabs)                                                    | 29 DAY          | Not Reported         |                |
|                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                            |                                                                                                                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Dec-2007                                                           | 6147461              | EXPEDITED (15-DAY) | N                  | DE              | S06-USA-03868-01                                |                                                                                                                 | 20 YR           | Male                 | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|------------------------------|---------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| Abdominal Pain Upper;<br>Accidental Death;<br>Analgesic Drug Level<br>Increased; Antidepressant<br>Drug Level Increased;<br>Arrhythmia; Cardiac<br>Arrest; Contusion; Drug<br>Interaction; Heart Rate<br>Increased; Insomnia;<br>Nervous System Disorder;<br>Unresponsive To Stimuli;<br>Weight Decreased | Lexapro<br>Zoloft<br>Methadone Hydrochloride<br>Ambien<br>Unspecified Ingredient<br>Cold Medicine (Nos) |                    |                    | S<br>S<br>S<br>C<br>C<br>C |                              |                                                         |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                  | <u>Case #</u>                                                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 21-Dec-2007                                                                                                                                                                                                                                                                                               | 6443532                                                                                                 | EXPEDITED (15-DAY) | Y                  | OT                         | S07-ESP-05278-01             |                                                         | 45 YR           | Female                                                                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Drug Interaction;<br>Galactorrhoea;<br>Hypothalamo-Pituitary<br>Disorder; Menstruation<br>Irregular; Overdose;<br>Weight Increased                                                                                                                                                                        | Cipralelex<br>Cipralelex<br>Cipralelex<br>Amitriptyline<br>Unspecified Ingredient                       |                    |                    | S<br>S<br>S<br>S<br>C      | Oral<br>Oral<br>Oral         | 50 Mg Qd Po<br>40 Mg Qd Po<br>25 Mg Qd Po               |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                  | <u>Case #</u>                                                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
| 21-Dec-2007                                                                                                                                                                                                                                                                                               | 6450372                                                                                                 | EXPEDITED (15-DAY) | Y                  | HO                         | S07-UKI-05382-01             |                                                         | 17 YR           | Male                                                                                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>                                                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Aggression; Anger;<br>Anxiety; Asthenia; Cardiac<br>Disorder; Chest Pain; Cold<br>Sweat; Conduction<br>Disorder; Decreased<br>Appetite; Depression;<br>Diarrhoea; Dizziness;<br>Drug Withdrawal                                                                                                           | Cipralelex<br>Cipralelex<br>Cipralelex<br>Cipralelex<br>Propranolol<br>Atenolol                         |                    |                    | S<br>S<br>S<br>S<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral | 5 Mg Qd Po<br>10 Mg Qd Po<br>5 Mg Qd Po<br>2.5 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Dyspnoea;  
Euphoric Mood;  
Extrasystoles; Fear;  
Feeling Abnormal; Feeling  
Hot; Frustration Tolerance  
Decreased; Headache;  
Heart Rate Decreased;  
Hyperhidrosis;  
Hypoaesthesia; Intentional  
Self-Injury; Malaise; Mood  
Altered; Muscular  
Weakness;  
Musculoskeletal Stiffness;  
Nausea; Pain In Extremity;  
Palpitations; Pulse  
Abnormal; Pulse Pressure  
Decreased; Respiratory  
Disorder; Sensory  
Disturbance; Suicidal  
Ideation; Vision Blurred

Omeprazole

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2007              | 6457743       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-GER-00142-01     |                      | 26 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;       | Cipralelex              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Maternal Exposure During | Cipralelex              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Pregnancy; Pregnancy;    | Cipralelex              |              |            | S           |              |                    |                 | Not Reported |
| Sciatica; Symphysiolysis | Cipralelex              |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                          | Iron                    |              |            | C           |              |                    |                 | Not Reported |
|                          | Folic Acid              |              |            | C           |              |                    |                 | Not Reported |
|                          | Minerals Nos            |              |            | C           |              |                    |                 | Not Reported |
|                          | Jod (Iodine)            |              |            | C           |              |                    |                 | Not Reported |
|                          | Enoxaparin Sodium       |              |            | C           |              |                    |                 | Not Reported |
|                          | Magno Sanol (Magnesium) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2007              | 6468633       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05778-01     |                      | 54 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Palpitations; Stress;<br>Ventricular Extrasystoles                                               | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Zolpidem Tartrate                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2007                                                                                      | 6472693                                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-CAN-05812-01     |                      | 48 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rhabdomyolysis; Viral<br>Infection                                                               | Cipralex                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Celebrex                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2007                                                                                      | 6495696                                 | EXPEDITED (15-DAY) | Y                  | HO              | S07-NLD-06075-01     |                      | 81 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokalaemia;<br>Hyponatraemia;<br>Somnolence; Vomiting                                          | Lexapro                                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Hydrochlorothiazide                     |                    |                    | S               | Oral                 | 12.5 Mg Qd Po        |                 | Not Reported |                |
|                                                                                                  | Enalapril                               |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Sotalol Hydrochloride                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                  | Carbasalaatcalcium(Carbasalate Calcium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                  | Nicardipine Hydrochloride               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                  | Lorazepam                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                  | Levothyroxine Sodium                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2007                                                                                      | 6510400                                 | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-06173-01     |                      | 19 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol<br>Increased; Blood Pressure<br>Fluctuation; Blood<br>Pressure Increased; Drug | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Withdrawal Syndrome;  
 Eye Swelling; Gait  
 Disturbance; Heart Rate  
 Increased; Irritability;  
 Micturition Frequency  
 Decreased; Movement  
 Disorder; Muscle  
 Twitching; Refusal Of  
 Treatment By Patient;  
 Restlessness; Thirst;  
 Vertigo; Weight Increased

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2007               | 6512073              | EXPEDITED (15-DAY) |                    | HO              | PHBS2007ES20811      |                      | 72 YR           | Female       | ESP            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Delirium;     | Stalevo              |                    |                    | S               | Oral                 | Unk, Bid             | 41760 MIN       | Orion        |                |
| Disorientation;           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg/D              |                 | Not Reported |                |
| Psychomotor Hyperactivity | Sinemet              |                    |                    | S               | Oral                 | Unk, Qd              |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2007               | 6519202              | DIRECT             | Y                  | RI              |                      |                      | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; | Lexapro              |                    |                    | S               | Oral                 | 10mg Po Daily        | 3 DAY           | Not Reported |                |
| Dizziness; Dry Mouth;     |                      |                    |                    |                 |                      |                      |                 |              |                |
| Serotonin Syndrome        |                      |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2007               | 6519204              | DIRECT             | Y                  | OT              |                      |                      | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Vomiting          | Lexapro              |                    |                    | S               | Oral                 | 10mg Once Po Qd Po   |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u> | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                  | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------------|--------------------|-----------------|----------------------------------------------------|---------------------------------------|------------|------------|----------------|
| 21-Dec-2007                                                                                                                                                                          | 6519377       | EXPEDITED (15-DAY)      | N                  | OT              | S07-USA-06332-01                                   |                                       |            | Male       | USA            |
| <div> <div>Preferred Term</div> <div>Product</div> <div>Comp.</div> <div>OTC</div> <div>Role</div> <div>Route</div> <div>Dosage Text</div> <div>Duration</div> <div>Mfr</div> </div> |               |                         |                    |                 |                                                    |                                       |            |            |                |
| Drug Interaction;<br>Serotonin Syndrome                                                                                                                                              |               | Lexapro                 |                    | S               |                                                    |                                       |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Alcohol                 |                    | S               |                                                    |                                       |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Adderall                |                    | S               |                                                    |                                       |            |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u> | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                  | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 21-Dec-2007                                                                                                                                                                          | 6520037       | EXPEDITED (15-DAY)      | Y                  | OT              | 231265J07USA                                       |                                       | 27 YR      | Female     | USA            |
| <div> <div>Preferred Term</div> <div>Product</div> <div>Comp.</div> <div>OTC</div> <div>Role</div> <div>Route</div> <div>Dosage Text</div> <div>Duration</div> <div>Mfr</div> </div> |               |                         |                    |                 |                                                    |                                       |            |            |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Pregnancy                                                                                                            |               | Rebif                   |                    | S               | Subcutaneous                                       | 44 Mcg, 3 In 1 Weeks,<br>Subcutaneous |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Lexapro                 |                    | S               |                                                    |                                       |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Klonopin                |                    | S               |                                                    |                                       |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Atenolol (Atenolol)     |                    | C               |                                                    |                                       |            |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u> | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                  | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 26-Dec-2007                                                                                                                                                                          | 6514705       | EXPEDITED (15-DAY)      |                    | HO              | IN-ROXANE<br>LABORATORIES, INC-<br>2007-DE-07472GD |                                       | 56 YR      | Male       | IND            |
| <div> <div>Preferred Term</div> <div>Product</div> <div>Comp.</div> <div>OTC</div> <div>Role</div> <div>Route</div> <div>Dosage Text</div> <div>Duration</div> <div>Mfr</div> </div> |               |                         |                    |                 |                                                    |                                       |            |            |                |
| Drug Ineffective; Drug<br>Interaction; Hypomania;<br>Serotonin Syndrome                                                                                                              |               | Sertraline              |                    | S               |                                                    |                                       | 5 WEEK     |            | Roxane         |
|                                                                                                                                                                                      |               | Trazodone Hydrochloride |                    | S               |                                                    |                                       | 5 WEEK     |            | Not Reported   |
|                                                                                                                                                                                      |               | Lithium Carbonate       |                    | S               |                                                    |                                       |            |            | Roxane         |
|                                                                                                                                                                                      |               | Phenytoin               |                    | S               |                                                    |                                       |            |            | Not Reported   |
|                                                                                                                                                                                      |               | Escitalopram Oxalate    |                    | S               |                                                    |                                       | 1 WEEK     |            | Not Reported   |
|                                                                                                                                                                                      |               | Amlodipine              |                    | C               |                                                    |                                       |            |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u> | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u>                  | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 27-Dec-2007                                                                                                                                                                          | 6509749       | EXPEDITED (15-DAY)      | Y                  | DE              | S07-USA-06105-01                                   |                                       | 27 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                    | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Fall; Head Injury;<br>Overdose; Self-Medication | Lexapro            |              |            | S           | Oral         | 30 Mg Qd Po        |                 | Not Reported |
|                                                                          | Lexapro            |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Lexapro            |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Seroquel           |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Klonopin           |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Zyprexa            |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Restoril           |              |            | C           |              |                    |                 | Not Reported |
|                                                                          | Emsam (Selegiline) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2007              | 6515199       | EXPEDITED (15-DAY) | N                  | HO              | B0500862A            |                      | 26 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Eosinophilia; Epidermal<br>Necrosis; Generalised<br>Erythema; Hyperthermia;<br>Lymphocytic Infiltration;<br>Odynophagia; Pruritus;<br>Rash Maculo-Papular;<br>Toxic Skin Eruption | Lamictal             |              |            | S           | Oral         | 50mg Per Day       | 12 DAY          | Glaxosmithkline |
|                                                                                                                                                                                   | Escitalopram Oxalate |              |            | S           | Oral         | 10mg Per Day       | 40 DAY          | Unknown         |
|                                                                                                                                                                                   | Ibuprofen            |              |            | S           | Oral         | 1tab Single Dose   | 1 DAY           | Unknown         |
|                                                                                                                                                                                   | Surmontil            |              |            | C           | Oral         |                    | 58 DAY          | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Dec-2007              | 6524590       | DIRECT           | N                  | OT              |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Chills; Cold Sweat;<br>Diarrhoea; Dizziness;<br>Drug Interaction;<br>Headache; Malaise;<br>Medication Error; Nausea;<br>Product Dispensing Error;<br>Tremor; Viral Infection;<br>Vomiting; Wrong Product<br>Administered | Lexapro        |              |            | S           | Oral         | 20 Mg 1 Daily Po Once |                 | Not Reported |
|                                                                                                                                                                                                                          | Lipitor        |              |            | S           |              |                       |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jan-2008                                                                                                                                   | 6523026                                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-BEL-06123-01     |                      | 42 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dyskinesia; Hyperreflexia;<br>Myoclonus; Serotonin<br>Syndrome; Speech<br>Disorder                                       | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                               | Omeprazole                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Insidon "Ciba-Geigy" (Opipramol Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2008                                                                                                                                   | 6528117                                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06491-01     |                      | 26 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epidermal Necrosis;<br>Epstein-Barr Virus<br>Infection; Hyperthermia;<br>Odynophagia; Parvovirus<br>B19 Test Positive; Toxic<br>Skin Eruption | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                               | Lamictal                                       |                    |                    | S               | Oral                 | 50 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                               | Ibuprofen                                      |                    |                    | S               | Oral                 | 1 Qd Po              |                 | Not Reported |                |
|                                                                                                                                               | Surmontil                                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Surmontal (Trimipramine)                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2008                                                                                                                                   | 6490621                                        | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-06089-01     |                      | 63 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash; Right Ventricular<br>Failure                                                                                                            | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram Oxalate                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                               | Mirtazapine                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Irbesartan                                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Novodigal (Digoxin)                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Beloc Zok (Metoprolol Succinate)               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Simvastatin                                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                               | Marcumar                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| Hct Hexal (Hydrochlorothiazide)                                                                                                                                                                                                                                       |                                 |                    | C                  |                 |                      |                      | Not Reported    |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Melperon (Melperone)                                                                                                                                                                                                                                                  |                                 |                    | C                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2008                                                                                                                                                                                                                                                           | 6526721                         | EXPEDITED (15-DAY) | Y                  | OT              | S07-SWI-06495-01     |                      | 43 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Cholelithiasis; Gamma-Glutamyltransferase Increased; Liver Disorder; Liver Function Test Abnormal | Ciprallex                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Crestor                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Atacand (Candesartan Cilexetil) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Logimax                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2008                                                                                                                                                                                                                                                           | 6527655                         | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06475-01     |                      | 13 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Overdose; Suicide Attempt                                                                                                                                                                                                                 | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 28 Tablet Once Po    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Tetrazepam                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                              | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2008                                                                                                                                                                                                                                                           | 6480967                         | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-03825-01     |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                 | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Diabetic Complication                                                                                                                                                                                                                      | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg, Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Geodon                          |                    |                    | S               |                      | 80 Mg Qd;            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                       | Geodon                          |                    |                    | S               |                      | 20 Mg, Bid,          |                 | Not Reported |                |



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|                                      |   |             |              |
|--------------------------------------|---|-------------|--------------|
| Geodon                               | S | 40 Mg, Bid; | Not Reported |
| Geodon                               | S | 60 Mg, Bid; | Not Reported |
| Lyrica                               | C |             | Not Reported |
| Glucophage                           | C |             | Not Reported |
| Esgic (Butalbital And Acetaminophen) | C |             | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jan-2008                                                                                                                                                             | 6490689                        | EXPEDITED (15-DAY) | Y                  | OT              | S07-GER-06063-01     |                      | 64 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar Disorder; Condition Aggravated; Gamma-Glutamyltransferase Increased; Major Depression | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                         | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                         | Chlorprothixene                |                    |                    | S               | Oral                 | 100 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                         | Zyprexa                        |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                         | Lithium Carbonate              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Lithium Carbonate              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Asa (Acetylsalicylic Acid)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Pantozol (Pantoprazole Sodium) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Voltaren                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Enalapril Maleate              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Dyazide                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                         | Novamin (Prochlorperazine)     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2008                                                                                                                                                             | 6518324                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-PRT-06345-01     |                      | 60 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acquired Haemophilia; Blood Thromboplastin Decreased; Gingival Bleeding; Haematoma; Haematuria; Prothrombin Level Abnormal; Treatment Noncompliance                     | Cipraxel                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                         | Ibuprofen                      |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                                                                                                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                                | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-------------------------------------------|-------------------------------------------------------------------------------------|----------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 07-Jan-2008                                                                            | 6528427                                                                                                                                                                                            | EXPEDITED (15-DAY) | Y                  | OT                                        | S08-CAN-00020-01                                                                    |                            | 36 YR           | Female                                                                                                                                       | CAN            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                                                                                                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                                        | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Paraesthesia; Pruritus;<br>Rash Erythematous;<br>Throat Irritation; Tongue<br>Disorder | Cipralext                                                                                                                                                                                          |                    |                    | S                                         | Oral                                                                                | 10 Mg Qd Po                |                 | Not Reported                                                                                                                                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                                                                                                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                                | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 08-Jan-2008                                                                            | 6459495                                                                                                                                                                                            | EXPEDITED (15-DAY) | Y                  | OT                                        | S07-USA-05468-01                                                                    |                            | 52 YR           | Female                                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                                                                                                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                                        | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased      | Lexapro<br>Lexapro<br>Ambien Cr                                                                                                                                                                    |                    |                    | S<br>S<br>C                               | Oral<br>Oral                                                                        | 10 Mg Qd Po<br>10 Mg Qd Po |                 | Not Reported<br>Not Reported<br>Not Reported                                                                                                 |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>                                                                                                                                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                           | <u>Mfr Control #</u>                                                                | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>                                                                                                                                   | <u>Country</u> |
| 08-Jan-2008                                                                            | 6521212                                                                                                                                                                                            | EXPEDITED (15-DAY) | Y                  | HO                                        | FR-JNJFOC-<br>20071206082                                                           |                            | 62 YR           | Female                                                                                                                                       | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>                                                                                                                                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                               | <u>Route</u>                                                                        | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |                |
| Pancreatitis                                                                           | Durogesic<br>Entecavir<br>Mabthera<br>Cyamemazine<br>Aceprometazine\Clorazepate<br>Dipotassium<br>Escitalopram Oxalate<br>Dulcolax (Bisacodyl)<br>Previscan (Fluindione)<br>Aerius (Desloratadine) |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Transdermal<br>Oral<br>Unknown<br>Oral<br>Oral<br>Oral<br>Rectal<br>Oral<br>Unknown |                            | 16 DAY          | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 08-Jan-2008                                                                | 6521749        | EXPEDITED (15-DAY) | N                  | HO              | US-ASTRAZENECA-2008UW00098 |                                           | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Decreased                                                       | Toprol XL      |                    |                    | S               | Oral                       |                                           |                 | Not Reported |                |
|                                                                            | Toprol XL      |                    |                    | S               | Oral                       | Dose Decreased                            |                 | Not Reported |                |
|                                                                            | Lexapro        |                    |                    | S               | Oral                       |                                           |                 | Not Reported |                |
|                                                                            | Lipitor        |                    |                    | C               |                            |                                           |                 | Not Reported |                |
|                                                                            | Paxil          |                    |                    | C               |                            |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2008                                                                | 6524364        | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-06385-01           |                                           | 74 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased;<br>Claustrophobia;<br>Headache; No Adverse Event | Lexapro        |                    |                    | S               | Oral                       | 10 Mg Qd Po                               |                 | Not Reported |                |
|                                                                            | Aggrenox       |                    |                    | S               |                            |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2008                                                                | 6525524        | DIRECT             |                    |                 |                            |                                           | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error; Product Dispensing Error                                 | Lexapro        |                    |                    | S               | Oral                       | Take 1 Tablet By Mouth Every Day Tablet   |                 | Forest       |                |
|                                                                            | Naprosyn       |                    |                    | S               | Oral                       | Take 1 Tablet By Mouth Twice Daily Tablet |                 | Teva         |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2008                                                                | 6522274        | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20080100478      |                                           | 20 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
|----------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------------------------|----------------|
| Drug Interaction; Drug Level Above Therapeutic; Overdose; Serotonin Syndrome                       | Dextromethorphan Hydrobromide |                    | Y                  | S               | Oral                  |                      |                 | Not Reported                 |                |
|                                                                                                    | Aripiprazole                  |                    |                    | S               | Oral                  |                      |                 | Not Reported                 |                |
|                                                                                                    | Benztropine Mesylate          |                    |                    | S               | Oral                  |                      |                 | Not Reported                 |                |
|                                                                                                    | Chlorpheniramine              |                    |                    | S               | Oral                  |                      |                 | Not Reported                 |                |
|                                                                                                    | Nicotine Escitalopram Oxalate |                    |                    | C<br>S          |                       |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Jan-2008                                                                                        | 6526692                       | EXPEDITED (15-DAY) | Y                  | DE              | S07-UKI-06442-01      |                      | 50 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Asphyxia; Completed Suicide                                                                        | Cipralax                      |                    |                    | S               | Oral                  | 20 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                    | Prozac                        |                    |                    | C               |                       |                      |                 | Not Reported                 |                |
|                                                                                                    | Quetiapine                    |                    |                    | C               |                       |                      |                 | Not Reported                 |                |
|                                                                                                    | Zopiclone                     |                    |                    | C               |                       |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Jan-2008                                                                                        | 6527928                       | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-00023-01      |                      |                 | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anger; Anxiety; Deafness; Flight Of Ideas; Insomnia; Somnolence; Suicidal Ideation; Vision Blurred | Lexapro                       |                    |                    | S               |                       |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 10-Jan-2008                                                                                        | 6524188                       | EXPEDITED (15-DAY) | Y                  | DE              | US-MERCK-0801USA00490 |                      | 65 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Overdose; Toxicity To Various Agents                                                               | Hydrocortone                  |                    |                    | S               | Oral                  |                      |                 | Merck                        |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |              |
|-------------------------|---|------|--------------|
| Risperidone             | S | Oral | Not Reported |
| Metaxalone              | S | Oral | Not Reported |
| Heparin                 | S | Oral | Not Reported |
| Oxycodone               | S | Oral | Not Reported |
| Escitalopram Oxalate    | S | Oral | Not Reported |
| Bupropion Hydrochloride | S | Oral | Not Reported |
| Clonidine               | S | Oral | Not Reported |
| Methadone Hydrochloride | S | Oral | Not Reported |
| Albuterol               | S | Oral | Not Reported |
| Haloperidol             | S | Oral | Not Reported |
| Acyclovir               | S | Oral | Not Reported |
| Vancomycin              | S | Oral | Not Reported |
| Lamotrigine             | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2008              | 6225797       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13587902 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Anorgasmia; Constipation;<br>Disturbance In Attention;<br>Dry Eye; Dry Mouth; Fall;<br>Fatigue; Somnolence;<br>Vertigo; Weight Increased | Desyrel               |              |            | S           | Oral          |                    |                 | Apothecon    |
|                                                                                                                                          | Lexapro               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                          | Lexapro               |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                          | Trileptal             |              |            | S           | Oral          |                    |                 | Not Reported |
|                                                                                                                                          | Klonopin              |              |            | S           |               |                    |                 | Sandoz       |
|                                                                                                                                          | Zyrtec                |              |            | C           |               |                    |                 | Not Reported |
|                                                                                                                                          | Vitamin B             |              |            | C           | Intramuscular |                    |                 | Not Reported |
|                                                                                                                                          | Grapeseed Extract     |              |            | C           |               |                    |                 | Not Reported |
|                                                                                                                                          | Vitamin C             |              |            | C           |               |                    |                 | Not Reported |
|                                                                                                                                          | Methylsulfonylmethane |              |            | C           |               |                    |                 | Not Reported |
|                                                                                                                                          | Iron                  |              |            | C           |               |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2008                | 6524525                   | EXPEDITED (15-DAY) | N                  | OT              | US-ROCHE-539562            |                      | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous       | Klonopin                  |                    |                    | S               | Unknown                    |                      |                 | Roche        |                |
|                            | Rebif                     |                    |                    | S               | Subcutaneous               |                      |                 | Not Reported |                |
|                            | Rebif                     |                    |                    | S               | Subcutaneous               |                      |                 | Not Reported |                |
|                            | Lexapro                   |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                            | Atenolol                  |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2008                | 6524629                   | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2008AC00096 |                      | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide          | Quetiapine                |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                            | Escitalopram Oxalate      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Atomoxetine Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2008                | 6526101                   | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20080101911      |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Acetaminophen             |                    | Y                  | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Acetaminophen             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Hydrocodone               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Escitalopram Oxalate      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Clonazepam                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Lisinopril                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                            | Cocaine                   |                    |                    | S               |                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2008              | 6526156       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20080101065 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Risperidone             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Haloperidol             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Metaxalone              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Oxycodone               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Bupropion               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Clonidine               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Unspecified Ingredient  |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Methadone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Albuterol               |              |            | S           |              |                    |                 | Not Reported |
|                            | Acyclovir               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Vancomycin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lamotrigine             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Heparin                 |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2008              | 6526385       | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2008AC00159 |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Quetiapine           |              |            | S           | Oral         |                    |                 | Zeneca       |
|                       | Bupropion            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Jan-2008              | 6526390       | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2008AC00142 |                      | 24 YR      | Male       | USA            |

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| <u>Preferred Term</u>                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Death                                           | Quetiapine                            |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                 | Escitalopram Oxalate                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Alprazolam                            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2008                                     | 6526406                               | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2008AC00149 |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                               | Lisinopril                            |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                 | Acetaminophen                         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Hydrocodone                           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Clonazepam                            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Cocaine                               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2008                                     | 7888834                               | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2008AC00113 |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Quetiapine                            |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                 | Unspecified Ingredient                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Butalbital Acetaminophen And Caffeine |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Aspirin                               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Acetaminophen                         |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Ibuprofen                             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Caffeine Citrate                      |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                 | Naproxen                              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Fexofenadine                                                                                                                                      |                         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2008                                                                                                                                       | 6515357                 | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2007105545 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Abuse; Blood Pressure Decreased; Heart Rate Increased; Hypertension; Nervousness; Panic Reaction; Presyncope; Sedation; Unevaluable Event | Norvasc                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                   | Xanax                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                   | Clonidine               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                   | Lexapro                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                   | Valium                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                   | Librium                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2008                                                                                                                                       | 6527099                 | EXPEDITED (15-DAY) | Y                  | DE, HO          | US-JNJFOC-20080101908    |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                                                        | Acetaminophen           |                    | Y                  | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Acetaminophen           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Trazodone Hydrochloride |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Zyprexa                 |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Oxcarbazepine           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Benzodiazepine          |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2008                                                                                                                                       | 6532074                 | EXPEDITED (15-DAY) | Y                  | HO              | S08-NOR-00119-01         |                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Bradykinesia; Cognitive                                                                                                         | Cipralext               |                    |                    | S               | Oral                     | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                                 |   |          |              |
|-----------------------------------|---------------------------------|---|----------|--------------|
| Disorder; Extrapyramidal Disorder | Trilafon                        | S | 4 Mg Qod | Not Reported |
|                                   | Exelon                          | S | 3 Mg Qod | Not Reported |
|                                   | Seroquel                        | S | 50 Mg Qd | Not Reported |
|                                   | Duroferon (Ferrous Sulfate)     | C |          | Not Reported |
|                                   | Akineton                        | C |          | Not Reported |
|                                   | Vi-Siblin                       | C |          | Not Reported |
|                                   | Nexium (Esomeprazole)           | C |          | Not Reported |
|                                   | Zopiclone                       | C |          | Not Reported |
|                                   | Evista (Raloxine Hydrochloride) | C |          | Not Reported |
|                                   | Duphalac                        | C |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-Jan-2008              | 6532077        | EXPEDITED (15-DAY) | Y                  | OT              | S08-IRL-00136-01     |                      | 70 YR           | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention        | Lexapro        |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 16-Jan-2008                                               | 6528021              | EXPEDITED (15-DAY) | N                  | HO              | FR-BAYER-200810630GPV |                      | 44 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Diarrhoea; Intestinal Ischaemia; Vomiting | Betaferon            |                    |                    | S               | Subcutaneous          |                      | 8 YR            | Bayer        |                |
|                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                           | Relpax               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 16-Jan-2008                                     | 6528307        | EXPEDITED (15-DAY) | Y                  | HO              | B0503596A            |                      | 59 YR           | Male            | CHE            |
| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Aphasia; Depression; Disorientation; | Zyban          |                    |                    | S               | Oral                 |                      | 14 DAY          | Glaxosmithkline |                |
|                                                 | Cipralext      |                    |                    | S               | Oral                 |                      |                 | Not Reported    |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                               |                                                                              |                       |                                         |               |  |  |  |  |                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------|-----------------------------------------|---------------|--|--|--|--|------------------------------------------------------------------------------------|
| Disturbance In Attention;<br>Drug Interaction; Drug<br>Level Increased; Memory<br>Impairment; Pre-Existing<br>Disease; Psychiatric<br>Symptom; Sleep Disorder | Valproate Sodium<br>Reniten<br>Aspirin<br>Metformin Hydrochloride<br>Remeron | C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Unknown |               |  |  |  |  | Not Reported<br>Not Reported<br>Glaxosmithkline<br>Glaxosmithkline<br>Not Reported |
|                                                                                                                                                               |                                                                              |                       |                                         | 10mg Per Day  |  |  |  |  |                                                                                    |
|                                                                                                                                                               |                                                                              |                       |                                         | 500mg Per Day |  |  |  |  |                                                                                    |
|                                                                                                                                                               |                                                                              |                       |                                         | 15mg Per Day  |  |  |  |  |                                                                                    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2008              | 6533320       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00096-01     |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                   |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-----------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------|
| Chronic Myeloid<br>Leukaemia; Diarrhoea;<br>Dizziness; Headache;<br>Malaise; Nausea; Pain In<br>Extremity | Lexapro<br>Famvir<br>Multi-Vitamin<br>Vitamin C<br>Fish Oil |              |            | S<br>C<br>C<br>C<br>C | Oral         | 20 Mg Qd Po        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2008              | 6536011       | DIRECT           | Y                  | OT              |                      |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Contusion; Faeces<br>Discoloured;<br>Haemorrhage; Muscle<br>Injury | Lexapro        |              |            | S           | Oral         | 1 Pill Per Day Po Qday<br>Since 7/11/07 On 5 Mg,<br>10mg 8/3/07 |                 | Forest       |
|                                                                    |                |              |            |             | Oral         | 1 Pill Per Day Po Qday<br>Since 7/11/07 On 5 Mg,<br>10mg 8/3/07 |                 |              |
|                                                                    | Dexedrine      |              |            | C           |              |                                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2008              | 6470440       | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-05814-01     |                      | 42 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intraocular Pressure  | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |          |   |      |                |              |
|--------------------------------|----------|---|------|----------------|--------------|
| Increased; Visual Field Defect | Abilify  | S | Oral | 1 Tablet Qd Po | Not Reported |
|                                | Depakote | S | Oral | 500 Mg Bid Po  | Not Reported |
|                                | Xalatan  | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2008              | 6488878       | EXPEDITED (15-DAY) |                    | HO              | 230297J07USA         |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|---------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Chills; Dystonia; Pyrexia; Tremor | Rebif               |              |            | S           | Subcutaneous | 44 Mcg, 3 In 1 Weeks, Subcutaneous |                 | Not Reported |
|                                   | Lexapro             |              |            | S           |              |                                    |                 | Not Reported |
|                                   | Remeron             |              |            | C           |              |                                    |                 | Not Reported |
|                                   | Fentanyl (Fentanyl) |              |            | C           |              |                                    |                 | Not Reported |
|                                   | Prozac              |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2008              | 6537927       | DIRECT           | N                  | OT              |                      |                      | 70 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Product Counterfeit; Product Quality Issue; Therapeutic Product Effect Decreased | Lexapro        |              |            | S           | Oral         | 90 Each 1 Daily Po | 70 DAY          | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2008              | 6383822       | EXPEDITED (15-DAY) | N                  | CA, DE          | B0483228A            |                      |            | Unknown    | NOR            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Maternal Exposure During Pregnancy; Oligohydramnios; Polydactyly; Pulmonary Malformation; Renal Aplasia | Becotide       |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                         | Ventolin       |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                         | Cipralex       |              |            | S           |              |                    | 3 MTH           | Not Reported    |
|                                                                                                         | Lithionit      |              |            | S           |              | 83mg Per Day       |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2008              | 6406655                                                     | EXPEDITED (15-DAY) | Y                  | OT              | NO-PFIZER INC-2007071541              |                      | 41 YR           | Female       | NOR            |
| <u>Preferred Term</u>    | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous     | Lyrica                                                      |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Lyrica                                                      |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Lamictal                                                    |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Lamictal                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Cipralex                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Cipralex                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Seroquel                                                    |                    |                    | S               | Oral                                  |                      |                 | Not Reported |                |
|                          | Seroquel                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Diazepam                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
|                          | Diazepam                                                    |                    |                    | S               |                                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2008              | 6530477                                                     | EXPEDITED (15-DAY) | N                  | HO              | FR-GENENTECH-254338                   |                      | 62 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis             | Mabthera                                                    |                    |                    | S               | Intravenous (not otherwise specified) | Unk, Unk             | 16 DAY          | Genentech    |                |
|                          | Fentanyl                                                    |                    |                    | S               |                                       | 50 Âµg, Q3d          |                 | Not Reported |                |
|                          | Escitalopram Oxalate                                        |                    |                    | S               | Oral                                  | Unk, Unk             |                 | Not Reported |                |
|                          | Acepromazine Maleate\Aceprometazine\Clorazepate Dipotassium |                    |                    | S               |                                       | 10 Mg, Qd            |                 | Not Reported |                |
|                          | Cyamemazine                                                 |                    |                    | S               | Oral                                  | 25 Mg, Qd            |                 | Not Reported |                |
|                          | Entecavir                                                   |                    |                    | S               | Oral                                  | 0.5 Mg, Qd           | 578 DAY         | Not Reported |                |
|                          | Dulcolax (Bisacodyl)                                        |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Previscan (Fluindione)                                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          | Aerius (Desloratadine)                                      |                    |                    | C               |                                       |                      |                 | Not Reported |                |
|                          |                                                             |                    |                    |                 |                                       |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Jan-2008                          | 6530846                 | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2008002622          |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                    | Alprazolam              |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                      | Unspecified Ingredient  |                    |                    | S               | Respiratory (inhalation)          |                      |                 | Not Reported |                |
|                                      | Zolpidem                |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                      | Estrogens               |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                      | Escitalopram Oxalate    |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2008                          | 6536198                 | EXPEDITED (15-DAY) | Y                  | HO              | CH-SANOFI-SYNTHELABO-A01200713881 |                      | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Subdural Haematoma | Plavix                  |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                      | Stilnox                 |                    |                    | C               | Unknown                           | Unk                  |                 | Not Reported |                |
|                                      | Neurontin               |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Simvastatin             |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Lorazepam               |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Trazodone Hydrochloride |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Cotenolol               |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Aprovel                 |                    |                    | C               | Oral                              |                      |                 | Not Reported |                |
|                                      | Cipralext               |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2008                          | 6536733                 | EXPEDITED (15-DAY) | Y                  | DE              | 2008001005                        |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                   |                                                       |   |   |      |                   |              |
|-----------------------------------------------------------------------------------|-------------------------------------------------------|---|---|------|-------------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Dextromethorphan Hydrobromide<br>Escitalopram Oxalate | Y | S | Oral | Unspecified, Oral | Not Reported |
|                                                                                   |                                                       |   | S | Oral | Unspecified, Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2008              | 7462161       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00123-01     |                      | 62 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>                                            | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Blood Creatine Increased; Pancreatitis Acute; Pulmonary Embolism | Escitalopram Oxalate       |              |            | S           |                                       |                    |                 | Not Reported |
|                                                                  | Baraclude                  |              |            | S           | Oral                                  | 500 Mcg Qd Po      |                 | Not Reported |
|                                                                  | Mabthera                   |              |            | S           | Intravenous (not otherwise specified) | 1 Unk Once Iv      |                 | Not Reported |
|                                                                  | Mabthera                   |              |            | S           | Intravenous (not otherwise specified) | 1 Unk Once Iv      |                 | Not Reported |
|                                                                  | Mabthera                   |              |            | S           | Intravenous (not otherwise specified) | 1 Unk Once Iv      |                 | Not Reported |
|                                                                  | Cyamemazine                |              |            | S           | Oral                                  | 25 Mg Qd Po        |                 | Not Reported |
|                                                                  | Aceprometazine\Clorazepate |              |            | S           | Oral                                  | 10 Mg Qd Po        |                 | Not Reported |
|                                                                  | Dipotassium Durogesic      |              |            | S           |                                       | 50 Mcg Tin Ap      |                 | Not Reported |
|                                                                  | Dulcolax (Bisacodyl)       |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                  | Previscan (Fluindione)     |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                  | Desloratadine              |              |            | C           |                                       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2008              | 6530979       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2008003761 |                      | 65 YR      | Male       | USA            |

  

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Heparin Sodium       |              |            | S           |              |                    |                 | Not Reported |
|                       | Risperidone          |              |            | S           |              |                    |                 | Not Reported |
|                       | Metaxalone           |              |            | S           |              |                    |                 | Not Reported |
|                       | Oxycodone            |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Bupropion            |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonidine            |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Unspecified Ingredient  | S | Not Reported |
| Methadone Hydrochloride | S | Not Reported |
| Albuterol               | S | Not Reported |
| Haloperidol             | S | Not Reported |
| Acyclovir               | S | Not Reported |
| Vancomycin              | S | Not Reported |
| Lamotrigine             | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2008              | 6531049       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2008002664 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Alprazolam             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lamotrigine            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Unspecified Ingredient |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zolpidem               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ramelteon              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ibuprofen              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2008              | 6531070       | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2008002666 |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Alprazolam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Quetiapine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2008              | 6531246       | EXPEDITED (15-DAY) | Y                  | DE              | US-WYE-H02026408     |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                     |                               |                    |                    |                 |                              |                      |                 |              |                |
|-----------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Intentional Overdose                                | Dextromethorphan Hydrobromide | S                  | Oral               | Unknown         | Wyeth                        |                      |                 |              |                |
|                                                     | Escitalopram Oxalate          | S                  | Oral               | Unknown         | Unknown                      |                      |                 |              |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2008                                         | 6531461                       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-07P-056-0423485-00 |                      |                 | Male         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intraocular Pressure Increased; Visual Field Defect | Depakote                      |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Escitalopram Oxalate          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Aripiprazole                  |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Esomeprazole Magnesium        |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                     | Latanoprost                   |                    |                    | C               | Ophthalmic                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2008                                         | 6491601                       | EXPEDITED (15-DAY) | Y                  | HO              | DE-JNJFOC-20071200209        |                      | 31 YR           | Female       | DEU            |
| <u>Preferred Term</u>                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Polyarthritis; Urticaria                            | Topamax                       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Topamax                       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Topamax                       |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                     | Cipralext                     |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2008                                         | 6511571                       | EXPEDITED (15-DAY) | Y                  | HO              | S07-FRA-06159-01             |                      | 78 YR           | Male         | DNK            |
| <u>Preferred Term</u>                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Memory Impairment; Tremor         | Escitalopram Oxalate          |                    |                    | S               | Oral                         | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                     | Artane                        |                    |                    | S               | Oral                         | 2 Mg Qd Po           |                 | Not Reported |                |
|                                                     | Lasilix (Furosemide)          |                    |                    | C               |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jan-2008                     | 6519394                           | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-06282-01     |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia                     | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                 | Toprol XL                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Toprol XL                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Lipitor                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Paxil                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2008                     | 6520130                           | EXPEDITED (15-DAY) | Y                  | DE              | S07-FRA-06428-01     |                      | 18 YR           | Female       | FRA            |
| <u>Preferred Term</u>           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose  | Escitalopram Oxalate              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Citalopram                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Atarax                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Valium                            |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Oxazepam                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                 | Tranxene T-Tab                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Nozinan (Levomepromazine)         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Trimeprazine Tartrate             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                 | Chlorpromazine Hydrochloride      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2008                     | 6536808                           | EXPEDITED (15-DAY) | Y                  | DE              | PAR_01890_2008       |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Hydralazine                       |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Amitriptyline                     |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Unspecified Ingredient            |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Escitalopram Oxalate              |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Amphetamine Salts (Not Specified) |                    |                    | C               | Oral                 | (Df Oral)            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| 22-Jan-2008                                                                                                                                                                          | 6539836                          | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00225-01     |                                                       | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Confusional State; Depression; Disorientation; Memory Impairment; Mental Disorder; Psychomotor Skills Impaired; Self Esteem Decreased; Self-Medication; Withdrawal Syndrome | Escitalopram Oxalate             |                    |                    | S               |                      | Anxiety                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2008                                                                                                                                                                          | 6540880                          | EXPEDITED (15-DAY) | Y                  | HO              | LTI2008A00013        |                                                       | 79 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Epilepsy; Loss Of Consciousness; Malaise; Status Epilepticus                                                                                                                   | Lansoprazole                     |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 - 2) 10 Mg (10 Mg, 1 - Oral           | 6 DAY           | Not Reported |                |
|                                                                                                                                                                                      |                                  |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 - 2) 10 Mg (10 Mg, 1 - Oral           |                 |              |                |
|                                                                                                                                                                                      | Escitalopram Oxalate             |                    |                    | S               | Oral                 | Oral 10 Mg (10 Mg, 1 In 1 D); 20 Mg (10 Mg, 2 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                      |                                  |                    |                    |                 | Oral                 | Oral 10 Mg (10 Mg, 1 In 1 D); 20 Mg (10 Mg, 2 In 1 D) | 29 DAY          |              |                |
|                                                                                                                                                                                      | Nisis                            |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Speciafoldine (Folic Acid)       |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Modopar (Madopar)                |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Oxazepam                         |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Hydrosol (Hydrosol Polyvitamine) |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Gaviscon                         |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Polyethylene Glycols             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                      | Anafranil                        |                    |                    | C               |                      |                                                       |                 | Not Reported |                |

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| Diovan Hct                                                                                             |                                               | C                  |                    | Not Reported    |                            |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2008                                                                                            | 6526410                                       | EXPEDITED (15-DAY) | Y                  | HO              | NO-ASTRAZENECA-2008SE00042 |                      | 78 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Bradykinesia; Cognitive<br>Disorder; Drug Interaction;<br>Extrapyramidal Disorder | Seroquel                                      |                    |                    | S               | Oral                       |                      | 7 MTH           | Zeneca       |                |
|                                                                                                        | Evista                                        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Nexium                                        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Akineton                                      |                    |                    | C               |                            |                      | 7 MTH           | Not Reported |                |
|                                                                                                        | Ferrous Sulfate                               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Duphalac                                      |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Sodium Chloride\Thiamine<br>Hydrochloride     |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Zopiclone                                     |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Exelon                                        |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Cipralex                                      |                    |                    | S               |                            |                      | 7 MTH           | Not Reported |                |
|                                                                                                        | Trilafon                                      |                    |                    | S               |                            |                      | 7 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2008                                                                                            | 6538381                                       | EXPEDITED (15-DAY) | Y                  | DS              | S08-FRA-00224-01           |                      | 50 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Disorder;<br>Hypermetropia;<br>Presbyopia                                                          | Escitalopram Oxalate                          |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Clonazepam                                    |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Zolpidem Tartrate                             |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                        | Acetaminophen\Caffeine\Dextro<br>propoxyphene |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2008                                                                                            | 6539301                                       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00226-01           |                      | 60 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Areflexia; C-Reactive<br>Protein Increased;                                                            | Escitalopram Oxalate                          |                    |                    | S               | Oral                       | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                           |                      |   |      |             |              |
|-----------------------------------------------------------------------------------------------------------|----------------------|---|------|-------------|--------------|
| Hyperhidrosis; Malaise;<br>Nuchal Rigidity; Pyrexia;<br>Red Blood Cell<br>Sedimentation Rate<br>Increased | Escitalopram Oxalate | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                                                           | Escitalopram Oxalate | S | Oral | 5 Mg Qd Po  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6539633       | DIRECT           | Y                  | HO              |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Serotonin Syndrome    | Celexa         |              |            | S           | Oral         | 40mg Daily Po      | 1 WEEK          | Forest     |
|                       | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6541194       | EXPEDITED (15-DAY) | Y                  | DE              | PAR_01865_2008       |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed | Ibuprofen                             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
| Suicide; Poisoning;       | Quetiapine                            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
| Respiratory Arrest        | Unspecified Ingredient                |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Butalbital Acetaminophen And Caffeine |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Aspirin                               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Acetaminophen                         |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Escitalopram Oxalate                  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Caffeine Citrate                      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Naproxen                              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                           | Fexofenadine                          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6542088       | EXPEDITED (15-DAY) | Y                  | DE              | CAR_00142_2008       |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                        |   |      |           |              |
|---------------------------------|------------------------|---|------|-----------|--------------|
| Completed Suicide;<br>Poisoning | Zolpidem               | S | Oral | (Df Oral) | Not Reported |
|                                 | Lamotrigine            | S | Oral | (Df Oral) | Not Reported |
|                                 | Escitalopram Oxalate   | S | Oral | (Df Oral) | Not Reported |
|                                 | Unspecified Ingredient | S | Oral | (Df Oral) | Not Reported |
|                                 | Ramelteon              | S | Oral | (Df Oral) | Not Reported |
|                                 | Alprazolam             | S | Oral | (Df Oral) | Not Reported |
|                                 | Ibuprofen              | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6542966       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_03305_2008       |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Alprazolam             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Unspecified Ingredient |              |            | S           | Nasal        | (Df Nasal)         |                 | Not Reported |
|                                 | Zolpidem               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Unspecified Ingredient |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram Oxalate   |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6543445       | EXPEDITED (15-DAY) | Y                  | DE              | BAI_00002_2008       |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Poisoning | Albuterol            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Risperidone          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Metaxalone           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Heparin              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Oxycodone            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Escitalopram Oxalate |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Bupropion            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Clonidine            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |           |              |
|-------------------------|---|------|-----------|--------------|
| Unspecified Ingredient  | S | Oral | (Df Oral) | Not Reported |
| Methadone Hydrochloride | S | Oral | (Df Oral) | Not Reported |
| Haloperidol             | S | Oral | (Df Oral) | Not Reported |
| Acyclovir               | S | Oral | (Df Oral) | Not Reported |
| Vancomycin              | S | Oral | (Df Oral) | Not Reported |
| Lamotrigine             | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6543476       | EXPEDITED (15-DAY) | Y                  | DE              | AVE_00174_2008       |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Poisoning | Clonidine               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Risperidone             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Metaxalone              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Heparin                 |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Oxycodone               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Escitalopram Oxalate    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Bupropion               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Unspecified Ingredient  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Methadone Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Albuterol               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Haloperidol             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Acyclovir               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Vancomycin              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Lamotrigine             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6543480       | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02030_2008       |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                        |   |                             |                                  |              |
|---------------------------------|------------------------|---|-----------------------------|----------------------------------|--------------|
| Completed Suicide;<br>Poisoning | Zolpidem               | S | Oral                        | (Df Oral)                        | Not Reported |
|                                 | Unspecified Ingredient | S | Respiratory<br>(inhalation) | (Df Respiratory<br>(Inhalation)) | Not Reported |
|                                 | Alprazolam             | S | Oral                        | (Df Oral)                        | Not Reported |
|                                 | Unspecified Ingredient | S | Oral                        | (Df Oral)                        | Not Reported |
|                                 | Escitalopram Oxalate   | S | Oral                        | (Df Oral)                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6543491       | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02034_2008       |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Zolpidem             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Ibuprofen            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Lamotrigine          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram Oxalate |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Zaleplon             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Ramelteon            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Alprazolam           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6544238       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_65077_2008       |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Naproxen                                 |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Quetiapine                               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Unspecified Ingredient                   |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Butalbital Acetaminophen And<br>Caffeine |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Aspirin                                  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Acetaminophen                            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                      |   |      |           |              |
|----------------------|---|------|-----------|--------------|
| Ibuprofen            | S | Oral | (Df Oral) | Not Reported |
| Escitalopram Oxalate | S | Oral | (Df Oral) | Not Reported |
| Caffeine             | S | Oral | (Df Oral) | Not Reported |
| Fexofenadine         | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6544293       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_03371_2008       |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Poisoning; Toxicity To Various Agents | Alprazolam           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                       | Escitalopram Oxalate |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                       | Quetiapine           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6544300       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_03370_2008       |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Poisoning | Alprazolam           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Lamotrigine          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Escitalopram Oxalate |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Verucerfont          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Zolpidem             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Ramelteon            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                              | Ibuprofen            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6553111       | DIRECT           | N                  |                 |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;   | Lexapro        |              |            | S           | Oral         | 20mg One A Day Po  | 8 MTH           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                         |         |   |      |                   |       |              |
|-------------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------------|-------|--------------|
| Alcoholism; Amnesia;<br>Mood Swings; Muscle<br>Twitching; Suicidal<br>Ideation; Therapeutic<br>Product Effect Decreased | Effexor | S | Oral | 75mg One A Day Po | 3 MTH | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------------|-------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2008              | 6634274       | EXPEDITED (15-DAY) | Y                  | DE              | CAR_00135_2008       |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Poisoning | Acyclovir               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Risperidone             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Metaxalone              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Heparin                 |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Oxycodone               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Escitalopram Oxalate    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Bupropion               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Clonidine               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Unspecified Ingredient  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Methadone Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Albuterol               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Haloperidol             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Vancomycin              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                     | Lamotrigine             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2008              | 6523070       | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2008NO00489      |                      | 78 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Bradykinesia; Cognitive<br>Disorder; Drug Interaction; | Exelon         |              |            | S           | Oral         | 6 Mg, Qd           |                 | Novartis     |
|                                                                             | Trilafon       |              |            | S           | Oral         | 8 Mg, Qd           | 213 DAY         | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                 |   |         |          |         |              |
|-------------------------|-----------------|---|---------|----------|---------|--------------|
| Extrapyramidal Disorder | Ciprallex       | S | Unknown | 10 Mg/D  | 213 DAY | Not Reported |
|                         | Seroquel        | S | Unknown | 50 Mg/D  | 213 DAY | Not Reported |
|                         | Evista          | C |         |          |         | Not Reported |
|                         | Duphalac        | C |         |          |         | Not Reported |
|                         | Nexium          | C |         |          |         | Not Reported |
|                         | Akineton        | C |         | 2 Mg, Qd | 213 DAY | Not Reported |
|                         | Ferrous Sulfate | C |         |          |         | Not Reported |
|                         | Vi-Siblin       | C |         |          |         | Not Reported |
|                         | Zopiclone       | C |         |          |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2008              | 6539224       | DIRECT           | Y                  |                 |                      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Confusional State; Fear;<br>Obsessive-Compulsive<br>Disorder; Thinking<br>Abnormal | Lexapro        |              |            | S           | Oral         | 10mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2008              | 6544839       | EXPEDITED (15-DAY) | Y                  | DE              | S08-USA-00176-01     |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Overdose | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                | Morphine       |              |            | S           |              |                    |                 | Not Reported |
|                                | Codeine        |              |            | S           |              |                    |                 | Not Reported |
|                                | Diazepam       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 28-Jan-2008              | 6401032       | EXPEDITED (15-DAY) | N                  | HO, OT          | GB-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13893086 |                      | 56 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Carcinoid Tumour; Hot | Abilify        |              |            | S           | Oral         |                    | 2 YR            | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|       |                      |   |      |              |
|-------|----------------------|---|------|--------------|
| Flush | Escitalopram Oxalate | S | Oral | Not Reported |
|       | Escitalopram Oxalate | S | Oral | Not Reported |
|       | Citalopram           | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 3783274       | NON-EXPEDITED    | N                  |                 | A0667108A            |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Fatigue | Wellbutrin     |              |            | S           | Oral         | 50mg Per Day       |                 | Glaxosmithkline |
|                           | Provigil       |              |            | S           | Oral         | 200mg Per Day      |                 | Not Reported    |
|                           | Lexapro        |              |            | S           | Oral         | 10mg Per Day       |                 | Not Reported    |
|                           | Topamax        |              |            | S           | Oral         | 50mg Per Day       |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6385396       | EXPEDITED (15-DAY) | Y                  | CA, DE          | S07-NOR-03383-01     |                      |            | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Induced;<br>Congenital Hand<br>Malformation; Maternal<br>Exposure During<br>Pregnancy;<br>Oligohydramnios;<br>Pulmonary Malformation;<br>Renal Aplasia | Cipralext         |              |            | S           |              | 10 Mg Qd           |                 | Not Reported |
|                                                                                                                                                                 | Ventolin          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                 | Lithium Carbonate |              |            | S           |              | 83 Mg Bid          |                 | Not Reported |
|                                                                                                                                                                 | Becotide          |              |            | S           | Nasal        |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6511358       | EXPEDITED (15-DAY) | N                  | OT              | US-SANOFI-<br>SYNTHELABO-<br>A03200706860 |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Road Traffic<br>Accident; Somnambulism;<br>Therapeutic Product Effect | Ambien Cr      |              |            | S           | Oral         |                    | 20 DAY          | Not Reported |
|                                                                                | Asacol         |              |            | C           | Unknown      | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |             |   |         |     |       |  |  |              |
|-----------|-------------|---|---------|-----|-------|--|--|--------------|
| Decreased | Plendil     | C | Unknown |     |       |  |  | Not Reported |
|           | Pravastatin | C | Unknown |     |       |  |  | Not Reported |
|           | Diovan      | C | Unknown |     |       |  |  | Not Reported |
|           | Lexapro     | S | Oral    | Unk | 3 DAY |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6537597       | NON-EXPEDITED    | N                  |                 | A0651482A            |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                      |
|-----------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|---------------------------------|
| Chest Discomfort;<br>Disorientation; Drug<br>Interaction; Irritability;<br>Paraesthesia; Withdrawal<br>Syndrome | Wellbutrin<br>Lexapro |              |            | S<br>S      |              |                    |                 | Glaxosmithkline<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6537690       | NON-EXPEDITED    | N                  |                 | A0682164A            |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                      |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|---------------------------------|
| Conversion Disorder   | Wellbutrin<br>Lexapro |              |            | S<br>S      |              |                    |                 | Glaxosmithkline<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6537887       | EXPEDITED (15-DAY) | Y                  | DE              | US-<br>KINGPHARMUSA00001<br>-K200800094 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Skelaxin             |              |            | S           | Oral         |                    |                 | King         |
|                       | Risperidone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Heparin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Oxycodone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Bupropion            |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |      |              |
|--------------------------|---|------|--------------|
| Clonidine                | S | Oral | Not Reported |
| Unspecified Ingredient   | S | Oral | Not Reported |
| Methadone Hydrochloride  | S | Oral | Not Reported |
| Albuterol                | S | Oral | Not Reported |
| Haloperidol              | S | Oral | Not Reported |
| Acyclovir                | S | Oral | Not Reported |
| Vancomycin Hydrochloride | S | Oral | Not Reported |
| Lamotrigine              | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6537890       | EXPEDITED (15-DAY) | Y                  | DE              | US-KINGPHARMUSA00001-K200800097 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Menest                 |              |            | S           | Oral         |                    |                 | King         |
|                       | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                       | Zolpidem               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alprazolam             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6549279       | EXPEDITED (15-DAY) | Y                  | DE              | 2008S1000033         |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Morphine             |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Fentanyl             |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6551228       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00262-01     |                      | 69 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                       |   |      |             |              |
|--------------------------------------------|---------------------------------------|---|------|-------------|--------------|
| Cerebral Haematoma;<br>Haemorrhagic Stroke | Escitalopram Oxalate                  | S | Oral | 20 Mg Qd Po | Not Reported |
|                                            | Androtardyl(Testosterone<br>Enantate) | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2008              | 6551235       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00269-01     |                      | 44 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Faeces; Ascites;<br>C-Reactive Protein<br>Increased; Intestinal<br>Ischaemia; Leukocytosis;<br>Murphy'S Sign Positive;<br>Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                             | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                             | Betaferon            |              |            | S           | Subcutaneous | 250 Qod Sc         |                 | Not Reported |
|                                                                                                                                             | Betaferon            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                             | Relpax               |              |            | S           | Oral         | 1 Qd Po            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2008              | 6466266       | EXPEDITED (15-DAY) | N                  | HO              | 239174K07USA         |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Furuncle; Multiple<br>Sclerosis | Rebif          |              |            | S           | Subcutaneous | 8.8 Mcg, 3 In 1 Weeks,<br>Subcutaneous |                 | Not Reported |
|                                 | Lexapro        |              |            | S           |              |                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2008              | 6530946       | EXPEDITED (15-DAY) | Y                  | DE              | 2008S1000108         |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Amitriptyline           |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Cocaine                 |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Chloral Hydrate         |              |            | S           |              |                    |                 | Not Reported |
|                                                          | Clonazepam              |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2008              | 6552264       | EXPEDITED (15-DAY) | Y                  | DE              | PAR_01889_2008       |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Haloperidol             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Risperidone             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Metaxalone              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Heparin                 |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Oxycodone               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Escitalopram Oxalate    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Bupropion               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Clonidine               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Unspecified Ingredient  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Methadone Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Albuterol               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Acyclovir               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Vancomycin              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                       | Lamotrigine             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2008              | 6552766       | EXPEDITED (15-DAY) | Y                  | DE              | 2008S1000101         |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Drug Reaction | Roxicodone              |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                       | Methadone Hydrochloride |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                       | Duraclon                |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                       | Risperidone             |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                       | Metaxalone              |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                       | Heparin                 |              |            | S           | Oral         | ; Po               |                 | Not Reported |



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|                        |   |      |      |              |
|------------------------|---|------|------|--------------|
| Escitalopram Oxalate   | S | Oral | ; Po | Not Reported |
| Bupropion              | S | Oral | ; Po | Not Reported |
| Unspecified Ingredient | S | Oral | ; Po | Not Reported |
| Albuterol              | S | Oral | ; Po | Not Reported |
| Haloperidol            | S | Oral | ; Po | Not Reported |
| Acyclovir              | S | Oral | ; Po | Not Reported |
| Vancomycin             | S | Oral | ; Po | Not Reported |
| Lamotrigine            | S | Oral | ; Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2008              | 6556519       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2008002186           |                      | 47 YR      | Male       | GBR            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Subarachnoid<br>Haemorrhage | Phenylephrine        |              | Y          | S           | Oral         | 36.6 Mg, Oral      |                 | Not Reported |
|                             | Acetaminophen        |              |            | S           | Oral         | 3000 Mg, Oral      |                 | Not Reported |
|                             | Caffeine             |              |            | S           | Oral         | 150mg, Oral        |                 | Not Reported |
|                             | Escitalopram Oxalate |              |            | S           |              | Unspecified,       |                 | Not Reported |
|                             | Mirtazapine          |              |            | S           |              | Unspecified,       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2008              | 6526505       | NON-EXPEDITED    | N                  |                 | US-BOEHRINGER<br>INGELHEIM GMBH,<br>GERMANY-2008-BP-<br>0040 |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Blood Pressure<br>Decreased;<br>Claustrophobia; Headache | Aggrenox       |              |            | S           |              |                    |                 | Boehringer Ingelheim |
|                                                          | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                          | Levoxyl        |              |            | C           |              |                    |                 | Not Reported         |
|                                                          | Aspirin        |              |            | C           |              |                    |                 | Not Reported         |
|                                                          | Lescol         |              |            | C           |              |                    |                 | Not Reported         |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2008                                     | 6540049              | EXPEDITED (15-DAY) | Y                  | DE              | US-KINGPHARMUSA00001-K200800135 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Avinza               |                    |                    | S               | Oral                            |                      |                 | King         |                |
|                                                 | Fentanyl             |                    |                    | S               | Transdermal                     |                      |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 31-Jan-2008                                   | 6555738                    | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00308-01     |                      | 79 YR           | Male         | FRA            |
| <u>Preferred Term</u>                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Interaction;<br>Status Epilepticus | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg Bid Po         |                 | Not Reported |                |
|                                               | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                               | Lansoprazole               |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                               | Lormetazepam               |                    |                    | S               | Oral                 | 1 Gm Qd Po           |                 | Not Reported |                |
|                                               | Olanzapine                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Anafranil                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Oxazepam                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Modopar                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Valsartan And              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Hydrochlorothiazide        |                    |                    |                 |                      |                      |                 |              |                |
|                                               | Atorvastatin Calcium       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Gaviscon                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Polyethylene Glycols       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Hydrosol (Vitamins)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Nisis (Valsartan)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                               | Speciafoldine (Folic Acid) |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-Feb-2008              | 6513485        | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWE-06190-01     |                      | 36 YR           | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                         |                 |   |              |               |              |
|-------------------------|-----------------|---|--------------|---------------|--------------|
| Cerebral Haemorrhage;   | Cipralext       | S | Oral         | 10mg Qd Po    | Not Reported |
| Concomitant Disease     | Fragmin         | S | Subcutaneous | 2500 MI Qd Sc | Not Reported |
| Aggravated; Deep Vein   | Warfarin Sodium | S |              |               | Not Reported |
| Thrombosis; Generalised | Seretide Diskus | C |              |               | Not Reported |
| Tonic-Clonic Seizure;   | Ventolin        | C |              |               | Not Reported |
| Hypertension; Pulmonary |                 |   |              |               |              |
| Embolism; Treatment     |                 |   |              |               |              |
| Noncompliance           |                 |   |              |               |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2008              | 6513488       | EXPEDITED (15-DAY) | Y                  | OT              | S07-IRL-06189-01     |                      | 42 YR      | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Haemorrhage            | Lexapro                       |              |            | S           | Oral         | 25 Mg Qd Po        |                 | Not Reported |
| Subcutaneous; Overdose | Eskim (Omega-3 Triglycerides) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2008              | 6530064       | EXPEDITED (15-DAY) | Y                  | DE              | US-BAYER-200810997GPV |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Ibuprofen                              |              |            | S           | Oral         |                    |                 | Bayer        |
|                            | Acetaminophen                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Aspirin                                |              | Y          | S           | Oral         |                    |                 | Bayer        |
|                            | Naproxen                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Quetiapine                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Unspecified Ingredient                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Butalbital, Acetaminophen And Caffeine |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram Oxalate                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Fexofenadine                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Caffeine                               |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------|-----------------|--------------|----------------|
| 04-Feb-2008                                                              | 6542886                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-08P-163-0435142-00 |                        | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Antidepressant Drug Level Above Therapeutic; Completed Suicide; Overdose | Morphine                |                    |                    | S               |                              | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                                          | Lexapro                 |                    |                    | S               | Oral                         |                        |                 | Not Reported |                |
|                                                                          | Lexapro                 |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                                          | Codeine                 |                    |                    | S               |                              | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                                          | Diazepam                |                    |                    | S               |                              | Overdose: Unknown Dose |                 | Not Reported |                |
|                                                                          | Diazepam                |                    |                    | S               |                              |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2008                                                              | 6556364                 | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02060_2008               |                        | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest                    | Clonazepam              |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
|                                                                          | Amitriptyline           |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
|                                                                          | Methadone Hydrochloride |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
|                                                                          | Cocaine                 |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
|                                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
|                                                                          | Chloral Hydrate         |                    |                    | S               | Oral                         | (Df Oral)              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2008                                                              | 6557221                 | EXPEDITED (15-DAY) | Y                  | OT              | 100#03#2008-00450            |                        | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Fear; Hallucination, Visual                                   | Citalopram Hydrobromide |                    |                    | S               | Oral                         | 20 Mg                  | 12 DAY          | Not Reported |                |
|                                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 10 Mg                  | 5 DAY           | Not Reported |                |

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| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2008                    | 6535645                   | EXPEDITED (15-DAY) | N                  | HO              | S08-USA-00113-01     |                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                       | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                | Lexapro                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2008                    | 6536189                   | EXPEDITED (15-DAY) | Y                  | HO              | S08-ITA-00121-01     |                      | 89 YR           | Female       | DNK            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Haematemesis; Melaena | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5 Drops Qd Po        |                 | Not Reported |                |
|                                | Haloperidol (Meprobamate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Promazine                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                | Pregabalin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2008                    | 6553288                   | DIRECT             |                    | DE              |                      |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Seizure      | Lexapro                   |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                | Zoloft                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2008                    | 6554717                   | DIRECT             | Y                  | OT              |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion                      | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg 1 Qd Po        |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2008                    | 6554863                   | DIRECT             | N                  | HO, LT          |                      |                      | 32 YR           | Female       | USA            |

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| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective; Feeling Abnormal; Intentional Overdose; Suicide Attempt                                         | Lexapro                 |                           |                             | S                        | Oral                          | 1 Pill 1 X Day Po             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Feb-2008                                                                                                       | 6555588                 | EXPEDITED (15-DAY)        | Y                           | DE                       | PAR_02052_2008                |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                                                                 | Clonazepam              |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
|                                                                                                                   | Lisinopril              |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
|                                                                                                                   | Acetaminophen           |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
|                                                                                                                   | Hydrocodone             |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
|                                                                                                                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
|                                                                                                                   | Cocaine                 |                           |                             | S                        | Oral                          | (Df Oral)                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Feb-2008                                                                                                       | 6556497                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-USA-00339-01              |                               | 43 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Deafness; Tinnitus                                                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                   | Xanax                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Feb-2008                                                                                                       | 6556505                 | EXPEDITED (15-DAY)        | N                           | DE                       | S08-USA-00360-01              |                               | 14 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Anxiety; Asphyxia; Completed Suicide; Depressed Mood; General Physical Health Deterioration; Hostility | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2008                                                                                                                             | 6557452                          | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00349-01     |                      | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypothermia; Overdose                                                                                                                   | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                         | Zuclopenthixol                   |                    |                    | S               | Oral                 | 25 Mg Qid Po         |                 | Not Reported |                |
|                                                                                                                                         | Alepsal                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Valpromide                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Dipiperon (Pipamperone)          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Tropatepine Hydrochloride        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Movicol                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Scopolamine                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                         | Oxazepam                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2008                                                                                                                             | 6408227                          | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2007ES14374      |                      | 75 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Sodium Decreased; Drug Interaction; Inappropriate Antidiuretic Hormone Secretion; Restlessness; Urine Sodium Decreased | Tegretol                         |                    |                    | S               | Oral                 | 200 Mg, Qd           |                 | Novartis     |                |
|                                                                                                                                         | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 20 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                         | Risperidone                      |                    |                    | S               | Oral                 | 2 Mg, Qd             |                 | Not Reported |                |
|                                                                                                                                         | Deprax (Trazodone Hydrochloride) |                    |                    | S               | Oral                 | 100 Mg, Qd           |                 | Not Reported |                |
|                                                                                                                                         | Coaprovel                        |                    |                    | S               |                      | Unk, Qd              |                 | Not Reported |                |
|                                                                                                                                         | Lactulose                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Feb-2008                                                                                                                             | 6557545                          | EXPEDITED (15-DAY) |                    | CA, DE          | 230864J08USA         |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Palate; Foetal Death; Limb Malformation; Maternal Exposure During                                                                 | Rebif                            |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                                                                                         | Neurontin                        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |           |   |                |                |              |
|-------------------------------|-----------|---|----------------|----------------|--------------|
| Pregnancy; Skull Malformation | Lexapro   | S | Transplacental | Transplacental | Not Reported |
|                               | Meclizine | S | Transplacental | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2008              | 6557775       | EXPEDITED (15-DAY) |                    | OT              | 230895J08USA         |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Feeling Abnormal; Foetal Disorder; Induced Labour; Maternal Exposure During Pregnancy; Multiple Sclerosis; Pregnancy; Skin Discolouration | Rebif          |              |            | S           | Subcutaneous | 44 Mcg, 3 In 1 Weeks, Subcutaneous |                 | Not Reported |
|                                                                                                                                           | Lexapro        |              |            | S           |              |                                    |                 | Not Reported |
|                                                                                                                                           | Neurontin      |              |            | S           |              |                                    |                 | Not Reported |
|                                                                                                                                           | Meclizine      |              |            | S           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Feb-2008              | 6441579       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007083215 |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Cancer; Constipation; Diarrhoea; Ill-Defined Disorder; Lung Neoplasm Malignant; Nausea; Vomiting; Weight Decreased | Chantix                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Imipramine             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Primidone              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Provigil               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Topamax                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Klonopin               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Lamictal               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Nexium                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Singulair              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                           | Requip                 |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2008              | 6472742       | EXPEDITED (15-DAY) | Y                  | HO              | S07-GER-05786-01     |                      | 86 YR      | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                            |   |      |             |              |
|-------------------------------------------|----------------------------|---|------|-------------|--------------|
| Cardiovascular Disorder;<br>Hyponatraemia | Escitalopram Oxalate       | S | Oral | 10 Mg Qd Po | Not Reported |
|                                           | Escitalopram Oxalate       | S | Oral | 20 Mg Qd Po | Not Reported |
|                                           | Aspirin                    | C |      |             | Not Reported |
|                                           | Clopidogrel                | C |      |             | Not Reported |
|                                           | Metoprolol                 | C |      |             | Not Reported |
|                                           | Allopurinol                | C |      |             | Not Reported |
|                                           | Repaglinid (Repaglinide)   | C |      |             | Not Reported |
|                                           | L-Dopa (Levodopa)          | C |      |             | Not Reported |
|                                           | Pantoprazol (Pantoprazole) | C |      |             | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Feb-2008                     | 6558620              | EXPEDITED (15-DAY) | Y                  | DE              | IMP_03333_2008       |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Bupropion            |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Quetiapine           |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |

| <u>FDA Received Date</u>            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Feb-2008                         | 6559397                 | EXPEDITED (15-DAY) | Y                  | DE              | IMP_03463_2008       |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction;<br>Poisoning | Oxycodone               |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Risperidone             |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Metaxalone              |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Heparin                 |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Bupropion               |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Clonidine               |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Unspecified Ingredient  |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Methadone Hydrochloride |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                     | Albuterol               |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                           |                         | Haloperidol        | S                  | Oral            | Df, Oral                       |                      | Not Reported    |              |                |
|-------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
|                                           |                         | Acyclovir          | S                  | Oral            | Df, Oral                       |                      | Not Reported    |              |                |
|                                           |                         | Vancomycin         | S                  | Oral            | Df, Oral                       |                      | Not Reported    |              |                |
|                                           |                         | Lamotrigine        | S                  | Oral            | Df, Oral                       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2008                               | 6559628                 | EXPEDITED (15-DAY) | Y                  | OT              | 2008S1001274                   |                      | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Fear;<br>Hallucination, Visual | Citalopram Hydrobromide |                    |                    | S               | Oral                           | 20 Mg; Oral          |                 | Not Reported |                |
|                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                           | 10 Mg; Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2008                               | 6561182                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00399-01               |                      | 22 YR           | Female       | GBR            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Fear;<br>Hallucination, Visual | Citalopram Hydrobromide |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                           | Escitalopram Oxalate    |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2008                               | 6548370                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-ASTRAZENECA-<br>2008AC00381 |                      | 52 YR           | Female       | ESP            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Respiratory Failure                       | Seroquel                |                    |                    | S               | Oral                           |                      |                 | Zeneca       |                |
|                                           | Ciprallex               |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                           | Bromazepam              |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                           | Seretide                |                    |                    | C               | Respiratory<br>(inhalation)    | 50/100 Ug            |                 | Not Reported |                |
|                                           | Amlodipine              |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                           | Atrovent                |                    |                    | C               | Respiratory<br>(inhalation)    |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2008              | 6548929       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-08P-163-0436968-00 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Hydrocodone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydrocodone          |              |            | S           |              |                    |                 | Not Reported |
|                       | Acetaminophen        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lisinopril           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cocaine              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2008              | 6549038       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-08P-163-0437347-00 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Hydrocodone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydrocodone          |              |            | S           |              |                    |                 | Not Reported |
|                       | Acetaminophen        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonazepam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lisinopril           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cocaine              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2008              | 6559805       | DIRECT           | Y                  | HO              |                      |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Condition Aggravated; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Od - Oral    |                 | Not Reported |
|                                                                        | Glimepiride          |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |            |   |              |
|---------------------------|------------|---|--------------|
| Delusion; Fear;           | Quinapril  | C | Not Reported |
| Hallucination;            | Carvedilol | C | Not Reported |
| Hallucination, Auditory;  |            |   |              |
| Major Depression; Marital |            |   |              |
| Problem; Paranoia;        |            |   |              |
| Psychotic Disorder;       |            |   |              |
| Treatment Noncompliance   |            |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2008              | 6560150       | EXPEDITED (15-DAY) | Y                  | DE              | US022462             |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed   | Fentanyl             |              |            | S           |              |                    |                 | Not Reported |
| Suicide; Respiratory Arrest | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                             | Morphine             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2008              | 6522864       | EXPEDITED (15-DAY) | Y                  | HO              | S07-DEN-06438-01     |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Level Decreased; | Cipralext           |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
| Feeling Abnormal;     | Cipralext           |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Palpitations;         | Zolpidem            |              |            | C           |              |                    |                 | Not Reported |
| Restlessness; Stress; | Oxazepam            |              |            | C           |              |                    |                 | Not Reported |
| Venous Bruit          | Pantoprazole Sodium |              |            | C           |              |                    |                 | Not Reported |
|                       | Yasmin              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2008              | 6549948       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20080200487 |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Asthenia; Fatigue; Feeling | Sandoz Fentanyl Trasdermal |              |            | S           | Transdermal  | 2 X 100 Ug/Hr Patches |                 | Not Reported |
| Abnormal; Hyperhidrosis;   | System                     |              |            |             |              |                       |                 |              |
| Infected Skin Ulcer;       | Sandoz Fentanyl Trasdermal |              |            | S           | Transdermal  |                       |                 | Not Reported |
| Product Administered At    | System                     |              |            |             |              |                       |                 |              |
| Inappropriate Site; Sleep  |                            |              |            |             |              |                       |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |          |   |             |              |
|-----------------|----------|---|-------------|--------------|
| Apnoea Syndrome | Fentanyl | S | Transdermal | Not Reported |
|                 | Fentanyl | S | Transdermal | Not Reported |
|                 | Lexapro  | S | Oral        | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 11-Feb-2008                      | 6557588        | DIRECT           | N                  | OT              |                      |                      | 47 YR           | Female     | USA            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dysgeusia; Product Quality Issue | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Once A Day Po  | 4 DAY           | Forest     |                |

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 12-Feb-2008                                    | 6142324        | EXPEDITED (15-DAY) | N                  | OT              | US-BOEHRINGER<br>INGELHEIM GMBH,<br>GERMANY-2006-BP-<br>1146 |                      | 81 YR           | Male                 | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Disorder; Colon Cancer Stage Ii;       | Flomax         |                    |                    | S               | Oral                                                         |                      |                 | Boehringer Ingelheim |                |
| Dehydration; Dizziness;                        | Lexapro        |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |
| Eye Disorder; Gait                             | Benicar        |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
| Disturbance; Insomnia;                         | Lipitor        |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
| Lacrimation Increased;                         | Aleve          |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
| Retrograde Ejaculation;                        | Advil          |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
| Rhinorrhoea; Urinary Retention; Vision Blurred | Tylenol        |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Feb-2008              | 6565670                 | EXPEDITED (15-DAY) | Y                  | DE              | 2008-00863           |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Fioricet                |                    |                    | S               |                      |                      |                 | Watson       |                |
|                          | Trazodone Hydrochloride |                    |                    | S               |                      |                      |                 | Watson       |                |
|                          | Oxcarbazepine           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Zyprexa                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                            |                    |                    |                 |                      |                                |                 |              |                |
|------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| Benzodiazepine                                                                                                   |                            |                    | C                  |                 |                      | Not Reported                   |                 |              |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2008                                                                                                      | 6565677                    | EXPEDITED (15-DAY) | Y                  | DE              | 2008-00922           |                                | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                            | Ibuprofen                  |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Zolpidem Tartrate          |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Alprazolam                 |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Lamotrigine                |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate       |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                  | Diazepam                   |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                  | Propamidine                |                    |                    | S               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2008                                                                                                      | 6579021                    | EXPEDITED (15-DAY) | Y                  | DE              | 2008-00885           |                                | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                            | Fioricet                   |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Clonazepam                 |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Lisinopril                 |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Hydrocodone Bitartrate And |                    |                    | S               |                      |                                |                 | Watson       |                |
|                                                                                                                  | Acetaminophen              |                    |                    |                 |                      |                                |                 |              |                |
|                                                                                                                  | Escitalopram Oxalate       |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                  | Cocaine                    |                    |                    | S               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2008                                                                                                      | 6551355                    | EXPEDITED (15-DAY) | Y                  | OT              | US-WYE-H02437608     |                                | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Intentional Overdose;<br>Road Traffic Accident;<br>Suicidal Ideation; Suicide<br>Attempt | Effexor                    |                    |                    | S               |                      | Overdose Amount<br>Unspecified |                 | Wyeth        |                |
|                                                                                                                  | Lithium                    |                    |                    | S               |                      |                                |                 | Unknown      |                |
|                                                                                                                  | Risperdal                  |                    |                    | S               |                      |                                |                 | Janssen      |                |
|                                                                                                                  | Lexapro                    |                    |                    | S               |                      | Overdose Amount<br>Unspecified |                 | Lundbeck     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             | Xanax                          |                    | S                  |                 |                       |                      |                 |              | Not Reported   |
|-----------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
|                                                                             | Xanax                          |                    | S                  |                 |                       |                      |                 |              | Not Reported   |
|                                                                             | Paroxetine Hydrochloride       |                    | C                  |                 |                       |                      | 13 DAY          |              | Unknown        |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2008                                                                 | 6552336                        | EXPEDITED (15-DAY) | Y                  | HO              | NO-MERCK-0802NOR00015 |                      | 69 YR           | Female       | NOR            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ankle Fracture;<br>Confusional State; Drug<br>Interaction;<br>Hyponatraemia | Hyzaar                         |                    |                    | S               | Oral                  |                      |                 | Merck        |                |
|                                                                             | Escitalopram Oxalate           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Carvedilol                     |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Simvastatin                    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Lercanidipine Hydrochloride    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                             | Aspirin\Magnesium Oxide        |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2008                                                                 | 6565920                        | EXPEDITED (15-DAY) | Y                  | DE              | 2008-01056            |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest                                                   | Amitriptyline                  |                    |                    | S               |                       |                      |                 | Watson       |                |
|                                                                             | Hydrochloride\Chlordiazepoxide |                    |                    |                 |                       |                      |                 |              |                |
|                                                                             | Clonazepam                     |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Methadone Hydrochloride        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Cocaine                        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Escitalopram Oxalate           |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                             | Chloral Hydrate                |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2008                                                                 | 6566703                        | EXPEDITED (15-DAY) | Y                  | DE              | 2008-01070            |                      | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                       | Hydralazine Hydrochloride      |                    |                    | S               |                       |                      |                 | Watson       |                |
|                                                                             | Chlordiazepoxide And           |                    |                    | S               |                       |                      |                 | Watson       |                |

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|                                           |   |              |
|-------------------------------------------|---|--------------|
| Amitriptyline                             |   |              |
| Amphetamine Asp Amphetamine               | S | Watson       |
| Sulf Dextroamphet Saccharate & Dextr Sulf |   |              |
| Beta Blocker                              | S | Not Reported |
| Escitalopram Oxalate                      | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2008              | 6511361       | EXPEDITED (15-DAY) | Y                  | DE              | US-SANOFI-SYNTHELABO-A03200706872 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose   | Ambien         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cymbalta       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Cymbalta       |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Vicodin        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Klonopin       |              |            | S           | Oral         | 1 Mg Qid Prn       |                 | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2008               | 6564116              | EXPEDITED (15-DAY) | Y                  | DE              | 2008-01100           |                      | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest | Fentanyl Patches     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Morphine Sulfate     |                    |                    | S               |                      |                      |                 | Watson       |                |
|                           | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2008              | 6564287        | EXPEDITED (15-DAY) | Y                  | DE              | 080206-0000107       |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Neoprofen      |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                          | Lamotrigine    |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |      |    |              |
|------------------------|---|------|----|--------------|
| Escitalopram Oxalate   | S | Oral | Po | Not Reported |
| Unspecified Ingredient | S | Oral | Po | Not Reported |
| Zolpidem               | S | Oral | Po | Not Reported |
| Ramelteon              | S | Oral | Po | Not Reported |
| Alprazolam             | S | Oral | Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------------------|-----------------|------------|----------------|
| 14-Feb-2008              | 6564343        | DIRECT           | N                  | HO              |                      |                                                                                                        | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                     | <u>Duration</u> | <u>Mfr</u> |                |
| Treatment Failure        | Lexapro        |                  |                    | S               |                      | 10 M.G 1 X Daily; 15 M.G.<br>To 20 M.G. 1 X Daily<br>10 M.G 1 X Daily; 15 M.G.<br>To 20 M.G. 1 X Daily |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2008              | 6564548                               | EXPEDITED (15-DAY) | Y                  | DE              | 080207-0000129       |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Neoprofen                             |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Quetiapine                            |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Unspecified Ingredient                |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Butalbital Acetaminophen And Caffeine |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Aspirin                               |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Acetaminophen                         |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Caffeine Citrate                      |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Naproxen                              |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |
|                          | Fexofenadine                          |                    |                    | S               | Oral                 | ; Po                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Feb-2008               | 6565542                | EXPEDITED (15-DAY) | Y                  | DE              | 2008-01206           |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest | Fioricet               |                    |                    | S               |                      |                      |                 | Watson       |                |
|                           | Fiorinal               |                    |                    | S               |                      |                      |                 | Watson       |                |
|                           | Ibuprofen              |                    |                    | S               |                      |                      |                 | Watson       |                |
|                           | Naproxen               |                    |                    | S               |                      |                      |                 | Watson       |                |
|                           | Quetiapine Fumarate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Unspecified Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Escitalopram Oxalate   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Caffeine Citrate       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Fexofenadine Hcl       |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 15-Feb-2008                                  | 6553722                     | EXPEDITED (15-DAY) | Y                  | HO              | AT-JNJFOC-20080201625 |                      | 33 YR           | Female       | AUT            |
| <u>Preferred Term</u>                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Diarrhoea; Hyponatraemia; Vomiting | Haldol                      |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                              | Trileptal                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                              | Trileptal                   |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                              | Cipralelex                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                              | Cipralelex                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                              | Ferrous Fumarate            |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                              | Akineton                    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                              | Amitriptyline Hydrochloride |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                              | Zolpidem Tartrate           |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                              | Lamictal                    |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 15-Feb-2008              | 6564652        | DIRECT           | N                  | OT              |                      |                      | 20 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |         |   |         |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|---------|--------------|
| Abdominal Pain Upper;<br>Chills; Crying; Diarrhoea<br>Haemorrhagic; Drug<br>Withdrawal Syndrome;<br>Hypersomnia; Impaired<br>Work Ability; Malaise | Lexapro | S | 10 Mg 1 | Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2008              | 6548249       | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-544305      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Anxiety; Fatigue; Pain;<br>Toxicity To Various Agents | Pegasys                          |              |            | S           | Subcutaneous |                                      |                 | Roche        |
|                                                       | Ribavirin                        |              |            | S           | Oral         | Dose: 400 Mg/ 600 Mg<br>Twice Daily. |                 | Not Reported |
|                                                       | Isopropanol                      |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Acetone                          |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Pseudoephedrine Hydrochloride    |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Methamphetamine<br>Hydrochloride |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Lexapro                          |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Remeron                          |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Cannabinoids                     |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Chlorpheniramine                 |              |            | S           | Unknown      |                                      |                 | Not Reported |
|                                                       | Prilosec                         |              |            | C           |              |                                      |                 | Not Reported |
|                                                       | Buspar                           |              |            | C           |              |                                      |                 | Not Reported |
| Risperdal                                             |                                  |              | C          |             |              |                                      | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2008              | 6568023       | EXPEDITED (15-DAY) | Y                  | LT              | S08-ESP-00436-01     |                      | 52 YR      | Female     | ESP            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Respiratory Failure | Ciprallex            |              |            | S           |              |                    |                 | Not Reported |
|                                          | Seroquel             |              |            | S           |              |                    |                 | Not Reported |
|                                          | Lexatin (Bromazepam) |              |            | S           | Oral         | 12 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                            | Seretide Accuhaler (Seretide) |                    |                    | C               |                        |                      |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                            | Amlodipine                    |                    |                    | C               |                        |                      |                 |              | Not Reported   |
|                                                                                            | Atrovent                      |                    |                    | C               |                        |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2008                                                                                | 6570526                       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00588-01       |                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| C-Reactive Protein Increased; Lymphopenia; Oedema Peripheral; Purpura; Rash Maculo-Papular | Escitalopram Oxalate          |                    |                    | S               | Oral                   | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                            | Cetirizine                    |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                            | Actonel                       |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                            | Alprazolam                    |                    |                    | C               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2008                                                                                | 6570528                       | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00589-01       |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejection Fraction Decreased; Overdose                                                      | Cipraxex                      |                    |                    | S               | Oral                   | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                            | Amitriptyline                 |                    |                    | C               |                        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2008                                                                                | 6557903                       | EXPEDITED (15-DAY) |                    | OT              | FR-AVENTIS-200810574FR |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis                                                                            | Lovenox                       |                    |                    | S               | Subcutaneous           |                      |                 | Aventis      |                |
|                                                                                            | Tavanic                       |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                                                            | Zyprexa                       |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                                                            | Inexium                       |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                                                            | Escitalopram Oxalate          |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                                                            | Zolpidem                      |                    |                    | S               | Oral                   |                      |                 | Not Reported |                |
|                                                                                            | Augmentin                     |                    |                    | C               |                        |                      |                 | Not Reported |                |
|                                                                                            | Rocephin                      |                    |                    | C               |                        |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2008              | 6570232       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00625-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amylase Increased; Lipids Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2008              | 6572255       | EXPEDITED (15-DAY) | Y                  | DE              | TPA2008A00205        |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Rozepam                   |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Alprazolam (Alprazolam)   |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Lamotrigine (Lamotrigine) |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Escitalopram Oxalate      |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Unspecified Ingredient    |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Zolpidem                  |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                       | Ibuprofen (Ibuprofen)     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2008              | 6572323       | DIRECT           | N                  | DE              |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 20 Mg Once Daily Po         |                 | Forest     |
|                       | Clonazepam     |              |            | S           | Oral         | 0.5 Mg Three Times Daily Po |                 | Caraco     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2008              | 6574686       | EXPEDITED (15-DAY) | Y                  | HO              | S08-NOR-00639-01     |                      | 69 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                          |                              |   |      |             |              |
|--------------------------|------------------------------|---|------|-------------|--------------|
| Ankle Fracture;          | Cipralex                     | S | Oral | 10 Mg Qd Po | Not Reported |
| Confusional State; Fall; | Hydrochlorothiazide\Losartan | S | Oral | 1 Qd Po     | Not Reported |
| Hyponatraemia            | Albyl-E                      | C |      |             | Not Reported |
|                          | Lercanidipine                | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2008              | 6575652       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00471-01     |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal;        | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Induced Labour; Maternal | Rebif          |              |            | S           | Subcutaneous | 44 Mcg Tiw Sc      |                 | Not Reported |
| Exposure During          | Neurontin      |              |            | S           |              |                    |                 | Not Reported |
| Pregnancy; Pregnancy;    | Meclizine      |              |            | S           |              |                    |                 | Not Reported |
| Skin Discolouration      |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2008              | 6523685       | EXPEDITED (15-DAY) | N                  | HO              | S07-USA-06424-01     |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dehydration; Drug        | Lexapro                               |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Ineffective; Dyskinesia; | Lexapro                               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Seizure; Tremor          | Minocycline\Minocycline Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2008              | 6561632       | EXPEDITED (15-DAY) | N                  | HO              | CH-BAYER-200813145GPV |                      | 61 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Blood Loss Anaemia;   | Aspirin Cardio       |              | Y          | S           | Oral         | Total Daily Dose: 100 Mg<br>Unit Dose: 100 Mg |                 | Bayer        |
| Gastrointestinal      | Phenprocoumon        |              |            | S           | Oral         |                                               |                 | Not Reported |
| Haemorrhage; Melaena  | Escitalopram Oxalate |              |            | S           | Oral         | Total Daily Dose: 20 Mg<br>Unit Dose: 10 Mg   |                 | Not Reported |

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|                |   |      |                                             |              |
|----------------|---|------|---------------------------------------------|--------------|
| Spironolactone | C | Oral | Total Daily Dose: 50 Mg<br>Unit Dose: 50 Mg | Not Reported |
| Metoprolol     | C | Oral | Total Daily Dose: 50 Mg<br>Unit Dose: 50 Mg | Not Reported |
| Torsemide      | C | Oral | Total Daily Dose: 40 Mg<br>Unit Dose: 20 Mg | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 26-Feb-2008               | 6571224        | DIRECT           |                    |                 |                      |                      |                 | Male       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Medication Error; Product | Lipitor        |                  |                    | S               |                      | Tablet               |                 | Pfizer     |                |
| Dispensing Error          | Lexapro        |                  |                    | S               |                      | Tablet               |                 | Forest     |                |

| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2008                         | 6574373        | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00481-01     |                      | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Suicidal Ideation | Ciprallex      |                    |                    | S               | Oral                 | 10 Mg Qd Por         |                 | Not Reported |                |
|                                     | Depakote       |                    |                    | S               | Oral                 | 1 G Qd Po            |                 | Not Reported |                |
|                                     | Mirtazapine    |                    |                    | S               | Oral                 | 45 Mg Qd Po          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Feb-2008              | 6574391                | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00666-01     |                      | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Enuresis; Neuropathy     | Ciprallex              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
| Peripheral; Paraesthesia | Chlorpromazine         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Diclofenac             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Tramadol Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|---------------------------|-----------------|--------------|----------------|
| 27-Feb-2008                              | 6310409              | NON-EXPEDITED      | Y                  | OT              | HQWYE776330OCT06      |                           | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Seizure                  | Effexor              |                    |                    | S               | Oral                  | Oral                      |                 | Not Reported |                |
|                                          | Lexapro              |                    |                    | S               | Oral                  | 20 Mg, 1x Per 1 Day, Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2008                              | 6521046              | EXPEDITED (15-DAY) | Y                  | DE              | US-MERCK-0801USA00141 |                           | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose              | Prinivil             |                    |                    | S               | Oral                  |                           |                 | Merck        |                |
|                                          | Acetaminophen        |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                          | Hydrocodone          |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                          | Escitalopram Oxalate |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                          | Clonazepam           |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                          | Cocaine              |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2008                              | 6561625              | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-00456-01      |                           | 77 YR           | Female       | ESP            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia; Syncope | Ciprallex            |                    |                    | S               | Oral                  | 5 Mg Qd Po                |                 | Not Reported |                |
|                                          | Moduretic 5-50       |                    |                    | S               | Oral                  | 0.5 Mg Tablet Qd Po       |                 | Not Reported |                |
|                                          | Atenolol             |                    |                    | C               |                       |                           |                 | Not Reported |                |
|                                          | Simvastatin          |                    |                    | C               |                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2008                              | 6578958              | EXPEDITED (15-DAY) | Y                  | HO              | S08-SWI-00710-01      |                           | 61 YR           | Male         | CHE            |



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| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| Blood Loss Anaemia;<br>Gastric Polyps;<br>Gastrointestinal<br>Haemorrhage;<br>International Normalised<br>Ratio Increased | Cipralext                                         |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                                           | Marcumar                                          |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported                 |                |
|                                                                                                                           | Aspirin                                           |                    |                    | S               | Oral                 | 100 Mg Qd Po         |                 | Not Reported                 |                |
|                                                                                                                           | Aldactone                                         |                    |                    | C               |                      |                      |                 | Not Reported                 |                |
|                                                                                                                           | Beloc [Metoprolol Tartrate]<br>Torem (Torasemide) |                    |                    | C<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 27-Feb-2008                                                                                                               | 6579054                                           | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00686-01     |                      |                 | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Urinary Retention                                                                                                         | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                                           | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 27-Feb-2008                                                                                                               | 6579362                                           | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00657-01     |                      | 45 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Asthenia; Fatigue; Feeling<br>Abnormal; Hyperhidrosis;<br>Infected Skin Ulcer; Sleep<br>Apnoea Syndrome                   | Lexapro                                           |                    |                    | S               | Oral                 | 20 Mg Qd;Po          |                 | Not Reported                 |                |
|                                                                                                                           | Fentanyl                                          |                    |                    | S               |                      | 25 Mcg; Id           |                 | Not Reported                 |                |
|                                                                                                                           | Fentanyl                                          |                    |                    | S               |                      |                      |                 | Not Reported                 |                |
|                                                                                                                           | Fentanyl                                          |                    |                    | S               |                      | 200 Mcg; Id          |                 | Not Reported                 |                |
|                                                                                                                           | Fentanyl                                          |                    |                    | S               |                      | 100 Mcg; Id          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-Feb-2008                                                                                                               | 6510469                                           | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06160-01     |                      | 43 YR           | Male                         | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Henoch-Schonlein<br>Purpura                                                                                               | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported                 |                |

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| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Feb-2008                          | 6557242                       | EXPEDITED (15-DAY) | Y                  | DE, HO          | L08-USA-00315-01     |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Toxicity To Various Agents | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Oxcarbazepine                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Acetaminophen                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Zyprexa                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Unspecified Ingredient        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Trazodone Hydrochloride       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2008                          | 6557243                       | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-02     |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose          | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Acetaminophen                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Hydrocodone                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Clonazepam                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Lisinopril                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Cocaine                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2008                          | 6557244                       | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-03     |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose          | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Lamotrigine                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Phenazopyridine Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Zolpidem                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Ramelteon                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Alprazolam                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Ibuprofen                     |                    |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Feb-2008                                                                                                  | 6567277               | EXPEDITED (15-DAY) | Y                  | OT              | GB-ABBOTT-08P-167-0437377-00 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Suicidal Ideation                                                                                  | Depakote              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                              | Cipralelex            |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                              | Cipralelex            |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Mirtazapine           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                              | Mirtazapine           |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2008                                                                                                  | 6580666               | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00699-01             |                      | 60 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Intolerance; Encephalopathy; Overdose; Renal Failure; Sepsis; Urosepsis                                 | Escitalopram Oxalate  |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Flecainide Acetate    |                    |                    | S               | Oral                         | 100 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                              | Flecainide Acetate    |                    |                    | S               | Oral                         | 100 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                              | Neoral                |                    |                    | S               | Oral                         | 50 Mg Bid Po         |                 | Not Reported |                |
|                                                                                                              | Depakene              |                    |                    | S               | Oral                         | 500 Mg Qid Po        |                 | Not Reported |                |
|                                                                                                              | Prednisone            |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Claforan              |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2008                                                                                                  | 6580676               | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00698-01             |                      | 77 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Facial Bones Fracture; Fall; Malaise; Obsessive-Compulsive Disorder; Orthostatic Hypotension; Pseudodementia | Escitalopram Oxalate  |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Nitroglycerin         |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Trimeprazine Tartrate |                    |                    | S               | Oral                         | 15 Drops Qd Po       |                 | Not Reported |                |
|                                                                                                              | Atenolol              |                    |                    | S               | Oral                         | 50 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                              | Depakote              |                    |                    | S               | Oral                         | 1.25 G Qd Po         |                 | Not Reported |                |

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| Aspirin                                                                                                       |                      | C                  |                    | Not Reported    |                      |                         |                 |            |                |
|---------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|------------|----------------|
| Clonazepam                                                                                                    |                      | C                  |                    | Not Reported    |                      |                         |                 |            |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Feb-2008                                                                                                   | 6580696              | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00729-02     |                         | < 1 DAY         | Unknown    | GBR            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Withdrawal Syndrome Neonatal; Maternal Exposure During Pregnancy                                         | Cipralelex           |                    |                    | S               |                      |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Feb-2008                                                                                                   | 6580978              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00473-01     |                         | 42 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Brief Psychotic Disorder With Marked Stressors; Hallucination; Mental Disorder; Personality Disorder | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Feb-2008                                                                                                   | 6586305              | EXPEDITED (15-DAY) | Y                  | CA, OT          | S08-PRT-00707-02     |                         |                 | Unknown    | PRT            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Abortion Induced; Congenital Central Nervous System Anomaly; Maternal Exposure During Pregnancy               | Cipralelex           |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Feb-2008                                                                                                   | 7051929              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00696-01     |                         | 78 YR           | Male       | FRA            |

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| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Creatinine Renal<br>Clearance Decreased;<br>Fall; Haemoglobin<br>Decreased; Limb Injury;<br>Thrombophlebitis<br>Superficial; Traumatic<br>Haematoma | Escitalopram Oxalate           |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                 | Zolpidem                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                 | Prazepam                       |              |            | S           | Oral         | 10 Mg Tid Po       |                 | Not Reported |
|                                                                                                                                                                                 | Aceprometazine\Meprobamate     |              |            | S           | Oral         | 0.5 Qd Po          |                 | Not Reported |
|                                                                                                                                                                                 | Zoxan (Doxazosin Mesilate)     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Aspirin                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Fenofibrate                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Furosemide                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Euphytose                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Metformin Hydrochloride        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Duphalac                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Acetaminophen                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Almond Oil (Prunus Dulcis Oil) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2008              | 6568248       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-08P-056-0439453-00 |                      | 60 YR      | Male       | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Encephalopathy; Renal<br>Failure; Sepsis | Depakene             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Flecainide Acetate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Flecainide Acetate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Ciclosporin          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Prednisone           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Cefotaxime Sodium    |              |            | C           |              |                    |                 | Not Reported |
|                                          | Cefotaxime Sodium    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2008              | 6568388       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-08P-056-0439459-00 |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Bones Fracture; | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |

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|                                                                                       |                       |   |             |              |
|---------------------------------------------------------------------------------------|-----------------------|---|-------------|--------------|
| Fall; Malaise; Obsessive-Compulsive Disorder; Orthostatic Hypotension; Pseudodementia | Escitalopram Oxalate  | S | Oral        | Not Reported |
|                                                                                       | Glyceryl Trinitrate   | S | Transdermal | Not Reported |
|                                                                                       | Trimeprazine Tartrate | S | Oral        | Not Reported |
|                                                                                       | Atenolol              | S | Oral        | Not Reported |
|                                                                                       | Aspirin Lysine        | C | Oral        | Not Reported |
|                                                                                       | Clonazepam            | C | Unknown     | Not Reported |
|                                                                                       | Olanzapine            | C |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2008              | 6582726       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S08-FRA-00632-01     |                      | 27 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Failure; Hepatitis Acute; Intentional Overdose | Escitalopram Oxalate                     |              |            | S           |              |                    |                 | Not Reported |
|                                                        | Escitalopram Oxalate                     |              |            | S           | Oral         | 10 Mg Qd;Po        |                 | Not Reported |
|                                                        | Acetaminophen\Caffeine\Morphine          |              |            | S           | Oral         | 1 Tid;Po           |                 | Not Reported |
|                                                        | Ventolin                                 |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Cefuroxime                               |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Solupred (Prednisolone Sodium Metazoate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Mar-2008              | 6586462       | EXPEDITED (15-DAY) | Y                  | CA, DE          | S08-SWE-00713-02     |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------------|-----------------|--------------|
| Abortion Induced; Cardiac Failure; Congenital Hydrocephalus; Foetal Chromosome Abnormality; Maternal Exposure During Pregnancy; Multiple Congenital Abnormalities; Renal Failure; Trisomy 13 | Ciprallex      |              |            | S           | Transplacental | 10 Mg Qd; Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Mar-2008                                                       | 6586490                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00689-01     |                      | 91 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis;<br>Dermatitis Bullous                            | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd; Po         |                 | Not Reported |                |
|                                                                   | Tavanic                 |                    |                    | S               | Oral                 | 500 Mg Qd; Po        |                 | Not Reported |                |
|                                                                   | Lovenox                 |                    |                    | S               | Subcutaneous         | 4000 lu Qd;Sc        |                 | Not Reported |                |
|                                                                   | Zyprexa                 |                    |                    | S               | Oral                 | 5 Mg Qd;Po           |                 | Not Reported |                |
|                                                                   | Inexium                 |                    |                    | S               | Oral                 | 20 Mg Qd;Po          |                 | Not Reported |                |
|                                                                   | Zolpidem                |                    |                    | S               | Oral                 | 1 Qd;Po              |                 | Not Reported |                |
|                                                                   | Xanax                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                   | Augmentin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                   | Rocephin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                   | Zeclar                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2008                                                       | 6586493                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00694-01     |                      | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dermatitis Allergic                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg Qd;Po          |                 | Not Reported |                |
|                                                                   | Unspecified Ingredient  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2008                                                       | 6586859                 | DIRECT             | N                  | DE, HO, LT      |                      |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Death; Pneumonia;<br>Respiratory Rate<br>Decreased; Snoring | Methadone Hydrochloride |                    |                    | S               | Oral                 | 1 3 Times Daily Po   | 1 DAY           | Roxane       |                |
|                                                                   | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                       | 6558556                 | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-34     |                      | 59 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Overdose                                        | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Amitriptyline Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Unspecified Ingredient      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Hydralazine                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Amfetamine                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                           | 6558560                     | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-33     |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose; Toxicity To<br>Various Agents         | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Quetiapine                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Bupropion                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                           | 6561157                     | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-38     |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Overdose;<br>Respiratory Arrest | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Amitriptyline Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Methadone Hydrochloride     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Cocaine                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Chloral Hydrate             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                       | Clonazepam                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                           | 6580749                     | DIRECT             | Y                  | OT              |                      |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia                                                            | Lexapro                     |                    |                    | S               | Oral                 | 5mg Qd Po            | 1 WEEK          | Forest       |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                           | 6580799                     | DIRECT             | Y                  | OT              |                      |                      | 56 YR           | Female       | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Hot Flush; Hyperhidrosis; Mastication Disorder; Muscle Tightness; Musculoskeletal Pain; Pain In Jaw; Therapy Non-Responder; Withdrawal Syndrome | Lexapro                        |                    |                    | S               | Oral                 | 10mg Once A Day Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2008                                                                                                                                     | 6587006                        | EXPEDITED (15-DAY) | Y                  | LT              | SO8-FIN-00749-01     |                      | 70 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; International Normalised Ratio Increased                                                                                      | Cipralext                      |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                 | Warfarin                       |                    |                    | S               | Oral                 | 3 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                 | Warfarin                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Spesicor (Metoprolol Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Furosemide                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Lipitor                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Ramipril Copyfarm (Ramipril)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                                                                                                     | 6550315                        | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-00219-01     |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness Transient; Loss Of Consciousness; Petit Mal Epilepsy                                                                                  | Lexapro                        |                    |                    | S               | Oral                 | 7.5 Mg Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                                                                                                     | 6557216                        | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-05     |                      | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Overdose;                                                                                                    | Escitalopram Oxalate           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                 | Dextromethorphan               |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Respiratory Arrest                                                                                                                                                                                                                                                                                                                                                                                                                  |                                     | Hydrobromide       |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                                                                                                                                                                                                                                                                                                                                                                                         | 6557220                             | EXPEDITED (15-DAY) | Y                  | DE, HO          | L08-USA-00315-19     |                      | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Blood Ph Decreased;<br>Blood Pressure Increased;<br>Brain Oedema; Cardiac<br>Arrest; Delirium;<br>Disseminated<br>Intravascular Coagulation;<br>Haemodialysis; Heart Rate<br>Increased; Hyperhidrosis;<br>Hyperpyrexia; Liver Injury;<br>Lower Gastrointestinal<br>Haemorrhage; Mucosal<br>Haemorrhage; Pulseless<br>Electrical Activity; Renal<br>Failure; Rhabdomyolysis;<br>Toxicity To Various Agents | Escitalopram Oxalate                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Cocaine                             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                            | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                                                                                                                                                                                                                                                                                                                                                                                         | 6557245                             | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-18     |                      | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Overdose;<br>Respiratory Arrest;<br>Toxicity To Various Agents                                                                                                                                                                                                                                                                                                                                | Escitalopram Oxalate                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Quetiapine                          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Unspecified Ingredient              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Axotal                              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | (Acetaminophen\Butalbital\Caffeine) |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Aspirin (Acetylsalicylic Acid)      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Acetaminophen (Paracetamol)         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Ibuprofen                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Caffeine Citrate                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                     | Naproxen                            |                    |                    | S               |                      |                      |                 | Not Reported |                |

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|                                      |                         |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Fexofenadine                         |                         |                    | S                  |                 |                      | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                          | 6557247                 | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-17     |                      | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed            | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Suicide; Respiratory                 | Fentanyl                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Arrest; Toxicity To Various Agents   | Morphine                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                          | 6557258                 | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-12     |                      | 24 YR           | Male         | DNK            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Toxicity To Various Agents | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Quetiapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Alprazolam              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                          | 6558552                 | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-21     |                      | 65 YR           | Male         | DNK            |
| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents           | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Risperidone             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Metaxalone              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Heparin                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Oxycodone               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Bupropion               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Clonidine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Unspecified Ingredient  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Methadone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Albuterol               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Haloperidol             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Acyclovir               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Vancomycin              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                      | Lamotrigine             |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 05-Mar-2008                                                   | 6558554                   | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-20          |                      | 19 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose; Toxicity To<br>Various Agents | Escitalopram Oxalate      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Quetiapine                |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Atomoxetine Hydrochloride |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                   | 6558574                   | EXPEDITED (15-DAY) | Y                  | DE              | L08-USA-00315-15          |                      | 58 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Overdose                                | Escitalopram Oxalate      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Zolpidem                  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Unspecified Ingredient    |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Alprazolam (Alprazolam)   |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                               | Estrogen Nos              |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                   | 6570188                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20080206136 |                      | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Muscle<br>Spasms; Myoclonus;<br>Rhabdomyolysis    | Durogesic                 |                    |                    | S               | Transdermal               |                      | 54 DAY          | Not Reported |                |
|                                                               | Enalapril                 |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                               | Lyrica                    |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                               | Escitalopram Oxalate      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                               | Ferrous Sulfate           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                               | Levothyrox                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                               | Furosemide                |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                   | 6576707                   | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00528-01          |                      | 57 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Drug Level Increased;<br>Impaired Driving Ability                                                                                                                 | Lexapro                           |                    |                    | S               | Oral                 | 20 Mg Qam Po         |                 | Not Reported |                |
|                                                                                                                                                                   | Klonopin                          |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Tagamet                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Unspecified Ingredient            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2008                                                                                                                                                       | 6586842                           | EXPEDITED (15-DAY) | Y                  | DE              | S08-SWI-00815-01     |                      | 55 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Cardiac Death                                                                                                                                              | Ciprallex                         |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                   | Methadone Hydrochloride           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Lexotanil (Bromazepam)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Antra                             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Aspegic [Acetylsalicylate Lysine] |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                                                                                                                       | 6519362                           | EXPEDITED (15-DAY) | Y                  | HO              | S07-SWI-06348-01     |                      | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Aphasia; Blood Pressure Systolic Increased; Fall; Head Injury; Headache; Mental Disorder; Nausea; Speech Disorder; Subdural Haematoma; Syncope; Vomiting | Ciprallex                         |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                   | Plavix                            |                    |                    | S               | Oral                 | 75 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                   | Irbesartan                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Cotenolol                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Trittico (Trazodone)              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Lorazepam                         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Simcora (Simvastatin)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                   | Neurotin (Acetylcarnitine)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                                                                                                                       | 6580976                           | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00693-01     |                      | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                      |                      |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------------------------------|----------------------|----------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dermatitis Allergic;<br>Oedema; Pruritus                            |                      | Escitalopram Oxalate |                    | S               | Oral                 |                      | 10 Mgqd Po      |              | Not Reported   |
|                                                                     |                      | Stresam (Etifoxine)  |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                         | 6586560              | DIRECT               | Y                  | HO              |                      |                      | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination                                                       | Lexapro              |                      |                    | S               | Oral                 | Po                   | 2 DAY           | Forest       |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                         | 6587581              | EXPEDITED (15-DAY)   | Y                  | OT              | S08-FRA-00810-01     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Respiratory<br>Disorder; Sense Of<br>Oppression         | Escitalopram Oxalate |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                         | 6587593              | EXPEDITED (15-DAY)   | Y                  | OT              | S08-FRA-00802-01     |                      | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence;<br>Epilepsy; Therapeutic<br>Response Unexpected | Escitalopram Oxalate |                      |                    | S               | Oral                 | 10 Mgqd Po           |                 | Not Reported |                |
|                                                                     | Citalopram           |                      |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                     | Clonazepam           |                      |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                     | Oxazepam             |                      |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2008                                                         | 6587603              | EXPEDITED (15-DAY)   | Y                  | OT              | S08-FRA-00811-01     |                      |                 | Female       | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Respiratory<br>Disorder                                 | Escitalopram Oxalate |                      |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2008              | 6549207       | EXPEDITED (15-DAY) | Y                  | DE              | TRP_01020_2008       |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety; Fatigue; Pain; Toxicity To Various Agents; Treatment Noncompliance | Ribavirin                     |              |            | S           | Oral         | 1 Df Bid [400 Mg/600 Mg]<br>Oral |                 | Not Reported |
|                                                                             | Pegasys                       |              |            | S           | Subcutaneous | 180 Mg 1/Week<br>Subcutaneous    |                 | Not Reported |
|                                                                             | Isopropanol                   |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Acetone                       |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Pseudoephedrine Hydrochloride |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Methamphetamine Hydrochloride |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Lexapro                       |              |            | S           |              | 40 Mg Qd                         |                 | Not Reported |
|                                                                             | Remeron                       |              |            | S           |              | As Needed                        |                 | Not Reported |
|                                                                             | Cannabinoids                  |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Chlorpheniramine              |              |            | S           |              | Df                               |                 | Not Reported |
|                                                                             | Buspar                        |              |            | C           |              |                                  |                 | Not Reported |
|                                                                             | Prilosec                      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                             | Risperdal                     |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2008              | 6572682       | NON-EXPEDITED    | N                  |                 | A0665598A            |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Depression; Drug Interaction | Requip         |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                              | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Mar-2008              | 6586578       | DIRECT           | N                  | HO, OT          |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                         |         |   |      |    |        |
|---------------------------------------------------------|---------|---|------|----|--------|
| Condition Aggravated;<br>Depression; Suicide<br>Attempt | Lexapro | S | Oral | Po | Forest |
|                                                         | Celexa  | S | Oral | Po | Forest |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 10-Mar-2008              | 6576283       | NON-EXPEDITED    | N                  |                 | US-BAYER-<br>200711416BCC |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>                   |
|------------------------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|------------------------------|
| Gastroesophageal Reflux<br>Disease | Aleve                         |              |            | S           | Oral         |                                             |                 | Bayer                        |
|                                    | Lexapro                       |              |            | S           |              | Total Daily Dose: 20 Mg<br>Unit Dose: 20 Mg |                 | Not Reported                 |
|                                    | Lexapro                       |              |            | S           |              | Total Daily Dose: 10 Mg<br>Unit Dose: 10 Mg | 2 YR            | Not Reported                 |
|                                    | Advil                         |              |            | S           |              |                                             |                 | Not Reported                 |
|                                    | Excedrin Migraine<br>Celebrex |              |            | S<br>S      |              |                                             |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2008              | 6587672       | DIRECT           | Y                  |                 |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression            | Lexapro        |              |            | S           | Oral         | 5mg Daily Po       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2008              | 6593140       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00813-01     |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder; Coma;<br>Hyponatraemia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Mar-2008              | 7025980       | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                           |                                                                                                                                                      |                                                          |                      |                                               |                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Amnesia; Attention Deficit/Hyperactivity Disorder; Brain Injury; Cerebrovascular Accident; Compulsions; Depression Suicidal; Incorrect Dose Administered; Suicide Attempt | Seroquel<br>Risperdal<br>Abilify<br>Tegretal<br>Depakote<br>Parnate<br>Librium<br>Paxil<br>Lexapro<br>Gabapentin<br>Buspar<br>Unspecified Ingredient | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>C<br>C<br>C | Oral<br><br><br>Oral | Too Much Too Often Po<br><br><br>Ibid Ibid Po | Astrazeneca<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Mar-2008              | 6522873                            | EXPEDITED (15-DAY) | Y                  | OT              | S07-FRA-06439-01     |                      | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Calcifications    | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                          | Seropram (Citalopram Hydrobromide) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Calciprat (Calcium Carbonate)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Fosamax                            |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Mar-2008                                                                                                                                                 | 6527924              | EXPEDITED (15-DAY) | Y                  | DE              | S07-ESP-06498-01     |                      | 52 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Candida Infection; Drug Resistance; Opportunistic Infection; Pseudomonas Infection; Septic Shock; Skin Necrosis; Subarachnoid Haemorrhage; Thrombocytopenia | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                             | Menorem (Meropenem)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Fenitoin (Phenytoin) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Ambisome             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Vancomycin           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Enoxaparin Sodium    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Levothyroxine Sodium |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                             | Cancidas             |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|---------------------------------------------|-----------------|--------------|----------------|
| 11-Mar-2008                                                                   | 6576636        | NON-EXPEDITED      | N                  | OT              | US-BAYER-200711930BCC |                                             | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Drug Hypersensitivity; Dyspnoea; Pharyngeal Oedema; Swelling Face | Aleve          |                    |                    | S               | Oral                  |                                             |                 | Bayer        |                |
|                                                                               | Lexapro        |                    |                    | S               | Oral                  | Total Daily Dose: 10 Mg<br>Unit Dose: 10 Mg | 2 YR            | Not Reported |                |
|                                                                               | Advil          |                    |                    | S               |                       |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2008                                                                   | 6577193        | NON-EXPEDITED      | N                  | OT              | US-BAYER-200712460BCC |                                             | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematochezia; Rectal Haemorrhage                                             | Aleve          |                    |                    | S               | Oral                  |                                             | 5 MTH           | Bayer        |                |
|                                                                               | Lexapro        |                    |                    | S               | Oral                  | Total Daily Dose: 10 Mg<br>Unit Dose: 10 Mg | 43 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2008                                                                   | 6589751        | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-00847-01      |                                             | 28 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide; Indifference; Sexual Abuse; Thinking Abnormal                       | Lexapro        |                    |                    | S               |                       |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2008                                                                   | 6590426        | DIRECT             | N                  | HO, LT, RI, OT  |                       |                                             | 37 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Communication Disorder; Mental Disorder; Muscle Contractions       | Cymbalta       |                    |                    | S               | Oral                  | Daily Po 1-2 Months                         | 1 MTH           | Not Reported |                |
|                                                                               | Lexapro        |                    |                    | S               | Oral                  | 10mg Up To 40mg Daily                       | 13 MTH          | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |         |   |                 |              |
|-------------------------------------------------------------------------------|---------|---|-----------------|--------------|
| Involuntary; Social Avoidant Behaviour; Suicidal Ideation; Tardive Dyskinesia | Remeron | C | Po 13-14 Months | Not Reported |
|-------------------------------------------------------------------------------|---------|---|-----------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2008              | 6593783       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00801-01     |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebellar Syndrome;<br>Confusional State;<br>Hyperkalaemia;<br>Hyponatraemia | Escitalopram Oxalate                     |              |            | S           | Oral         | 1 Qd Po            |                 | Not Reported |
|                                                                               | Plavix                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Solupred (Prednisolone Sodium Metazoate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Permixon (Serenoa Repens)                |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Vastarel                                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Acetaminophen                            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2008              | 6531885       | EXPEDITED (15-DAY) | N                  | HO              | S08-USA-00107-01     |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Localised Infection;<br>Procedural Pain;<br>Staphylococcal Infection | Lexapro                       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                      | Sulindac                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Potassium Chloride            |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Chlorthalidone                |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Cenestin                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Actonel (Risendronate Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                                                                      | Aspirin                       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2008              | 6574931       | EXPEDITED (15-DAY) | Y                  | HO, LT          | PHFR2008GB00826      |                      | 37 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Body Temperature Increased; | Clozaril       |              |            | S           | Oral         | 200mg Daily        |                 | Novartis     |
|                                                      | Diazepam       |              |            | S           | Oral         | 5 Mg, Prn          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                |                      |   |      |            |              |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|------------|--------------|
| Cerebrovascular Accident;<br>Diarrhoea; Dizziness;<br>Fatigue; Headache; Heart<br>Rate Increased; Malaise;<br>Nausea; Vomiting | Aripiprazole         | S | Oral | 30mg Daily | Not Reported |
|                                                                                                                                | Escitalopram Oxalate | S | Oral | 20mg Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2008              | 6578628       | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20070101079 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Prolactin Increased;<br>Hypothalamo-Pituitary<br>Disorder; Weight<br>Increased | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                      | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2008              | 6591639       | DIRECT           | Y                  |                 |                      |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Torticollis           | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |
|                       | Ciprofloxacin  |              |            | C           |              |                    |                 | Not Reported |
|                       | Belladonna     |              |            | C           |              |                    |                 | Not Reported |
|                       | Amlodipine     |              |            | C           |              |                    |                 | Not Reported |
|                       | Modafinil      |              |            | C           |              |                    |                 | Not Reported |
|                       | Mtx Low Dose   |              |            | C           |              |                    |                 | Not Reported |
|                       | Desidronate    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2008              | 6528510       | EXPEDITED (15-DAY) | Y                  | OT              | US-WYE-H01986008     |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Brain Neoplasm Benign;<br>Demyelinating<br>Polyneuropathy | Effexor Xr              |              |            | S           | Oral         |                    |                 | Wyeth           |
|                                                           | Lexapro                 |              |            | S           |              |                    |                 | Lundbeck        |
|                                                           | Bupropion Hydrochloride |              |            | S           | Oral         |                    |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 13-Mar-2008                                                                                         | 6574537                        | EXPEDITED (15-DAY) | N                  | OT              | B0511476A            |                      | 58 YR           | Female          | SWE            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Fatigue; Leukopenia;<br>Pancytopenia;<br>Somnolence;<br>Thrombocytopenia;<br>Vitamin B12 Deficiency | Lamictal                       |                    |                    | S               | Oral                 | 200mg Per Day        |                 | Glaxosmithkline |                |
|                                                                                                     | Cipralelex                     |                    |                    | S               | Oral                 | 15mg Per Day         |                 | Not Reported    |                |
|                                                                                                     | Folic Acid                     |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Behepan                        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Lithionit                      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Mar-2008                                                                                         | 6593842                        | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00911-01     |                      |                 | Female          | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Gallbladder Disorder;<br>Haemolytic Anaemia                                                         | Cipralelex                     |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                                                     | Atenolol                       |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Mar-2008                                                                                         | 6594057                        | EXPEDITED (15-DAY) | Y                  | LT              | S08-FIN-00749-01     |                      | 70 YR           | Male            | FIN            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction;<br>International Normalised<br>Ratio Increased                                    | Cipralelex                     |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                                                                     | Warfarin                       |                    |                    | S               | Oral                 | 3 Mg Qd Po           |                 | Not Reported    |                |
|                                                                                                     | Warfarin                       |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Spesicor (Metoprolol Tartrate) |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Furosemide                     |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Lipitor                        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                     | Ramipril Copyfarm (Ramipril)   |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Mar-2008                                                                                         | 6594134                        | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-00893-01     |                      | 89 YR           | Female          | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Phosphorus Decreased; Condition Aggravated; Diarrhoea; Faeces Discoloured; Hypomagnesaemia; Major Depression; Malnutrition; Overdose; Proteus Infection; Radicular Pain; Rhabdomyolysis; Toxicity To Various Agents; Urinary Tract Infection; White Blood Cell Count Increased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Enalapril Maleate    |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Lyrica               |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Lyrica               |                    |                    | S               | Oral                 | 1 Unk Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Durogesic            |                    |                    | S               |                      | 50 Mcg Biw Ap        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Ferrous Sulfate      |                    |                    | S               | Oral                 | 80 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Levothyroxine Sodium |                    |                    | S               | Oral                 | 50 Mcg Qd Po         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Furosemide           |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2008                                                                                                                                                                                                                                                                          | 6561628              | EXPEDITED (15-DAY) | Y                  | HO, OT          | S08-AUT-00459-01     |                      | 54 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Oedema                                                                                                                                                                                                                                                                        | Cipraxel             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Risperdal            |                    |                    | S               | Oral                 | 3 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2008                                                                                                                                                                                                                                                                          | 6587595              | EXPEDITED (15-DAY) | Y                  | HO              | S08-CHN-00806-01     |                      | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Shock; Suicide Attempt                                                                                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 700 Mg Once Po       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Diazepam             |                    |                    | S               | Oral                 | 10 Tablet Once Po    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                      | Diazepam             |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2008                                                                                                                                                                                                                                                                          | 6600894              | EXPEDITED (15-DAY) | Y                  | DS              | S08-CAN-00995-01     |                      | 56 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Gastrooesophageal Reflux Disease; Glossodynia; Therapy Non-Responder; Tongue Blistering; Tongue Ulceration | Ciprallex                            |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Wellbutrin (Bupropion Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Strattera                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                            | Imovane (Zopiclone)                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2008                                                                                                | 6601148                              | EXPEDITED (15-DAY) | Y                  | DE, OT          | 025060               |                      | 29 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents                          | Mirtazapine                          |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                            | Doxepin Hydrochloride                |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                            | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                            | Unspecified Ingredient               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2008                                                                                                | 6603464                              | EXPEDITED (15-DAY) | Y                  | HO              | S08-ESP-00951-01     |                      | 72 YR           | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Inappropriate Antidiuretic Hormone Secretion; Muscular Weakness                                    | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2008                                                                                                | 6525320                              | EXPEDITED (15-DAY) | Y                  | HO              | S07-USA-06161-01     |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dystonia; Loss Of Consciousness; Muscle Rigidity; Seizure; Vomiting                      | Lexapro                              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro                              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                            | Lexapro                              |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   | Yasmin                 |                    |                    | S               |                                                   |                      |                 |              | Not Reported   |
|---------------------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                   | Yasmin                 |                    |                    | S               |                                                   |                      |                 |              | Not Reported   |
|                                                   | Centrum (Multivitamin) |                    |                    | C               |                                                   |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2008                                       | 6582757                | EXPEDITED (15-DAY) | Y                  | LT              | S08-FRA-00745-01                                  |                      | 49 YR           | Male         | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Gastric Ulcer;<br>Helicobacter Infection | Escitalopram Oxalate   |                    |                    | S               | Oral                                              | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                   | Voltaren               |                    |                    | S               | Oral                                              | 100 Mg Qd Po         |                 | Not Reported |                |
|                                                   | Omeprazole             |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2008                                       | 6588580                | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200800345 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide   | Methadose              |                    |                    | S               |                                                   |                      |                 | Tyco         |                |
|                                                   | Amitriptyline          |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                   | Cocaine                |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                   | Escitalopram Oxalate   |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                   | Chloral Hydrate        |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                   | Clonazepam             |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2008                                       | 6588623                | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200800363 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide   | Morphine               |                    |                    | S               |                                                   |                      |                 | Tyco         |                |
|                                                   | Fentanyl               |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                   | Escitalopram Oxalate   |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2008                                       | 6601054                | DIRECT             | N                  | DS, LT, OT      |                                                   |                      | 27 YR           | Female       | USA            |



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| <u>Preferred Term</u>                                                  | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
|------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------|--------------------|---------------------------------|----------------------|--------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------|----------------|
| Mood Swings; Suicidal Ideation; Wrong Product Administered             | Lexapro                                                                  |                    |                    | S                               | Oral                 | 10mg Once A Day Po                                     |                 | Not Reported                                                                                                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 19-Mar-2008                                                            | 6602528                                                                  | EXPEDITED (15-DAY) | Y                  | OT                              | S08-CHL-01012-01     |                                                        |                 | Female                                                                                                       | CHL            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Pregnancy                                                              | Lexapro<br>Unspecified Ingredient                                        |                    |                    | S<br>S                          |                      |                                                        |                 | Not Reported<br>Not Reported                                                                                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 19-Mar-2008                                                            | 6603973                                                                  | EXPEDITED (15-DAY) | N                  | HO                              | S08-USA-00918-01     |                                                        | 70 YR           | Female                                                                                                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Balance Disorder;<br>Contusion; Dizziness; Fall                        | Lexapro<br>Coumadin<br>Oxygen<br>Inhalers (Nos)                          |                    |                    | S<br>C<br>C<br>C                |                      |                                                        |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                                 |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                 | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>                                                                                                   | <u>Country</u> |
| 20-Mar-2008                                                            | 6533176                                                                  | EXPEDITED (15-DAY) | Y                  | OT                              | S08-USA-00024-01     |                                                        | 27 YR           | Female                                                                                                       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>                                                                                                   |                |
| Abortion Spontaneous;<br>Maternal Exposure During Pregnancy; Pregnancy | Lexapro<br>Lexapro<br>Rebif<br>Rebif<br>Klonopin<br>Atenolol<br>Klonopin |                    |                    | S<br>S<br>S<br>S<br>S<br>C<br>C | Oral<br>Oral         | 20 Mg Qd;Po<br>10 Mg Qd;Po<br>44 Mcg Tiw<br>44 Mcg Tiw |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 20-Mar-2008                                                                                           | 6567996              | EXPEDITED (15-DAY) | Y                  | OT              | S08-CHN-00524-01         |                      | 30 YR           | Female       | CHN            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced; Foetal Death; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Pregnancy | Lexapro              |                    |                    | S               | Oral                     | 15 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2008                                                                                           | 6589713              | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2008022451 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Rash Erythematous; Weight Decreased                                                 | Celebrex             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                       | Tylenol              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                       | Lipitor              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                       | Fosamax              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                       | Celebrex             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                       | Lexapro              |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2008                                                                                           | 6589871              | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2008023106 |                      | 44 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intestinal Ischaemia                                                                                  | Relpax               |                    |                    | S               | Oral                     | Text:1 Df            |                 | Not Reported |                |
|                                                                                                       | Betaferon            |                    |                    | S               | Subcutaneous             | Text:250ng           |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2008                                                                                           | 6603276              | EXPEDITED (15-DAY) | Y                  | OT              | S08-HKG-00883-01         |                      | 30 YR           | Female       | HKG            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                    |                                     |                    |                    |                 |                      |                      |                 |              |                |
|--------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Abortion Induced; Foetal Death; Maternal Exposure During Pregnancy |                                     | Lexapro            | S                  | Oral            | 15 Mg Qd Po          |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2008                                                        | 6570230                             | EXPEDITED (15-DAY) | Y                  | OT              | S08-IRL-00605-01     |                      | 35 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Urticaria                                                          | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                    | Gerax (Alprazolam)                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2008                                                        | 6392233                             | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-03453-01     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Progression; Fall; Hereditary Spastic Paraplegia           | Lexapro                             |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                    | Posamax (Alendronate Sodium)        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                    | Topranil (Imipramine Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2008                                                        | 6603019                             | DIRECT             |                    |                 |                      |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error; Product Dispensing Error                         | Lexapro                             |                    |                    | S               |                      | Tablet               |                 | Forest       |                |
|                                                                    | Lipitor                             |                    |                    | S               |                      | Tablet               |                 | Pfizer       |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Mar-2008                                                        | 6574377                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | S08-FRA-00669-01     |                      | 83 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Coma; Intentional                            | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                      |   |      |              |              |
|---------------------------|----------------------|---|------|--------------|--------------|
| Overdose; Suicide Attempt | Escitalopram Oxalate | S | Oral | 5 Mg Qd Po   | Not Reported |
|                           | Atarax               | S | Oral | 25 Mg Prn Po | Not Reported |
|                           | Lorazepam            | S |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2008              | 6606884       | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01025-01     |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Impulsive Behaviour;<br>Irritability; Libido<br>Increased; Panic Attack;<br>Unevaluable Event;<br>Weight Increased | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2008              | 6575095       | EXPEDITED (15-DAY) | Y                  | CA              | S08-CZE-00638-01     |                      | 37 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Benign Hydatidiform Mole;<br>Maternal Exposure During<br>Pregnancy; Pregnancy | Ciprallex      |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2008              | 6596126       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200800488 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Butalbital Acetaminophen And<br>Caffeine |              |            | S           | Oral         |                    |                 | Tyco         |
|                                                 | Quetiapine                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Unspecified Ingredient                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Aspirin                                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Acetaminophen                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                 | Ibuprofen                                |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |              |
|----------------------|---|------|--------------|
| Escitalopram Oxalate | S | Oral | Not Reported |
| Caffeine Citrate     | S | Oral | Not Reported |
| Naproxen             | S | Oral | Not Reported |
| Fexofenadine         | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 27-Mar-2008              | 6596130       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200800492 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Oxycodone                |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Methadose                |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Risperidone              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Metaxalone               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Heparin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Bupropion                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Clonidine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Unspecified Ingredient   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Albuterol                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Haloperidol              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Acyclovir                |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Vancomycin Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lamotrigine              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Mar-2008              | 6611518              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01142-01     |                      | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                         |   |              |
|--|-------------------------|---|--------------|
|  | Citalopram Hydrobromide | S | Not Reported |
|  | Equanil                 | S | Not Reported |
|  | Euthyral                | C | Not Reported |
|  | Mirtazapine             | C | Not Reported |
|  | Atarax                  | C | Not Reported |
|  | Cyamemazine             | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2008              | 6570540       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S08-FRA-00545-01     |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Cogwheel Rigidity; Cold<br>Sweat; Headache; Initial<br>Insomnia; Nausea;<br>Parkinsonism; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                               | Stresam (Etifoxine)  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2008              | 6606975       | DIRECT           | Y                  | DE              |                      |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 5 Mg Daily Po      |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Mar-2008              | 6603572       | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-00730-01     |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;    | CipraleX       |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
| Blood Cholesterol        | CipraleX       |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Increased; Blood         | Alprazolam     |              |            | C           |              |                    |                 | Not Reported |
| Triglycerides Increased; |                |              |            |             |              |                    |                 |              |
| Decreased Appetite;      |                |              |            |             |              |                    |                 |              |
| Depressed Mood;          |                |              |            |             |              |                    |                 |              |
| Dizziness; Dyspnoea;     |                |              |            |             |              |                    |                 |              |
| Fluid Retention;         |                |              |            |             |              |                    |                 |              |
| Headache; Hot Flush;     |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting; Weight Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2008              | 6542826       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00168-01     |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood Pressure Decreased; Facial Paralysis; Fatigue; Headache; Hyperhidrosis; Insomnia; Loss Of Personal Independence In Daily Activities; Nausea; Vision Blurred | Lexapro               |              |            | S           | Oral         | 10 Mg Once Po      |                 | Not Reported |
|                                                                                                                                                                             | Lexapro               |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                                             | Toprol XL             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                             | Nexium (Esomeprazole) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2008              | 6591760       | EXPEDITED (15-DAY) | Y                  | HO              | GXKR2008CH02125      |                      | 84 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug Level Decreased; Incorrect Dose Administered; Serotonin Syndrome | Cyclosporine                |              |            | S           |              | 1.25 Mg/Kg,Day     |                 | Not Reported |
|                                                                                         | Escitalopram Oxalate        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                         | Azathioprine (Azathioprine) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2008              | 6610323       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01049-01     |                      | 61 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sinus Arrhythmia; Sinus Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                     | Levothyroxine Sodium |              |            | C           |              |                    |                 | Not Reported |
|                                     | Lexomil (Bromazepam) |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 01-Apr-2008                                                                        | 6614180                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-01192-01     |                          | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Parosmia                                                                           | Cipralext               |                    |                    | S               | Oral                 | 5 Mg Qd Po               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2008                                                                        | 6611997                 | DIRECT             | N                  | HO              |                      |                          | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Dyspnoea; Nausea                                                       | Lexapro                 |                    |                    | S               | Oral<br>Oral         | 200 Bid Po<br>200 Bid Po |                 | Pfizer       |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2008                                                                        | 6614917                 | EXPEDITED (15-DAY) | Y                  | OT              | 070125-0000141       |                          | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced; Infection; Maternal Exposure During Pregnancy                    | Clorazepate Dipotassium |                    |                    | S               | Oral                 | 20 Mg; ; Po              |                 | Not Reported |                |
|                                                                                    | Cipralext               |                    |                    | S               | Oral                 | ; Po                     |                 | Not Reported |                |
|                                                                                    | Alcohol                 |                    |                    | S               | Oral                 | ; Po                     |                 | Not Reported |                |
|                                                                                    | Lorazepam               |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2008                                                                        | 6615124                 | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-01185-01     |                          | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma; Blood Pressure Increased; Condition Aggravated; Depression | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg Qd Po              |                 | Not Reported |                |
|                                                                                    | Lexapro                 |                    |                    | S               | Oral                 | 30 Mg Qd Po              |                 | Not Reported |                |
|                                                                                    | Wellbutrin XI           |                    |                    | S               |                      | 450 Mg Qd                |                 | Not Reported |                |
|                                                                                    | Wellbutrin XI           |                    |                    | S               |                      | 300 Mg Qd                |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              | Neurontin            |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|----------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                              | Klonopin             |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                              | Ambien               |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2008                                  | 6615126              | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-01207-01     |                      | 31 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Paranoia; Psychotic Disorder                 | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Topamax              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Klonopin             |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2008                                  | 6592096              | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-00832-01     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplastic Anaemia; Contusion                  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Od Po          |                 | Not Reported |                |
|                                              | Ferrous Sulfate      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Yaz                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2008                                  | 6600855              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00930-01     |                      | 62 YR           | Male         | DNK            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness; Road Traffic Accident | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                              | Amaryl               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Seloken              |                    |                    | S               |                      | 25 Mg Daily          |                 | Not Reported |                |
|                                              | Omeprazole           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2008                                  | 6615889              | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06450-01     |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                 |         |   |      |             |              |
|---------------------------------|---------|---|------|-------------|--------------|
| Recurrent Cancer; Testis Cancer | Lexapro | S | Oral | 20 Mg Od Po | Not Reported |
|                                 | Lexapro | S | Oral | 10 Mg Od Po | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-Apr-2008                       | 6616250                | EXPEDITED (15-DAY)        | Y                           | LT                       | S08-NLD-01250-01              |                               | 38 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Interaction;               | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
| Electrocardiogram Qt Prolonged; | Oxazepam                |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |
| Ventricular Fibrillation        | Levothyroxine           |                       |                     | S                    | Oral                  | 0.025 Mg Qd Po              |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-Apr-2008                       | 6616258                | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-BEL-01239-01              |                               | 40 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Ineffective; Urinary Retention | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 03-Apr-2008                       | 6616318                | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-IRL-01241-01              |                               | 43 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>       | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Pruritus; Wrong Product Administered | Citalopram              |                       |                     | S                    | Oral                  | 20 Mg Qd Po                 |                          | Not Reported        |
|                                      | Lexapro                 |                       |                     | S                    | Oral                  | 20 Mg Qd Po                 |                          | Not Reported        |
|                                      | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg Qd Po                 |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>     | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-----------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 07-Apr-2008                       | 6607826                | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-SANOFI-SYNTHELABO-A02200800994 |                               | 83 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                             |                      |   |      |     |       |  |              |
|-------------------------------------------------------------------------------------------------------------|----------------------|---|------|-----|-------|--|--------------|
| Confusional State;<br>Depressed Level Of<br>Consciousness;<br>Disorientation; Fall;<br>Hyponatraemia; Sopor | Stilnox              | S | Oral | Unk |       |  | Not Reported |
|                                                                                                             | Escitalopram Oxalate | S | Oral | Unk | 3 DAY |  | Not Reported |
|                                                                                                             | Lipanthyl            | C | Oral | Unk |       |  | Not Reported |
|                                                                                                             | Piracetam            | C | Oral | Unk |       |  | Not Reported |
|                                                                                                             | Vastarel             | C | Oral | Unk |       |  | Not Reported |
|                                                                                                             | Nisis                | C | Oral | Unk |       |  | Not Reported |
|                                                                                                             | Ginkor Fort          | C | Oral | Unk |       |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2008              | 6620049       | EXPEDITED (15-DAY) | Y                  | OT              | DSA_31640_2008       |                      | 39 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Infection; Maternal<br>Exposure During<br>Pregnancy; Premature<br>Labour | Lorazepam               |              |            | S           | Oral         | (2.5 Mg Qd Oral)   |                 | Not Reported |
|                                                                          | Alcohol                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                          | Cipraxel                |              |            | S           |              | (Df)               |                 | Not Reported |
|                                                                          | Clorazepate Dipotassium |              |            | S           | Oral         | (10 Mg Bid Oral)   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2008              | 6616545       | DIRECT           | N                  | HO, RI, OT      |                      |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Dependence; Family<br>Stress; Loss Of<br>Employment; Loss Of<br>Personal Independence In<br>Daily Activities | Xanax                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Risperdal              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Clonopin               |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2008              | 6616567       | DIRECT           | Y                  | OT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anorgasmia; Libido    | Lexapro        |              |            | S           | Oral         | 20mg Once A Day Po |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased

| <u>FDA Received Date</u>                     | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2008                                  | 6592010          | EXPEDITED (15-DAY) | Y                  | OT              | S08-CAN-00846-01     |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                        | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Petit Mal Epilepsy | Cipralext        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Cipralext        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                              | Valproate Sodium |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Axert            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                              | Clonazepam       |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2008                                                                                                                | 6592091        | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-00862-01     |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Condition<br>Aggravated; Dysarthria;<br>Furuncle; Gait Inability;<br>Multiple Sclerosis; Urinary<br>Incontinence | Lexapro        |                    |                    | S               | Oral                 | 10 Mg Qd;Po          |                 | Not Reported |                |
|                                                                                                                            | Rebif          |                    |                    | S               |                      | 8.8 Mcg;Tiw;         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2008              | 6611014        | EXPEDITED (15-DAY) | Y                  | OT              | GB-JNJFOC-20080401367 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis               | Ibuprofen      |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Ibuprofen      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                          | Cipralext      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2008              | 6621722        | EXPEDITED (15-DAY) | Y                  | HO              | S08-UKI-01338-01     |                      | 23 YR           | Female     | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                           |   |              |
|--------------------------|---------------------------|---|--------------|
| Blood Creatine           | Ciprallex                 | S | Not Reported |
| Phosphokinase Increased; | Contraceptive Pills (Nos) | C | Not Reported |
| Dizziness; Headache;     |                           |   |              |
| Vertigo                  |                           |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2008              | 6622540       | EXPEDITED (15-DAY) | Y                  | HO              | S08-NOR-01323-01     |                      | 51 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Mouth | Ciprallex              |              |            | S           |              |                    |                 | Not Reported |
| Haemorrhage; Rectal     | Acomplia               |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Haemorrhage;            | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
| Thrombocytopenia;       |                        |              |            |             |              |                    |                 |              |
| Vaginal Haemorrhage     |                        |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2008              | 6594326       | EXPEDITED (15-DAY) | N                  | OT              | 2008SP004596         |                      | 76 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;      | Miralax              |              |            | S           | Oral         | ;Unk;Po            |                 | Not Reported |
| Constipation; Dyspnoea;    | Advair Hfa           |              |            | S           |              |                    |                 | Not Reported |
| Flatulence;                | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Gastrointestinal Disorder; | Lexapro              |              |            | C           |              |                    |                 | Not Reported |
| Oedema Mouth;              | Levothyroxine Sodium |              |            | C           |              |                    |                 | Not Reported |
| Oesophageal Discomfort;    | Synthroid            |              |            | C           |              |                    |                 | Not Reported |
| Oesophageal Oedema;        | Naprosyn             |              |            | C           |              |                    |                 | Not Reported |
| Swollen Tongue             |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2008              | 6613939       | EXPEDITED (15-DAY) | Y                  | OT              | S08-NOR-01143-01     |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Anxiety;   | Ciprallex           |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Depression; Drug            | Delapril            |              |            | S           |              |                    |                 | Not Reported |
| Intolerance; Hallucination; | Imovane (Zopiclone) |              |            | C           |              |                    |                 | Not Reported |
| Malaise; Poisoning;         |                     |              |            |             |              |                    |                 |              |
| Schizoid Personality        |                     |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Social Anxiety  
Disorder; Vertigo;  
Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2008              | 6624549       | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01276-01     |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Autoimmune Thyroiditis;  | Lexapro        |              |            | S           | Oral         | 10 Mg Once Po      |                 | Not Reported |
| Contusion; Dyskinesia;   | Lexapro        |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |
| Encephalitis; Fall; Gait | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Disturbance;             | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Hypertension; Incorrect  | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Dose Administered;       |                |              |            |             |              |                    |                 |              |
| Malaise; Thyroid         |                |              |            |             |              |                    |                 |              |
| Neoplasm                 |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2008              | 6291716       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S07-ITA-01291-01     |                      |            | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------------|--------------|------------|-------------|----------------|-------------------------|-----------------|--------------|
| Aspartate                | Ciprallex                     |              |            | S           | Transplacental | 20 Mg Qd Transplacental |                 | Not Reported |
| Aminotransferase         | Ciprallex                     |              |            | S           | Oral           | 15 Mg Qd Po             |                 | Not Reported |
| Increased; Caesarean     | Ciprallex                     |              |            | S           | Oral           | 15 Mg Qd Po             |                 | Not Reported |
| Section; Insomnia;       | Ciprallex                     |              |            | S           | Oral           | 5 Mg Qd Po              |                 | Not Reported |
| Maternal Exposure During | Ciprallex                     |              |            | S           | Oral           |                         |                 | Not Reported |
| Pregnancy; Nervousness;  |                               |              |            |             |                |                         |                 |              |
| Perinatal Depression;    | Sedatol (Matricaria Recutita) |              |            | C           |                |                         |                 | Not Reported |
| Pregnancy; Toxicity To   |                               |              |            |             |                |                         |                 |              |
| Various Agents           |                               |              |            |             |                |                         |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-Apr-2008              | 6591767       | EXPEDITED (15-DAY) | Y                  | HO, OT          | NO-PFIZER INC-<br>2008023942 |                      | 19 YR      | Female     | NOR            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depression; Drug   | Zoloft         |              |            | S           | Oral         |                    |                 | Not Reported |
| Intolerance; Hallucination; |                |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                    |                         |   |      |              |
|------------------------------------|-------------------------|---|------|--------------|
| Poisoning; Social Anxiety Disorder | Triphasil-21            | S | Oral | Not Reported |
|                                    | Citalopram Hydrobromide | S | Oral | Not Reported |
|                                    | Cipralelex              | S | Oral | Not Reported |
|                                    | Zopiclone               | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2008              | 6620101       | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood;<br>Medication Error; Product Dispensing Error; Wrong Product Administered | Lexapro        |              |            | S           |              | Tablet             |                 | Not Reported |
|                                                                                           | Propecia       |              |            | S           |              | Tablet             |                 | Merck        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2008              | 6625843       | EXPEDITED (15-DAY) | Y                  | OT              | S08-CAN-01339-01     |                      | 59 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Fatigue;<br>Suicidal Ideation; Thinking Abnormal; Tinnitus;<br>Weight Decreased | Cipralelex                                                          |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Cipralelex                                                          |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Cipralelex                                                          |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Cipralelex                                                          |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |
|                                                                                            | Seroquel                                                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                            | Valerian Tea (Valeriana Officinalis Extract)<br>Holy Basil (Herbal) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2008              | 6641985       | DIRECT           | N                  | LT, RI, OT      |                      |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Agitation; Alcohol Use;<br>Anger; Anxiety; Arthralgia; | Lexapro        |              |            | S           | Oral         | 10 Mg Once A Day Po |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chills; Deafness; Lexapro S 10 Mg Twice A Day Po Not Reported  
 Depersonalisation/Derealisation Disorder; Fall;  
 Fatigue; Feeling Abnormal; Foot Fracture;  
 Hip Fracture;  
 Hypoaesthesia; Insomnia;  
 Memory Impairment;  
 Nerve Injury; Nervous System Disorder;  
 Palpitations; Rash;  
 Salivary Hypersecretion;  
 Serotonin Syndrome;  
 Sexual Dysfunction;  
 Thinking Abnormal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2008              | 6576705       | EXPEDITED (15-DAY) | N                  | DE, HO, OT      | S08-USA-00566-01     |                      | 87 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiovascular Disorder;               | Lexapro              |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Confusional State;                     | Isosorbide Dinitrate |              |            | C           |              |                    |                 | Not Reported |
| General Physical Health Deterioration; | Prinivil             |              |            | C           |              |                    |                 | Not Reported |
| Musculoskeletal Stiffness;             | Colace               |              |            | C           |              |                    |                 | Not Reported |
| Peripheral Vascular Disorder; Seizure; | Thiamine             |              |            | C           |              |                    |                 | Not Reported |
| Somnolence; Tremor                     | Warfarin Sodium      |              |            | C           |              |                    |                 | Not Reported |
|                                        | Neurontin            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2008              | 6622826       | DIRECT           | Y                  |                 |                      |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal      | Lexapro        |              |            | S           |              | 5 Mg Qd Inj        | 2 YR            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2008              | 6628142       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01395-01     |                      | 21 YR      | Male       | DNK            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Dermatitis Exfoliative;<br>Hypotension                                                                                                                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                                                                            | 6617729              | EXPEDITED (15-DAY) | N                  | DE              |                      | S08-USA-01234-01     | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death; Anxiety;<br>Apnoea; C-Reactive<br>Protein Increased; Cardiac<br>Arrest; Depressed Mood;<br>Depression; Dry Mouth;<br>Fatigue; Feeling<br>Abnormal; Pain; Pulse<br>Absent; Stress Urinary<br>Incontinence; Sudden<br>Death; Toxicity To Various<br>Agents; Unresponsive To<br>Stimuli | Lexapro              |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                 | 40 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Lexapro              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Neurontin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                                                                            | 6625313              | DIRECT             | N                  | OT              |                      |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Disorientation; Heart Rate<br>Increased; Hypertension;<br>Libido Decreased;<br>Withdrawal Syndrome                                                                                                                                                                              | Lexapro              |                    |                    | S               | Oral                 | 10 Mg Per Day Po     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                                                                            | 6626880              | EXPEDITED (15-DAY) | N                  | DE              |                      | S08-USA-01321-01     | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                          |                         |                    |                    |                 |                      |                           |                 |                              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|------------------------------|----------------|
| Completed Suicide; Gun Shot Wound                                                                                                                                                                                                                        |                         | Lexapro            | S                  | Oral            | 10 Mg Qd Po          | Not Reported              |                 |                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                              | 6630127                 | EXPEDITED (15-DAY) | Y                  | CA              | S08-UKI-01402-02     |                           |                 | Unknown                      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Diaphragmatic Hernia; Maternal Exposure During Pregnancy                                                                                                                                                                                                 | Ciprallex<br>Co-Codamol |                    |                    | S<br>C          |                      |                           |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                              | 6630150                 | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01403-02     |                           | < 1 DAY         | Male                         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abdominal Distension; Abdominal Pain; Abnormal Faeces; Agitation                                                                                                                                                                                         | Escitalopram Oxalate    |                    |                    | S               | Transplacental       | 10 Mg Bid Transplacental  |                 | Not Reported                 |                |
| Neonatal; Bacterial Infection; Drug Withdrawal Syndrome Neonatal; Dysmorphism; Foetal Distress Syndrome; Hypertonia Neonatal; Hypoglycaemia Neonatal; Maternal Exposure During Pregnancy; Meconium In Amniotic Fluid; Neonatal Disorder; Tremor Neonatal | Cyamemazine             |                    |                    | S               | Transplacental       | 50 Mg Qd Transplacental   |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Xanax                   |                    |                    | S               | Transplacental       | 0.5 Mg Tid Transplacental |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Atarax                  |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Subutex                 |                    |                    | S               | Transplacental       | 8 Mg Qd Transplacental    |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Alcohol                 |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Heroin                  |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Cannabis                |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Cocaine                 |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Apr-2008                                                                                                                                                                                                                                              | 6630216                 | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01396-01     |                           | 83 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |                |
| Arteriosclerosis; Confusional State; Fall; Hyponatraemia; Pituitary                                                                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Zolpidem Tartrate       |                    |                    | S               |                      |                           |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                          | Nisis                   |                    |                    | C               |                      |                           |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                               |   |              |
|----------------------|-------------------------------|---|--------------|
| Enlargement;         | Vastarel                      | C | Not Reported |
| Somnolence; Urine    | Nootropyl (Piracetam)         | C | Not Reported |
| Osmolarity Decreased | Fenofibrate                   | C | Not Reported |
|                      | Ginkor                        | C | Not Reported |
|                      | Biloba/Heptaminol/Troxerutine |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2008              | 6569908       | EXPEDITED (15-DAY) | Y                  | OT              | S08-UKI-00607-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amaurosis Fugax       | Cipralext      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2008              | 6631413       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S08-FRA-01416-01     |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Ectopic Pregnancy; Maternal Exposure During Pregnancy | Escitalopram Oxalate          |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                         | Desogestrel/Ethinyl Estradiol |              |            | S           |              |                    |                 | Not Reported |
|                                                                         | Lormetazepam                  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Apr-2008              | 6561161       | EXPEDITED (15-DAY) |                    | HO, OT          | CH-ABBOTT-08P-151-0438724-00 |                      | 84 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Serotonin Syndrome    | Cyclosporine   |              |            | S           | Oral         |                                                       |                 | Not Reported |
|                       | Cyclosporine   |              |            | S           | Oral         |                                                       |                 | Not Reported |
|                       | Cyclosporine   |              |            | S           |              | Not Reported                                          |                 | Not Reported |
|                       | Cyclosporine   |              |            | S           |              |                                                       |                 | Not Reported |
|                       | Cipralext      |              |            | S           |              | Initial Dose 2.5 Mg/D, Gradually Increased To 15 Mg/D |                 | Not Reported |
|                       | Cipralext      |              |            | S           |              | Not Reported                                          |                 | Not Reported |
|                       | Cipralext      |              |            | S           |              |                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |                                       |              |
|-------------------------|---|---------------------------------------|--------------|
| Ciprallex               | S |                                       | Not Reported |
| Azathioprine            | C | Oral                                  | Not Reported |
| Paracetamol             | C | Intravenous (not otherwise specified) | Not Reported |
| Memantine Hydrochloride | C |                                       | Not Reported |
| Memantine Hydrochloride | C |                                       | Not Reported |
| Haloperidol             | C | Oral                                  | Not Reported |
| Haloperidol             | C |                                       | Not Reported |
| Lorazepam               | C | Oral                                  | Not Reported |
| Calcitriol              | C | Oral                                  | Not Reported |
| Calcium-Sandoz          | C | Oral                                  | Not Reported |
| Cefuroxime Axetil       | C | Not Reported                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2008              | 6626589       | DIRECT           | N                  | OT              |                      |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Drug Screen Positive; Malaise | Maxalt         |              |            | S           | Oral         | 10mg Twice A Day Po |                 | Merck      |
|                               | Lexapro        |              |            | S           | Oral         | 10mg Once A Day Po  |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2008              | 6631549       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01421-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bulimia Nervosa; Hyperphagia; Weight Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2008              | 6520465       | EXPEDITED (15-DAY) | Y                  | DE              | S07-GRC-06255-01     |                      | 63 YR      | Female     | GRC            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                               |   |      |             |              |
|------------------------------------|-------------------------------|---|------|-------------|--------------|
| Myocardial Infarction;<br>Overdose | Ciprallex                     | S | Oral | 10 Mg Qd Po | Not Reported |
|                                    | Ciprallex                     | S | Oral | 30 Mg Qd Po | Not Reported |
|                                    | Amisulpride                   | C |      |             | Not Reported |
|                                    | Digoxine                      | C |      |             | Not Reported |
|                                    | Acetylsalicylic Acid          | C |      |             | Not Reported |
|                                    | Clopidogrel                   | C |      |             | Not Reported |
|                                    | Metoprolol                    | C |      |             | Not Reported |
|                                    | Ramipril/ Hydrochlorothiazide | C |      |             | Not Reported |
|                                    | Albuterol                     | C |      |             | Not Reported |
|                                    | Ipratropium                   | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Apr-2008              | 6636411       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S08-FRA-01342-01     |                      | 84 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged; Hypokalaemia;<br>Syncope; Torsade De<br>Pointes | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Furosemide           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                       | Sectral              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2008              | 6623291       | EXPEDITED (15-DAY) | Y                  | OT              | DE-WYE-G01393308     |                      | 75 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                        | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Drug<br>Interaction; Fall; Gait<br>Disturbance | Venlafaxine Hydrochloride    |              |            | S           | Oral         |                    |                 | Wyeth        |
|                                                              | Rythmol                      |              |            | C           | Oral         |                    |                 | Knoll        |
|                                                              | Norvasc                      |              |            | C           | Oral         |                    |                 | Pfizer       |
|                                                              | Sortis                       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                              | Levodopa                     |              |            | C           | Oral         |                    |                 | Unknown      |
|                                                              | Kalinor (Potassium Chloride) |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                              | Methionine                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                              | Ascorbic Acid                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                              | Pantoprazole Sodium          |              |            | C           | Oral         |                    |                 | Wyeth        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |      |  |  |  |       |  |              |
|---------------------------|---|------|--|--|--|-------|--|--------------|
| Movicol                   | C |      |  |  |  |       |  | Not Reported |
| Marcumar                  | C | Oral |  |  |  |       |  | Roche        |
| Venlafaxine Hydrochloride | S | Oral |  |  |  | 6 DAY |  | Wyeth        |
| Enalapril                 | S | Oral |  |  |  |       |  | Unknown      |
| Esidrix                   | S | Oral |  |  |  |       |  | Novartis     |
| Cipralelex                | S | Oral |  |  |  |       |  | Lundbeck     |
| Lithium Carbonate         | S | Oral |  |  |  |       |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2008              | 6631367       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01417-01     |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fixed Eruption        | Escitalopram Oxalate       |              |            | S           | Oral         | 1 Unk Qd Po        |                 | Not Reported |
|                       | Aceprometazine\Meprobamate |              |            | S           | Oral         | 1 Unk Bid Po       |                 | Not Reported |
|                       | Atarax                     |              |            | C           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2008              | 6638600       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-01508-01     |                      | 47 YR      | Female     | DEU            |

| <u>Preferred Term</u>            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure | Lexapro           |              |            | S           |              |                    |                 | Not Reported |
|                                  | Lexapro           |              |            | S           |              |                    |                 | Not Reported |
|                                  | Betaseron         |              |            | S           | Subcutaneous | 8 Unk Qod Sc       |                 | Not Reported |
|                                  | Iv Steroids (Nos) |              |            | C           |              |                    |                 | Not Reported |
|                                  | Prednisone        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2008              | 6574375       | EXPEDITED (15-DAY) | Y                  | OT              | S08-SWE-00674-01     |                      | 59 YR      | Female     | SWE            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Leukopenia; Thrombocytopenia; | Cipralelex     |              |            | S           | Oral         | 15 Mg Qd Po        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                        |                             |   |      |              |              |
|------------------------|-----------------------------|---|------|--------------|--------------|
| Vitamin B12 Deficiency | Lamictal                    | S | Oral | 200 Mg Qd Po | Not Reported |
|                        | Lithionit (Lithium Sulfate) | C |      |              | Not Reported |
|                        | Folacin                     | C |      |              | Not Reported |
|                        | Behepan (Cyanocobalamin)    | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2008              | 6580081       | EXPEDITED (15-DAY) | Y                  | HO              | S08-SWE-00705-01     |                      | 54 YR      | Male       | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|---------------------|--------------|------------|-------------|----------------------|--------------------|-----------------|--------------|
| Haemoglobin Decreased; | Cipralex            |              |            | S           | Oral                 | 25 Mg Qd Po        |                 | Not Reported |
| Post Procedural        | Enoxaparin Sodium   |              |            | S           | Intravenous (not     | 100 Mg Once Iv     |                 | Not Reported |
| Haemorrhage            |                     |              |            |             | otherwise specified) |                    |                 |              |
|                        | Fish Oil            |              |            | S           | Oral                 | 4 Mg Qd Po         |                 | Not Reported |
|                        | Ventolin            |              |            | C           |                      |                    |                 | Not Reported |
|                        | Pulmicort Flexhaler |              |            | C           |                      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 25-Apr-2008              | 6596961       | EXPEDITED (15-DAY) | N                  | OT              | US-RANBAXY-2008US-14022 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastroenteritis Viral; | Isotretinoin   |              |            | S           | Oral         | 40 Mg, Qd          | 14 DAY          | Ranbaxy      |
| Pregnancy              | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                        | Wellbutrin     |              |            | S           |              | Unk,Unk            |                 | Not Reported |
|                        | Mirena         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Apr-2008              | 6639800       | EXPEDITED (15-DAY) | Y                  | DE              | 2008-176130-NL       |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Anxiety; Fatigue; Pain; | Remeron        |              |            | S           |              |                         |                 | Not Reported |
| Toxicity To Various     | Ribavirin      |              |            | S           | Oral         | 1 Df Bid Oral, 400 Mg / |                 | Not Reported |
| Agents; Treatment       |                |              |            |             |              | 600 Mg                  |                 |              |
| Noncompliance           | Pegasys        |              |            | S           |              | 180 Ug Daily            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |          |              |
|-------------------------------|---|----------|--------------|
| Isopropanol                   | S | Df       | Not Reported |
| Acetone                       | S | Df       | Not Reported |
| Pseudoephedrine Hydrochloride | S | Df       | Not Reported |
| Methamphetamine Hydrochloride | S | Df       | Not Reported |
| Lexapro                       | S | 40 Mg Qd | Not Reported |
| Cannabinoids                  | S | Df       | Not Reported |
| Chlorphenamine                | C | Df       | Not Reported |
| Buspar                        | C |          | Not Reported |
| Prilosec                      | C |          | Not Reported |
| Risperdal                     | C |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2008              | 6516650       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06226-01     |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Threatened;<br>Foetal Heart Rate<br>Decreased; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Lexapro                                             |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                             | Lexapro                                             |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                             | Lexapro                                             |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                             | Clonazepam                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Ambien                                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Metamucil Therapy For<br>Regularity                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Progesterone                                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                             | Prenatal Vitamin With Dha<br>(Docosahexaenoic Acid) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2008              | 6571255       | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-00441-01     |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Depression; Overdose;<br>Substance Abuse; | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                    | Lexapro        |              |            | S           | Oral         | 40 Mg Qd Po        |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                         |   |      |             |              |
|-------------------------|-------------------------|---|------|-------------|--------------|
| Treatment Noncompliance | Lexapro                 | S | Oral | 10 Mg Qd Po | Not Reported |
|                         | Lorcet                  | C |      |             | Not Reported |
|                         | Lamictal (Lamotrioline) | C |      |             | Not Reported |
|                         | Seroquel                | C |      |             | Not Reported |
|                         | Lorazepam               | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2008              | 6603723       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00948-01     |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2008              | 6608037       | EXPEDITED (15-DAY) | Y                  | OT              | 2008S1004401         |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Albuterol               |              |            | S           |              |                    |                 | Not Reported |
|                       | Risperidone             |              |            | S           |              |                    |                 | Not Reported |
|                       | Metaxalone              |              |            | S           |              |                    |                 | Not Reported |
|                       | Heparin                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Oxycodone               |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                       | Bupropion               |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonidine               |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient  |              |            | S           |              |                    |                 | Not Reported |
|                       | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                       | Haloperidol             |              |            | S           |              |                    |                 | Not Reported |
|                       | Acyclovir Sodium        |              |            | S           |              |                    |                 | Not Reported |
|                       | Vancomycin              |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamotrigine             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2008              | 6635793       | DIRECT           | Y                  | HO              |                      |                      | 76 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                               |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|-----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Inappropriate Antidiuretic Hormone Secretion                                                  |                         | Escitalopram Oxalate      |                             | S                        | Oral                          |                               | 20 Mg Every Day Po       |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Apr-2008                                                                                   | 6636715                 | DIRECT                    | N                           | HO                       |                               |                               | 21 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Blood Glucose Decreased; Weight Increased                                            | Lexapro                 |                           |                             | S                        |                               | One Tablet Once A Day         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Apr-2008                                                                                   | 6641547                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-USA-01484-01              |                               | 75 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated; Extrasystoles                                                           | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                               | Lexapro                 |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |
|                                                                                               | Tiazac                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                               | Cozaar                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Apr-2008                                                                                   | 6629922                 | EXPEDITED (15-DAY)        | Y                           | DE, OT                   | US-PFIZER INC-2008035810      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide; Depression; Intentional Self-Injury; Suicidal Ideation; Vascular Operation | Chantix                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                                               | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Apr-2008                                                                                   | 6635133                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 233423J08USA                  |                               | 26 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                          |                  |        |                              |
|------------------------------------------------------------------------------------------|------------------|--------|------------------------------|
| Abdominal Pain;<br>Dehydration; Depression;<br>Nausea; Panic Attack;<br>Retching; Tremor | Rebif<br>Lexapro | S<br>S | Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------|------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2008              | 6642525       | EXPEDITED (15-DAY) | Y                  | HO              | S08-GER-01562-01     |                      |            | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertensive Crisis   | Escitalopram Oxalate                               |              |            | S           | Oral         | 10 Mg Bid Po       |                 | Not Reported |
|                       | Sartan (Losartan)                                  |              |            | C           |              |                    |                 | Not Reported |
|                       | St. John'S Wort "Herron"<br>(Hypericum Perforatum) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2008              | 6642530       | EXPEDITED (15-DAY) | Y                  | OT              | S08-SAF-01302-01     |                      | 41 YR      | Female     | ZAF            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;<br>Dysgeusia; Hypertension;<br>Weight Increased | Cipralelex     |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                     | Cipralelex     |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2008              | 6642531       | EXPEDITED (15-DAY) | Y                  | HO, LT          | S08-NOR-01521-01     |                      | 87 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Potassium<br>Decreased; Blood Sodium<br>Decreased; Fall;<br>Hyponatraemia; Loss Of<br>Consciousness | Cipralelex     |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                           | Selozok        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2008              | 6643415       | EXPEDITED (15-DAY) | Y                  | LT              | S08-NLD-01250        |                      | 38 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Ventricular<br>Fibrillation | Lexapro        |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                     | Oxazepam       |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                     | Levothyroxine  |                    |                    | S               | Oral                      | 0.025 Mg Qd Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2008                                                                         | 6639822        | DIRECT             |                    |                 |                           |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intercepted Product<br>Dispensing Error;<br>Medication Error                        | Lexapro        |                    |                    | S               |                           | Tablet               |                 | Not Reported |                |
|                                                                                     | Lipitor        |                    |                    | S               |                           | Tablet               |                 | Pfizer       |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2008                                                                         | 6643503        | DIRECT             | Y                  | DS, HO          |                           |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure                                                              | Lexapro        |                    |                    | S               |                           | Prior To Admission   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2008                                                                         | 6539805        | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-<br>20080105813 |                      | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction                                                               | Invega         |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                     | Lexapro        |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2008                                                                         | 6702971        | NON-EXPEDITED      | N                  | DE              | T200701010                |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                               | Methadose      |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                     | Zoloft         |                    |                    | S               |                           |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                |                                           |                  |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------------------|-------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                                                                        |                                           |                  | S                  |                 |                      |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2008                                                                                    | 6646248                                   | DIRECT           | Y                  | RI              |                      |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                                                             | Lexapro                                   |                  |                    | S               | Oral                 | One Daily Po         | 18 MTH          | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2008                                                                                    | 6704367                                   | NON-EXPEDITED    | Y                  | DE              | 544089               |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest                                       | Naproxen                                  |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Quetiapine Fumarate                       |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Unspecified Ingredient                    |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Acetaminophen, Butalbital And<br>Caffeine |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Aspirin (Aspirin)                         |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Acetaminophen (Paracetamol)               |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Ibuprofen (Ibuprofen)                     |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Escitalopram Oxalate                      |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Caffeine Citrate                          |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                | Fexofenadine Hcl                          |                  |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-May-2008                                                                                    | 6648695                                   | DIRECT           | N                  | RI              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Asthenia;<br>Constipation; Food<br>Craving; Gait Disturbance;<br>Migraine; Pain In | Lexapro                                   |                  |                    | S               |                      | 20 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Extremity; Sleep Disorder;  
Tendon Pain; Weight  
Increased

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-May-2008                                                                  | 6649025                              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01681-01     |                      | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health<br>Deterioration; Hypertonia;<br>Parkinson'S Disease | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                              | Valium                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                              | Athymil (Mianserin<br>Hydrochloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                              | Ramipril                             |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-May-2008                                                                                      | 6649026              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01680-01     |                      | 30 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis;<br>Cholangitis Sclerosing;<br>Hepatic Steatosis;<br>Hepatitis; Hepatitis A | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                  | Lexomil (Bromazepam) |                    |                    | S               | Oral                 | 0.5 Qd Po            |                 | Not Reported |                |
|                                                                                                  | Lexomil (Bromazepam) |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-May-2008                                                                                 | 6649672              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01660-01     |                      | 60 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional<br>Overdose; Pneumonia<br>Aspiration; Septic Shock;<br>Serotonin Syndrome | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Levomepromazine      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Levomepromazine      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Meprobamate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Meprobamate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Imovane (Zopiclone)  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                             | Imovane (Zopiclone)  |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Oxazepam                   |                      | S                  |                    | Not Reported    |                          |                      |                 |              |                |
|----------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Oxazepam                   |                      | S                  |                    | Not Reported    |                          |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2008                | 6631783              | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2008037040 |                      | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension;      | Xanax                |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Abdominal Pain; Agitation; | Atarax               |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Anxiety; Hypertonia;       | Subutex              |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Hypoglycaemia; Maternal    | Escitalopram Oxalate |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Exposure During            | Cyamemazine          |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Pregnancy; Tremor          |                      |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2008                | 6648579              | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01644-01         |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Disorder;      | Escitalopram Oxalate |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Leukopenia;                | Antiallergics        |                    |                    | C               |                          |                      |                 | Not Reported |                |
| Thrombocytopenia           |                      |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2008                | 6648929              | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01622-01         |                      | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia;       | Lexapro              |                    |                    | S               |                          |                      |                 | Not Reported |                |
| Anger; Feeling Abnormal;   |                      |                    |                    |                 |                          |                      |                 |              |                |
| Flashback; Headache;       |                      |                    |                    |                 |                          |                      |                 |              |                |
| Homicide; Imprisonment;    |                      |                    |                    |                 |                          |                      |                 |              |                |
| Loss Of Consciousness;     |                      |                    |                    |                 |                          |                      |                 |              |                |
| Tinnitus; Visual           |                      |                    |                    |                 |                          |                      |                 |              |                |
| Impairment                 |                      |                    |                    |                 |                          |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-May-2008                                                                                                                                               | 6459496                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S07-USA-05498-01     |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Anxiety;<br>Condition Aggravated;<br>Depression; Homicide;<br>Overdose; Road Traffic<br>Accident; Suicidal<br>Ideation; Suicide Attempt | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Lexapro                     |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                                                                           | Xanax                       |                    |                    | S               | Oral                 | Mg Once Po           |                 | Not Reported |                |
|                                                                                                                                                           | Xanax                       |                    |                    | S               |                      | 0.5 Mg Tid           |                 | Not Reported |                |
|                                                                                                                                                           | Xanax                       |                    |                    | S               |                      | 0.25 Mg Tid          |                 | Not Reported |                |
|                                                                                                                                                           | Pexeva                      |                    |                    | S               | Oral                 | Mg Once Po           |                 | Not Reported |                |
|                                                                                                                                                           | Pexeva                      |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Risperdal                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                           | Lithium                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2008                                                                                                                                               | 6570228                     | EXPEDITED (15-DAY) | Y                  | OT              | S08-SWI-00608-01     |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug<br>Interaction; Hyperhidrosis;<br>Ill-Defined Disorder;<br>Restlessness; Serotonin<br>Syndrome                                  | Ciprallex                   |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Amitriptyline Hydrochloride |                    |                    | S               | Oral                 | 25 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Remeron                     |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                           | Meto Zerok                  |                    |                    | S               | Oral                 | 100 Mg Bid Po        |                 | Not Reported |                |
|                                                                                                                                                           | Lorazepam                   |                    |                    | S               | Oral                 | 1 Mg Qd Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-May-2008                                                                                                                                               | 6649744                     | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01629-01     |                      | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Sensation In<br>Eye; Anger; Hallucination,<br>Auditory; Headache; Loss                                                                           | Lexapro                     |                    |                    | S               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Of Consciousness;  
Sensory Disturbance;  
Visual Impairment

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|----------------------|----------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|----------------|
| 13-May-2008                                                                                                         | 6650278                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | DE                                   | S08-CAN-01694-01     |                      | 18 YR           | Female                                                                                                                       | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Suicidal Ideation                                                                                                   | Ciprallex<br>Zopiclone                                                                                                                          |                    |                    | S<br>S                               |                      |                      |                 | Not Reported<br>Not Reported                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 13-May-2008                                                                                                         | 6650286                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | OT                                   | S08-ITA-01716-01     |                      | 81 YR           | Male                                                                                                                         | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Hallucination, Tactile;<br>Hallucination, Visual                                                                    | Ciprallex<br>Amiodarone<br>Bisoprolol (Bisoprolol)<br>Warfarin Sodium<br>Atorvastatine (Atorvastatin)<br>Glimepiride<br>Ramipril<br>Barnidipine |                    |                    | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                                                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 14-May-2008                                                                                                         | 6652618                                                                                                                                         | EXPEDITED (15-DAY) | Y                  | HO                                   | S08-CAN-01713-01     |                      | 24 YR           | Female                                                                                                                       | CAN            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                                                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Agitation; Anxiety; Drug<br>Interaction; Insomnia;<br>Mood Swings;<br>Palpitations; Sinusitis;<br>Thinking Abnormal | Ciprallex<br>Biaxin                                                                                                                             |                    |                    | S<br>S                               | Oral                 | 10 Mg Qd Po          |                 | Not Reported<br>Not Reported                                                                                                 |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-May-2008                                                                                                                                                   | 6636618                                  | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-01491-01     |                      | 60 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Weight Increased                                                                                                                       | Ciprallex                                |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Lorazepam                                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Lexatin (Bromazepam)                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Lovastatin                               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Amitriptyline Hydrochloride              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2008                                                                                                                                                   | 6640540                                  | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01529-01     |                      | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Blood Alkaline<br>Phosphatase Increased;<br>Constipation; Depression;<br>Disease Recurrence; Drug<br>Interaction; Fall; Gait<br>Disturbance; Overdose | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                                               | Lithium Carbonate                        |                    |                    | S               |                      | 225 Qd               |                 | Not Reported |                |
|                                                                                                                                                               | Enalapril Maleate                        |                    |                    | S               |                      | 10 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                               | Esidrix                                  |                    |                    | S               |                      | 25 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                               | Venlafaxine Hydrochloride                |                    |                    | S               |                      | 75 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                               | Venlafaxine Hydrochloride                |                    |                    | S               |                      | 75 Mg Qd             |                 | Not Reported |                |
|                                                                                                                                                               | Rythmonorm (Propafenone<br>Hydrchloride) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Norvasc                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Sortis (Atorvastatin)                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Restex                                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Kalinor (Potassium Chloride)             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Acimethin (Methionine)                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Cebion (Ascorbic Acid)                   |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Pantozol (Pantoprazole Sodium)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Movicol                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                               | Marcumar (Phenpropcpumon)                |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2008                                                                                                                                                   | 6651540                                  | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-01721-01     |                      | 44 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Amnesia;<br>Electrocardiogram Delta<br>Waves Abnormal; Gait<br>Disturbance; Insomnia;<br>Intentional Self-Injury;<br>Mental Impairment | Lexapro                               |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2008                                                                                                                            | 7334627                               | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-01664-01          |                      | 85 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Contusion; Fall;<br>Seizure; Somnolence;<br>Unresponsive To Stimuli                                                           | Lexapro                               |                    |                    | S               | Oral                      | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                                        | Lisinopril And<br>Hydrochlorothiazide |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Amiodarone                            |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Isosorbide Dinitrate                  |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Fosamax Plus D                        |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Plavix                                |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Coreg                                 |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Zetia (Ezetimibe)                     |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Sular                                 |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                                                                        | Furosemide                            |                    |                    | C               |                           |                      |                 | Not Reported |                |
| Aspirin                                                                                                                                |                                       |                    | C                  |                 |                           |                      | Not Reported    |              |                |
| Warfarin Sodium                                                                                                                        |                                       |                    | C                  |                 |                           |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2008                                                                                                                            | 6636607                               | EXPEDITED (15-DAY) | Y                  | HO              | ES-JNJFOC-<br>20080407429 |                      | 48 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Cholestatic                                                                                                                  | Topamax                               |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                        | Cipralext                             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                        | Seroquel                              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                        | Clorazepate                           |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                                                        | Bromazepam                            |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

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|                                                                                          |                |                    |                    |                 |                          |                                               |                 |                 |                |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------------------------|-----------------|-----------------|----------------|
| Clomethiazole                                                                            |                |                    | S                  |                 | Oral                     |                                               | Not Reported    |                 |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 16-May-2008                                                                              | 6655312        | DIRECT             | N                  | HO              |                          |                                               | 53 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure Increased;<br>Drug Ineffective;<br>Dyspnoea; Feeling<br>Abnormal          | Lisinopril     |                    |                    | S               | Oral                     | 20mg Daily Po                                 | 12 DAY          | Zenith Goldline |                |
|                                                                                          | Lexapro        |                    |                    | S               | Oral                     | 10mg Daily Po                                 | 5 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-May-2008                                                                              | 6612684        | EXPEDITED (15-DAY) | Y                  | OT              | US-BAYER-<br>200818779NA |                                               | 39 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Behaviour;<br>Hallucination; Violence-<br>Related Symptom                       | Avelox         |                    |                    | S               | Oral                     | Total Daily Dose: 400 Mg<br>Unit Dose: 400 Mg | 1 DAY           | Bayer           |                |
|                                                                                          | Lexapro        |                    |                    | S               |                          | Total Daily Dose: 10 Mg                       | 6 MTH           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-May-2008                                                                              | 6656404        | DIRECT             | N                  | OT              |                          |                                               | 51 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Depression;<br>Fatigue; Loss Of Personal<br>Independence In Daily<br>Activities | Lexapro        |                    |                    | S               | Oral                     | 20 Mg Once Daily Po                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-May-2008                                                                              | 6705476        | NON-EXPEDITED      | N                  |                 | TPA2008A00104            |                                               | 59 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Fatigue; Somnolence                                                                      | Rozerem        |                    |                    | S               | Oral                     | 8 Mg, 1 In 1 D, Per Oral                      |                 | Not Reported    |                |

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|                                                                                                    |                                    |                    |                    |                 |                                          |                      |                 |                              |                |
|----------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| Lexapro                                                                                            |                                    |                    | S                  | Ophthalmic      | 10 Mg, 1 In 1 D, Per Oral                |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-May-2008                                                                                        | 6611555                            | EXPEDITED (15-DAY) | Y                  | DE, HO, OT      | GB-WYE-G01372008                         |                      | 64 YR           | Male                         | GBR            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Disease Progression;<br>Fatigue; Hyperkalaemia;<br>Hyponatraemia; Malaise;<br>Mucosal Inflammation | Torisel                            |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      | 78 DAY          | Wyeth                        |                |
|                                                                                                    | Escitalopram Oxalate               |                    |                    | S               |                                          | Unknown              |                 | Unknown                      |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-May-2008                                                                                        | 6650929                            | EXPEDITED (15-DAY) | Y                  | OT              | S07-UKI-05229-01                         |                      | 39 YR           | Female                       | GBR            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pregnancy                             | Ciprallex                          |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                    | Fluoxetine Hcl                     |                    |                    | S               |                                          |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 20-May-2008                                                                                        | 6654557                            | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01741-01                         |                      | 75 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Arteriosclerosis Coronary<br>Artery; Fatigue                                                       | Lexapro                            |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported                 |                |
|                                                                                                    | Lexapro                            |                    |                    | S               |                                          | 5 Mg Qd Po           |                 | Not Reported                 |                |
|                                                                                                    | Xanax                              |                    |                    | C               |                                          |                      |                 | Not Reported                 |                |
|                                                                                                    | Gemfibrozil                        |                    |                    | C               |                                          |                      |                 | Not Reported                 |                |
|                                                                                                    | Multi-Vitamin                      |                    |                    | C               |                                          |                      |                 | Not Reported                 |                |
|                                                                                                    | Calcium Supplement<br>"Water Pill" |                    |                    | C<br>C          |                                          |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 22-May-2008                                                                                        | 6585218                            | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00677-01                         |                      | 76 YR           | Male                         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Blood Pressure Decreased; Fatigue; Hyperhidrosis; Panic Attack; Sleep Disorder; Withdrawal Syndrome | Lexapro                                          |              |            | S           | Oral         | 10 Mg Qd; Po       |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 2.5 Mg,Qd;Po       |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 2.5 Mg,Qd;Po       |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 5 Mg, Qd; Po       |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 10 Mg Qd;Po        |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 30 Mg Qd;Po        |                 | Not Reported |
|                                                                                                            | Lexapro                                          |              |            | S           | Oral         | 10 Mg Qd;Po        |                 | Not Reported |
|                                                                                                            | Benicar Hct<br>(Olmesartan/Hydrochlorothiazide ) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Aricept                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Meloxicam                                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Aspirin                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Vytorin                                          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Protonix                                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                            | Ambien                                           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-May-2008              | 6605834       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-06459-01     |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Dizziness; Drug Interaction; Genital Haemorrhage; Headache; Intentional Self-Injury; Rash | Lexapro                            |              |            | S           | Oral         | 5 Mg Qd;Po         |                 | Not Reported |
|                                                                                                      | Lexapro                            |              |            | S           | Oral         | 10 Mg Qd;Po        |                 | Not Reported |
|                                                                                                      | Norgestimate And Ethinyl Estradiol |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 22-May-2008              | 6642406       | EXPEDITED (15-DAY) | Y                  | HO              | CA-ABBOTT-08P-028-0451028-00 |                      | 24 YR      | Female     | CAN            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Drug Interaction; Insomnia; | Biaxin         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |            |   |      |              |
|---------------------------------------------------------------|------------|---|------|--------------|
| Mood Swings;<br>Palpitations; Sinusitis;<br>Thinking Abnormal | Cipralelex | S | Oral | Not Reported |
|---------------------------------------------------------------|------------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2008              | 6658447       | DIRECT           | N                  | HO, RI, OT      |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Akathisia; Dehydration;     | Ultram         |              |            | S           | Oral         | 50 Mg. 8 Times Daily Po  |                 | Not Reported |
| Diarrhoea; Faeces           | Lexapro        |              |            | S           | Oral         | 10 Mg Of Lexapro 4 Times |                 | Not Reported |
| Discoloured; Gastric Ulcer; |                |              |            |             |              | Daily Po                 |                 |              |
| Impaired Driving Ability;   | Cymbalta       |              |            | S           |              | 30-60 Of Cym             |                 | Not Reported |
| Impaired Work Ability;      |                |              |            |             |              |                          |                 |              |
| Menopause; Polyp;           |                |              |            |             |              |                          |                 |              |
| Product Quality Issue; Rib  |                |              |            |             |              |                          |                 |              |
| Fracture; Tremor; Vertigo;  |                |              |            |             |              |                          |                 |              |
| Weight Decreased            |                |              |            |             |              |                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2008              | 6658642       | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01834-01     |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Intentional | Cipralelex                 |              |            | S           |              |                    |                 | Not Reported |
| Overdose; Sopor; Suicide | Cipralelex                 |              |            | S           |              |                    |                 | Not Reported |
| Attempt                  | Alcohol                    |              |            | S           |              |                    |                 | Not Reported |
|                          | Unspecified Ingredient     |              |            | S           |              |                    |                 | Not Reported |
|                          | Prothipendyl Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2008              | 6659566       | EXPEDITED (15-DAY) | Y                  | DE              | S08-JPN-01849-01     |                      | 71 YR      | Female     | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;          | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd, Po       |                 | Not Reported |
| Depression; Drug             | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd; Po       |                 | Not Reported |
| Ineffective; Illness Anxiety | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd;Po        |                 | Not Reported |
| Disorder; Malaise; Mini      |                      |              |            |             |              |                    |                 |              |
| Mental Status Examination    |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                               |   |              |
|-------------------------|-------------------------------|---|--------------|
| Abnormal; Obesity; Oral | Mohrus Tape (Ketoprofen)      | C | Not Reported |
| Disorder; Ventricular   | Ms Onshippe (Methyl Salicylat | C | Not Reported |
| Extrasystoles; Weight   | Comphor Capsicum Extract)     |   |              |
| Decreased               | Etizolam                      | C | Not Reported |
|                         | Sennaride (Sennoside A+B)     | C | Not Reported |
|                         | Magnesium Oxide               | C | Not Reported |
|                         | Paruleon (Triazolam)          | C | Not Reported |
|                         | Keflex                        | C | Not Reported |
|                         | Baramycin                     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2008              | 6661448       | DIRECT           | N                  | RI              |                      |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Burning Sensation; Dry  | Lexapro        |              |            | S           | Oral         | 20 Mg 1x/Day Po    |                 | Not Reported |
| Mouth; Ill-Defined      | Celexa         |              |            | S           | Oral         | 40 Mg 1x/Day Po    |                 | Not Reported |
| Disorder; Impaired Work |                |              |            |             |              |                    |                 |              |
| Ability; Muscle Spasms; |                |              |            |             |              |                    |                 |              |
| Muscle Tightness;       |                |              |            |             |              |                    |                 |              |
| Musculoskeletal Pain;   |                |              |            |             |              |                    |                 |              |
| Neck Pain; Therapy Non- |                |              |            |             |              |                    |                 |              |
| Responder               |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-May-2008              | 6661804       | EXPEDITED (15-DAY) | Y                  | HO              | S08-NOR-01519-01     |                      | 16 YR      | Female     | NOR            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colitis Ulcerative; Serum | Cipralext      |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Ferritin Decreased        |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-May-2008              | 6550308       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S08-USA-00201-01     |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agranulocytosis; Cough; | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
| Full Blood Count        | Amoxicillin    |              |            | C           |              |                    |                 | Not Reported |
| Abnormal; Heart Rate    |                |              |            |             |              |                    |                 |              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Leukocytosis;  
Leukopenia;  
Lymphadenopathy;  
Neutropenia;  
Oropharyngeal Pain;  
Pharyngitis; Platelet  
Disorder; Poikilocytosis;  
Pyrexia; Rash; Rash  
Maculo-Papular; Red  
Blood Cell Schistocytes  
Present; Skin Infection;  
Ulcer; White Blood Cell  
Count Decreased

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|------------------------------|----------------|
| 29-May-2008                                                                                                                                                                                                                                                                                                                                        | 6551254                         | EXPEDITED (15-DAY) | Y                  | HO              | S08-GER-00245-01                 |                      | 32 YR           | Female                       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bacterial Test Positive;<br>Erythema; Hepatic<br>Steatosis; Hepatomegaly;<br>Joint Effusion; Joint<br>Swelling; Oedema<br>Peripheral; Overdose;<br>Pain In Extremity;<br>Pancreatic Steatosis;<br>Polyarthritis; Protein Urine<br>Present; Pruritus;<br>Rheumatoid Arthritis; Skin<br>Disorder; Upper<br>Respiratory Tract<br>Infection; Urticaria | Escitalopram Oxalate<br>Topamax |                    |                    | S<br>C          | Oral                             | 40 Mg Qd Po          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                           | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-May-2008                                                                                                                                                                                                                                                                                                                                        | 6629597                         | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-08P-056-<br>0448858-00 |                      | 45 YR           | Female                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                              | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Optic Neuritis                                                                                                                                                                                                                                                                                                                                     | Escitalopram Oxalate            |                    |                    | S               | Oral                             |                      |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 29-May-2008                       | 6661376                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-YUG-01884-01              |                               | 44 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Oedema                | Cipralext               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-May-2008                       | 6662107                 | EXPEDITED (15-DAY)        | N                           | OT                       | CHPA2008US08629               |                               | 24 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Vaginal Haemorrhage               | Excedrin Extra Strength |                           | Y                           | S                        | Oral                          | 2 Df, Qd, Oral                |                          | Not Reported        |                         |
|                                   | Lexapro                 |                           |                             | S                        |                               | 1 Df, Qd                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-May-2008                       | 6663112                 | EXPEDITED (15-DAY)        | Y                           | CA                       | S08-USA-01773-02              |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Jaundice Neonatal;                | Celexa                  |                           |                             | S                        | Transplacental                | 20 Mg Qd Transplacental       |                          | Not Reported        |                         |
| Maternal Drugs Affecting          | Lexapro                 |                           |                             | S                        | Transplacental                | 20 Mg Qd Transplacental       |                          | Not Reported        |                         |
| Foetus; Talipes                   | Prednisone              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-May-2008                       | 6663113                 | EXPEDITED (15-DAY)        | N                           | OT                       | S08-USA-01812-01              |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Uterine Haemorrhage               | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-May-2008                       | 6667093                 | DIRECT                    | N                           | OT                       |                               |                               | 49 YR                    | Male                | USA                     |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
|-------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Disturbance In Sexual Arousal; Male Orgasmic Disorder | Lexapro                 |                    |                    | S               | Oral                                     | 1 Tablet Daily Po    |                 | Forest               |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-May-2008                                           | 6667080                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-PRT-01905-01                         |                      | 23 YR           | Female               | PRT            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Palpitations; Ventricular Tachycardia                 | Ciprallex               |                    |                    | S               | Oral                                     | 10 Mg Qd Po          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Jun-2008                                           | 6655041                 | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-14196950 |                      | 63 YR           | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Confusional State; Diabetic Ketoacidosis              | Tequin                  |                    |                    | S               | Oral                                     |                      | 10 DAY          | Bristol Myers Squibb |                |
|                                                       | Percocet                |                    |                    | S               |                                          |                      |                 | Endo                 |                |
|                                                       | Trazodone Hydrochloride |                    |                    | S               |                                          |                      |                 | Apothecon            |                |
|                                                       | Famvir                  |                    |                    | S               | Oral                                     |                      | 7 DAY           | Not Reported         |                |
|                                                       | Biaxin                  |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                       | Accupril                |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                       | Lexapro                 |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                       | Prandin                 |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                       | Avandia                 |                    |                    | S               |                                          |                      |                 | Glaxosmithkline      |                |
|                                                       | Prilosec                |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
| Oxycontin                                             |                         |                    | S                  |                 |                                          |                      | Endo            |                      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 02-Jun-2008                                           | 6668382                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01883-01                         |                      | 43 YR           | Female               | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Alopecia Areata                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 20 Mg Qd Po          |                 | Not Reported         |                |
|                                                       | Levothyroxine Sodium    |                    |                    | C               |                                          |                      |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
| 02-Jun-2008                                                    | 6668384                  | EXPEDITED (15-DAY) | Y                  | DE              | S08-SWI-01801-01     |                                             | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                              | Cipralext                |                    |                    | S               | Oral                 | 10 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                | Cipralext                |                    |                    | S               | Oral                 | 15 Mg Qd Po                                 |                 | Not Reported |                |
|                                                                | Dalmadorm (Flurazepam)   |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                | Lorazepam                |                    |                    | C               |                      |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2008                                                    | 6669825                  | EXPEDITED (15-DAY) | Y                  | HO              | DSA_31876_2008       |                                             | 43 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Somnolence; Suicide Attempt; Tachycardia | Tavor (Lorazepam)        |                    |                    | S               | Oral                 | Not The Prescribed Amount, Oral             |                 | Not Reported |                |
|                                                                | Cipralext                |                    |                    | S               | Oral                 | 400 Mg 1x , Not The Prescribed Amount, Oral |                 | Not Reported |                |
|                                                                | Haldol                   |                    |                    | S               | Oral                 | Not The Prescribed Amount, Oral             |                 | Not Reported |                |
|                                                                | Mellaril                 |                    |                    | S               | Oral                 | Not The Prescribed Amount, Oral             |                 | Not Reported |                |
|                                                                | Flurazepam Hydrochloride |                    |                    | S               | Oral                 | Not The Prescribed Amount, Oral             |                 | Not Reported |                |
|                                                                | Zopiclone                |                    |                    | S               | Oral                 | Not The Prescribed Amount, Oral             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2008                                                    | 6670730                  | DIRECT             | Y                  | HO              |                      |                                             | 71 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Palpitations; Skin Burning Sensation                  | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Daily Po                              |                 | Forest       |                |
|                                                                | Xanax                    |                    |                    | C               |                      |                                             |                 | Not Reported |                |

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## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jun-2008                                                                                                            | 6656187                  | EXPEDITED (15-DAY) | Y                  | OT              | HN-ABBOTT-08P-074-0453051-00 |                      | 15 YR           | Female       | HND            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Lymphocytic Leukaemia                                                                                            | Sibutramine              |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                        | Lexapro                  |                    |                    | S               | Oral                         |                      | 15 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2008                                                                                                            | 6541833                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-PFIZER INC-2008007755     |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Anxiety; Depression; Intentional Overdose; Road Traffic Accident; Suicidal Ideation; Suicide Attempt | Xanax                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                        | Xanax                    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                        | Lexapro                  |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                        | Lexapro                  |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                        | Effexor                  |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                        | Paroxetine Hydrochloride |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                        | Paroxetine Hydrochloride |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                        | Risperdal                |                    |                    | C               |                              | Daily Dose:9mg       |                 | Not Reported |                |
|                                                                                                                        | Lithium                  |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2008                                                                                                            | 6636357                  | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-01444-01             |                      | 39 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Hallucination; Thinking Abnormal                                                                   | Lexapro                  |                    |                    | S               | Oral                         | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                                        | Avelox                   |                    |                    | S               |                              | 400 Mg Once          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jun-2008                                                                                                            | 6642526                  | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01559-01             |                      | 45 YR           | Female       | DNK            |

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| <a href="#">Preferred Term</a>    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-----------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Optic Neuritis                    | Escitalopram Oxalate       |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jun-2008                       | 6670341                    | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-FRA-01957-01              |                               | 38 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Neutropenia                       | Escitalopram Oxalate       |                           |                             | S                        | Oral                          | 10 Mg Qd;Po                   |                          | Not Reported        |                         |
|                                   | Zolpidem                   |                           |                             | S                        | Oral                          | 10 Mg Qd;Po                   |                          | Not Reported        |                         |
|                                   | Motilium                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jun-2008                       | 6670386                    | EXPEDITED (15-DAY)        | Y                           | HO                       | S08-FRA-01956-01              |                               |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Thrombocytopenia                  | Escitalopram Oxalate       |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Tranxene T-Tab             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Levothyroxine Sodium       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jun-2008                       | 6670405                    | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-FRA-01268-01              |                               | 52 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatic Steatosis                 | Escitalopram Oxalate       |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
|                                   | Aceprometazine\Meprobamate |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Propranolol                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jun-2008                       | 6573327                    | EXPEDITED (15-DAY)        | Y                           | HO                       | S08-USA-00477-01              |                               | 16 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                            |                          |   |      |             |              |
|----------------------------|--------------------------|---|------|-------------|--------------|
| Abnormal Behaviour;        | Lexapro                  | S | Oral | 30 Mg Qd Po | Not Reported |
| Aggression; Agitation;     | Lexapro                  | S | Oral | 40 Mg Qd Po | Not Reported |
| Bipolar Disorder;          | Lexapro                  | S | Oral | 20 Mg Qd Po | Not Reported |
| Depression; Intermittent   | Lexapro                  | S | Oral | 5 Mg Qd Po  | Not Reported |
| Explosive Disorder;        | Lexapro                  | S | Oral | 10 Mg Qd Po | Not Reported |
| Irritability; Overdose;    | Lexapro                  | S | Oral | 20 Mg Qd Po | Not Reported |
| Personality Disorder;      | Lexapro                  | S | Oral |             | Not Reported |
| Refusal Of Treatment By    | Lexapro                  | S | Oral |             | Not Reported |
| Patient; Screaming; Social | Adderall (Amphetamine Ex | C |      |             | Not Reported |
| Avoidant Behaviour;        | Release)                 |   |      |             |              |
| Thinking Abnormal          | Birth Control (Nos)      | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2008              | 6657998       | EXPEDITED (15-DAY) | N                  | HO              | B0522808A            |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction;      | Arixtra              |              |            | S           | Subcutaneous | 2.5mg Per Day      | 19 DAY          | Glaxosmithkline |
| Haemoglobin Decreased; | Aspirin              |              |            | S           | Oral         | 75mg Per Day       |                 | Unknown         |
| Hernial Eventration;   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Unknown         |
| Subcutaneous           | Propylthiouracil     |              |            | C           | Oral         |                    |                 | Not Reported    |
| Haematoma; Subileus;   | Inexium              |              |            | C           | Oral         |                    |                 | Not Reported    |
| Thrombosis             | Alprazolam           |              |            | C           | Oral         |                    |                 | Not Reported    |
|                        | Triflucan            |              |            | C           | Oral         |                    |                 | Not Reported    |
|                        | Aldalix              |              |            | C           | Unknown      |                    |                 | Not Reported    |
|                        | Cozaar               |              |            | C           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2008              | 6672555       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-01958-01     |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Blood Pressure    | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
| Systolic Increased; Fall;  | Lisinopril           |              |            | C           |              |                    |                 | Not Reported |
| Iatrogenic Injury; Loss Of |                      |              |            |             |              |                    |                 |              |
| Consciousness; Malaise;    |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

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### Detailed Report

Pallor

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Jun-2008                                                                                               | 6672563                   | EXPEDITED (15-DAY) | Y                  | OT              | S08-HND-01978-01     |                      | 15 YR           | Female       | HND            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Lymphocytic Leukaemia                                                                               | Lexapro                   |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Sibutramine Hydrochloride |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jun-2008                                                                                               | 6672588                   | EXPEDITED (15-DAY) | Y                  | DE              | S08-SWI-01994-01     |                      | 43 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Cardiac Arrest; Cyanosis; Overdose; Pulse Absent; Respiratory Arrest; Unresponsive To Stimuli | Ciprallex                 |                    |                    | S               | Oral                 | 30 Mg Qd Po          |                 | Not Reported |                |
|                                                                                                           | Seroquel                  |                    |                    | S               | Oral                 | 400 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                           | Chloral Hydrate           |                    |                    | S               | Oral                 | 500 Mg Qd Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jun-2008                                                                                               | 6644616                   | EXPEDITED (15-DAY) | Y                  | HO              | S08-ESP-01594-01     |                      | 50 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Neoplasm; Cerebral Haemorrhage                                                                      | Ciprallex                 |                    |                    | S               | Oral                 | 3.3 Mg Qd Po         |                 | Not Reported |                |
|                                                                                                           | Ciprallex                 |                    |                    | S               | Oral                 | 7 Mg Qd Po           |                 | Not Reported |                |
|                                                                                                           | Bisoprolol                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Enalapril Maleate         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Sutril (Torasemide)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                           | Lorazepam                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jun-2008                                                                                               | 6650648                   | EXPEDITED (15-DAY) | N                  | OT              | NO-WYE-G01584008     |                      |                 | Male         | NOR            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                        |                               |   |                             |                   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---|-----------------------------|-------------------|----------------|
| Depression; Dizziness;<br>Drug Withdrawal<br>Syndrome; Erectile<br>Dysfunction; Fatigue;<br>Feeling Abnormal; Suicide<br>Attempt; Unevaluable<br>Event | Effexor                       | S | Oral                        | Dose Unknown      | Wyeth          |
|                                                                                                                                                        | Cipraxel                      | S | Oral                        | Dose Unknown      | Lundbeck       |
|                                                                                                                                                        | Levomepromazine               | S | Oral                        | Dose Unknown      | Aventis        |
|                                                                                                                                                        | Zoloft                        | S | Oral                        | Daily Dose 150 Mg | Pfizer         |
|                                                                                                                                                        | Anafranil                     | S | Oral                        | Dose Unknown      | Novartis       |
|                                                                                                                                                        | Buprenorphine Hydrochloride   | C | Oral                        | Dose Unknown      | Unknown        |
|                                                                                                                                                        | Carisoprodol                  | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Codeine Phosphate             | C |                             |                   | Not Reported   |
|                                                                                                                                                        | Surmontil                     | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Paroxetine Hydrochloride      | C | Oral                        | Dose Unknown      | Unknown        |
|                                                                                                                                                        | Citalopram Hydrobromide       | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Akineton                      | C | Oral                        | Dose Unknown      | Knoll          |
|                                                                                                                                                        | Remeron                       | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Caffeine\Carisoprodol         | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Zantac                        | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Esucos                        | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Zolpidem Tartrate             | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Zopiclone                     | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Ventolin                      | C | Respiratory<br>(inhalation) | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Valproate Sodium              | C | Oral                        | Dose Unknown      | Unknown        |
|                                                                                                                                                        | Mianserin Hydrochloride       | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Chlorprothixene Hydrochloride | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Oxazepam                      | C | Oral                        | Dose Unknown      | Fresenius Kabi |
|                                                                                                                                                        | Zyprexa                       | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Diazepam                      | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Morphine                      | C |                             |                   | Unknown        |
|                                                                                                                                                        | Vallergan                     | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Tramadol Hydrochloride        | C | Oral                        | Dose Unknown      | Not Reported   |
|                                                                                                                                                        | Rivotril                      | C | Oral                        | Dose Unknown      | Roche          |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |      |              |              |
|--|-----------------|---|------|--------------|--------------|
|  | Alprazolam      | C | Oral | Dose Unknown | Not Reported |
|  | Lithium Citrate | C | Oral | Dose Unknown | Not Reported |
|  | Heroin          | C |      |              | Unknown      |
|  | Cannabis        | C |      |              | Unknown      |
|  | Amphetamine     | C |      |              | Unknown      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2008              | 6673170       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01976-01     |                      | 75 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jun-2008              | 6673595       | EXPEDITED (15-DAY) |                    | OT              | S08-FRA-01975-01     |                      | 60 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Consciousness | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jun-2008              | 6655076       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ELI_LILLY_AND_COMP<br>ANY-FR200805004210 |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Drug Interaction; Fall;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>International Normalised<br>Ratio Increased | Prozac                 |              |            | S           | Oral         | 20 Mg, Daily (1/D) | 8 DAY           | Eli Lilly And Co |
|                                                                                                                                              | Eupantol               |              |            | C           | Oral         |                    |                 | Not Reported     |
|                                                                                                                                              | Previscan (Fluindione) |              |            | S           | Oral         |                    |                 | Not Reported     |
|                                                                                                                                              | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg, Daily (1/D) | 6 DAY           | Not Reported     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2008              | 6673848       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02008-01     |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                          |                                        |                    |                    |                 |                      |                         |                 |            |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|------------|----------------|
| Rectal Haemorrhage                                                                                                                                                       | Escitalopram Oxalate                   |                    |                    | S               |                      |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jun-2008                                                                                                                                                              | 6674941                                | EXPEDITED (15-DAY) | N                  | DE              | S08-USA-01926-02     |                         | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Maternal Drugs Affecting Foetus; Myocardial Infarction; Post Procedural Complication; Respiratory Distress; Upper Respiratory Tract Infection; Ventricular Septal Defect | Lexapro                                |                    |                    | S               |                      |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jun-2008                                                                                                                                                              | 6519387                                | EXPEDITED (15-DAY) | Y                  | DE              | S07-USA-06329-01     |                         | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Bipolar Disorder; Completed Suicide; Grief Reaction; Gun Shot Wound; Melanocytic Naevus; Procedural Pain                                                        | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 |            | Not Reported   |
|                                                                                                                                                                          | Oxycontin                              |                    |                    | C               |                      |                         |                 |            | Not Reported   |
|                                                                                                                                                                          | Percocet (Oxycodone And Acetaminophen) |                    |                    | C               |                      |                         |                 |            | Not Reported   |
|                                                                                                                                                                          | Avapro                                 |                    |                    | C               |                      |                         |                 |            | Not Reported   |
|                                                                                                                                                                          | Protonix                               |                    |                    | C               |                      |                         |                 |            | Not Reported   |
|                                                                                                                                                                          | Prempro                                |                    |                    | C               |                      |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jun-2008                                                                                                                                                              | 6646307                                | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01576-02     |                         | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Caesarean Section; Eye Movement Disorder; Fatigue; Large For Dates Baby; Maternal Death Affecting Foetus; Maternal                                                       | Lexapro                                |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 |            | Not Reported   |
|                                                                                                                                                                          | Lexapro                                |                    |                    | S               |                      | 10 Mg Qd Bf             |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Exposure During Breast Feeding

| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 10-Jun-2008                                          | 6676168              | DIRECT             | Y                  | OT              |                                                 |                      | 38 YR           | Female               | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Eye Pain; Mydriasis;<br>Vision Blurred               | Lexapro              |                    |                    | S               | Oral                                            | 10 Mg Qam Po         |                 | Forest               |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Jun-2008                                          | 6598362              | EXPEDITED (15-DAY) | Y                  | HO              | S08-ITA-00366-01                                |                      | 36 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Gastric Disorder;<br>Gastrointestinal<br>Haemorrhage | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 10 Mg Qd Po          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Jun-2008                                          | 6662514              | NON-EXPEDITED      | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13805619 |                      | 67 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Drug Interaction;<br>Parkinsonism         | Carbidopa & Levodopa |                    |                    | S               | Oral                                            |                      |                 | Bristol Myers Squibb |                |
|                                                      | Wellbutrin           |                    |                    | C               |                                                 |                      |                 | Not Reported         |                |
|                                                      | Lexapro              |                    |                    | S               | Oral                                            |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 11-Jun-2008                                          | 6679723              | EXPEDITED (15-DAY) | Y                  | OT              | 2008SP010986                                    |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatic Enzyme<br>Increased; Status<br>Epilepticus   | Temodar              |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                      | Bactrim              |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |
|                                                      | Lexapro              |                    |                    | S               |                                                 |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                          |                    |                    |                 |                       |                      |                 |              |                |
|---------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Keppra                    |                          | S                  |                    |                 |                       |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2008               | 6650270                  | EXPEDITED (15-DAY) | Y                  | DE, DS, HO, OT  | S08-UKI-01696-01      |                      | 64 YR           | Male         | GBR            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate                 | Escitalopram Oxalate     |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Aminotransferase          | Torisel                  |                    |                    | S               | Intravenous (not      | 20 Mg Qd Iv          |                 | Not Reported |                |
| Increased; Blood Alkaline |                          |                    |                    |                 | otherwise specified)  |                      |                 |              |                |
| Phosphatase Increased;    | Sutent                   |                    |                    | C               |                       |                      |                 | Not Reported |                |
| Blood Creatinine          |                          |                    |                    |                 |                       |                      |                 |              |                |
| Increased; C-Reactive     |                          |                    |                    |                 |                       |                      |                 |              |                |
| Protein Increased;        |                          |                    |                    |                 |                       |                      |                 |              |                |
| Fatigue; General Physical |                          |                    |                    |                 |                       |                      |                 |              |                |
| Health Deterioration;     |                          |                    |                    |                 |                       |                      |                 |              |                |
| Hyperkalaemia;            |                          |                    |                    |                 |                       |                      |                 |              |                |
| Hyponatraemia; Malaise;   |                          |                    |                    |                 |                       |                      |                 |              |                |
| Mucosal Inflammation;     |                          |                    |                    |                 |                       |                      |                 |              |                |
| Neoplasm Malignant;       |                          |                    |                    |                 |                       |                      |                 |              |                |
| Refusal Of Treatment By   |                          |                    |                    |                 |                       |                      |                 |              |                |
| Patient; Renal Cancer     |                          |                    |                    |                 |                       |                      |                 |              |                |
| Metastatic                |                          |                    |                    |                 |                       |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2008               | 6663380                  | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20080600582 |                      | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache;      | Norgestimate And Ethinyl |                    |                    | S               |                       |                      |                 | Not Reported |                |
| Intentional Self-Injury;  | Estradiol                |                    |                    |                 |                       |                      |                 |              |                |
| Metrorrhagia; Nausea;     | Lexapro                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| Rash                      | Lexapro                  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jun-2008               | 6680270                  | DIRECT             |                    | OT              |                       |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                      |                    |                    |                 |                              |                                 |                 |                              |                |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------|-----------------|------------------------------|----------------|
| Drug Hypersensitivity;<br>Drug Ineffective; Eczema                  |                      | Lexapro<br>Lexapro |                    | S<br>S          |                              |                                 |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 13-Jun-2008                                                         | 6681193              | EXPEDITED (15-DAY) | Y                  | OT              | 2008014731                   |                                 | 30 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Disorientation; Drug<br>Interaction; Road Traffic<br>Accident       | Benadryl             |                    | Y                  | S               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Lexapro              |                    |                    | S               | Oral                         | 10 Mg Daily (1 In 1 D),<br>Oral |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 13-Jun-2008                                                         | 6681238              | EXPEDITED (15-DAY) | Y                  | CA              | S08-SWI-02030-02             |                                 |                 | Unknown                      | CHE            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abortion Induced;<br>Maternal Drugs Affecting<br>Foetus; Trisomy 21 | Cipralext            |                    |                    | S               | Transplacental               | 10 Mg Qd Transplacental         |                 | Not Reported                 |                |
|                                                                     | Cipralext            |                    |                    | S               | Transplacental               | 5 Mg Qd Transplacental          |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Jun-2008                                                         | 6621018              | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2008033686 |                                 | 62 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Somnolence; Urinary<br>Incontinence                                 | Chantix              |                    |                    | S               | Oral                         |                                 |                 | Not Reported                 |                |
|                                                                     | Lexapro              |                    |                    | S               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Metoprolol           |                    |                    | S               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Percocet             |                    |                    | S               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Lovastatin           |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Omeprazole           |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Topamax              |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Nifedipine           |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Niacin               |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Hydrocodone          |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Naproxen             |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |
|                                                                     | Acetylsalicylic Acid |                    |                    | C               |                              |                                 |                 | Not Reported                 |                |

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| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|------------------|----------------------|---------------------------|-----------------|--------------------------------------------------------------|----------------|
| 16-Jun-2008                                                                               | 6686578                                     | EXPEDITED (15-DAY) | Y                  | HO, OT           | S08-FRA-01240-01     |                           | 72 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Confusional State;<br>Hyponatraemia; Speech<br>Disorder                                   | Escitalopram Oxalate<br>Imovane (Zopiclone) |                    |                    | S<br>C           | Oral                 | 10 Mg Qd Po               |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Jun-2008                                                                               | 6555740                                     | EXPEDITED (15-DAY) | Y                  | OT               | S08-CAN-00290-01     |                           | 30 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Colitis Ulcerative;<br>Frequent Bowel<br>Movements                                        | Cipraxel<br>Unspecified Ingredient          |                    |                    | S<br>C           | Oral                 | 20 Mg Qd Po               |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Jun-2008                                                                               | 6674610                                     | EXPEDITED (15-DAY) | Y                  | DS               | S08-USA-01938-01     |                           | 30 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Cerebrovascular Accident;<br>Chest Pain; Overdose;<br>Pain; Paralysis; Suicide<br>Attempt | Lexapro<br>Xanax<br>Adderall<br>Ibuprofen   |                    |                    | S<br>C<br>C<br>C | Oral                 | 20 Mg Qd Po               |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 17-Jun-2008                                                                               | 6686445                                     | EXPEDITED (15-DAY) | Y                  | HO               | S08-NOR-02080-01     |                           | 28 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Urinary Retention                                                                         | Cipraxel<br>Cipraxel                        |                    |                    | S<br>S           | Oral<br>Oral         | 20 Mg Qd Po<br>5 Mg Qd Po |                 | Not Reported<br>Not Reported                                 |                |

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| <u>FDA Received Date</u>                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 17-Jun-2008                                            | 6686449                            | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02068-01     |                      | 54 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Antinuclear Antibody Positive; Inflammation; Urticaria | Escitalopram Oxalate<br>Alprazolam |                    |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                     | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------|---------------------------------------|-----------------|------------------------------------------------------------------------------|----------------|
| 18-Jun-2008                                                                                                                                                                                                  | 6648367                                                               | EXPEDITED (15-DAY) | Y                  | OT                    | S08-USA-01581-01     |                                       | 31 YR           | Female                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Arthralgia; Blood Potassium Decreased; Gallbladder Disorder; Hepatitis Acute; Neutrophil Count Increased; Protein Total Decreased; Pruritus; Pruritus Generalised; Pyrexia; White Blood Cell Count Increased | Lexapro<br>Clonazepam<br>Protonix<br>Labetalol<br>Hydrochlorothiazide |                    |                    | S<br>S<br>S<br>C<br>C | Oral                 | 10 Mg Qd Po<br>0.5 Mg Prn<br>40 Mg Qd |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                         | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>                                                                                   | <u>Country</u> |
|--------------------------|----------------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|----------------------------------------------|-------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------|----------------|
| 18-Jun-2008              | 6650274                                                                                                        | EXPEDITED (15-DAY) | Y                  | HO                         | S08-ESP-01708-01                             |                                                                                     | 48 YR           | Female                                                                                       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                 | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>                                                                                   |                |
| Hepatitis Cholestatic    | Ciprallex<br>Seroquel<br>Topamax<br>Clorazepate Dipotassium<br>Lexatin (Bromazepam)<br>Clomethiazole Edisylate |                    |                    | S<br>S<br>S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 10 Mg Qd Po<br>100 Mg Qd Po<br>100 Mg Qd Po<br>10 Mg Qd Po<br>3 Mg Qd Po<br>3 Mg Po |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |



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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2008              | 6687461       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-02070-01     |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Haemoglobin Decreased;<br>Prothrombin Level<br>Decreased; Subcutaneous<br>Haematoma | Escitalopram Oxalate                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                          | Arixtra                                 |              |            | S           | Subcutaneous | 2.5 Mg Qd Sc       |                 | Not Reported |
|                                                                                                          | Arixtra                                 |              |            | S           | Subcutaneous | 2.5 Mg Qam Sc      |                 | Not Reported |
|                                                                                                          | Kardegic (Acetylsalicylate<br>Lysine)   |              |            | S           | Oral         | 75 Mg Qd Po        |                 | Not Reported |
|                                                                                                          | Propylthiouracile<br>(Propylthiouracil) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                          | Inexium (Esomeprazole)                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                          | Alprazolam                              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                          | Fluconazole                             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                          | Calciparine                             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2008              | 6861420       | EXPEDITED (15-DAY) | Y                  | HO              | S08-TUN-00276-01     |                      | 25 YR      | Female     | TUN            |

| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Threatened;<br>Maternal Drugs Affecting<br>Foetus; Pregnancy | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                       | Temestat (Lorazepam) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jun-2008              | 6672427       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ROCHE-543673      |                      | 38 YR      | Unknown    | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Clonazepam                                |              |            | S           | Oral         |                    |                 | Roche        |
|                                                          | Hydrocodone Bitartrate &<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                          | Hydrocodone Bitartrate &<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |

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| Escitalopram Oxalate                                     |                         |                    | S                  | Oral            |                      |                                                               | Not Reported    |              |                |
|----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2008                                              | 6672437                 | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ROCHE-543703      |                                                               | 40 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Death;<br>Respiratory Arrest             | Clonazepam              |                    |                    | S               | Unknown              | Route: Asp And Or Ing.                                        |                 | Roche        |                |
|                                                          | Quetiapine              |                    |                    | S               | Unknown              | Route: Asp And Or Ing.                                        |                 | Not Reported |                |
|                                                          | Escitalopram Oxalate    |                    |                    | S               | Unknown              | Route: Asp And Or Ing.                                        |                 | Not Reported |                |
|                                                          | Unspecified Ingredient  |                    |                    | S               | Unknown              |                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2008                                              | 6672454                 | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ROCHE-543952      |                                                               | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Clonazepam              |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Roche        |                |
|                                                          | Amitriptyline           |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Roche        |                |
|                                                          | Methadone Hydrochloride |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Not Reported |                |
|                                                          | Cocaine                 |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Not Reported |                |
|                                                          | Escitalopram Oxalate    |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Not Reported |                |
|                                                          | Chloral Hydrate         |                    |                    | S               | Unknown              | Route Reported As Oral<br>(Ingst) And/Or Parenteral<br>(Par). |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 19-Jun-2008                                                      | 6672471              | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-544122                                              |                      | 55 YR           | Female               | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Overdose                                                         | Clonazepam           |                    |                    | S               | Oral                                                         |                      |                 | Roche                |                |
|                                                                  | Acetaminophen        |                    |                    | S               | Oral                                                         |                      |                 | Roche                |                |
|                                                                  | Hydrocodone          |                    |                    | S               | Oral                                                         |                      |                 | Not Reported         |                |
|                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                                                         |                      |                 | Not Reported         |                |
|                                                                  | Lisinopril           |                    |                    | S               | Oral                                                         |                      |                 | Not Reported         |                |
|                                                                  | Cocaine              |                    |                    | S               | Oral                                                         |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Jun-2008                                                      | 6672730              | NON-EXPEDITED      | N                  |                 | US-BOEHRINGER<br>INGELHEIM GMBH,<br>GERMANY-2008-BP-<br>0859 |                      | 51 YR           | Female               | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Nausea                                                           | Mirapex              |                    |                    | S               |                                                              |                      |                 | Boehringer Ingelheim |                |
|                                                                  | Lexapro              |                    |                    | S               | Oral                                                         |                      |                 | Not Reported         |                |
|                                                                  | Lexapro              |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Xanax                |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Klonopin             |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Soma                 |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Vistaril             |                    |                    | C               |                                                              |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Jun-2008                                                      | 6689141              | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-02114-01                                             |                      | 29 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Condition Aggravated;<br>Headache; Injury;<br>Subdural Haematoma | Escitalopram Oxalate |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Escitalopram Oxalate |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Kidrolase            |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |
|                                                                  | Kidrolase            |                    |                    | S               |                                                              |                      |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                            |   |              |
|----------------------------|---|--------------|
| Kidrolase                  | S | Not Reported |
| Kidrolase                  | S | Not Reported |
| Kidrolase                  | S | Not Reported |
| Cytarabine                 | S | Not Reported |
| Cytarabine                 | S | Not Reported |
| Purinethol                 | S | Not Reported |
| Purinethol                 | S | Not Reported |
| Purinethol                 | S | Not Reported |
| Vincristine Sulfate        | S | Not Reported |
| Vincristine Sulfate        | S | Not Reported |
| Vincristine Sulfate        | S | Not Reported |
| Vincristine Sulfate        | S | Not Reported |
| Methotrexate               | S | Not Reported |
| Methotrexate               | S | Not Reported |
| Methotrexate               | S | Not Reported |
| Bactrim                    | C | Not Reported |
| Valacyclovir Hydrochloride | C | Not Reported |
| Cyclophosphamide           | C | Not Reported |
| Prednisone                 | C | Not Reported |
| Daunorubicine              | C | Not Reported |
| Etoposide                  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2008              | 6688774       | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-01791-01     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Labour;<br>Caesarean Section;<br>Maternal Exposure During<br>Pregnancy | Lexapro                  |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                 | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Lexapro                  |              |            | S           | Oral         | 2.5 Mg Qd Po       |                 | Not Reported |
|                                                                                 | Tums (Calcium Carbonate) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2008              | 6690428       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PERC20080051         |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Confusional State;<br>Dehydration; Diabetic | Percocet       |              |            | S           | Oral         | 1 Tablet Bid, Prn, Per Oral |                 | Not Reported |
|                                                                        | Oxycontin      |              |            | S           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                         |   |      |          |              |
|--------------------------|-------------------------|---|------|----------|--------------|
| Ketoacidosis;            | Avandia                 | S | Oral | Per Oral | Not Reported |
| Electrocardiogram T Wave | Prandin                 | S |      |          | Not Reported |
| Inversion; Hypertension; | Lexapro                 | S |      |          | Not Reported |
| International Normalised | Trazodone Hydrochloride | S |      |          | Not Reported |
| Ratio Decreased;         | Accupril                | S |      |          | Not Reported |
| International Normalised | Prilosec                | C |      |          | Not Reported |
| Ratio Increased; Pain;   |                         |   |      |          |              |
| Pneumonia                |                         |   |      |          |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 23-Jun-2008              | 6674947       | EXPEDITED (15-DAY) | N                  | HO              | US-KINGPHARMUSA00001-K200800677 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| General Physical Health | Altace                     |              |            | S           | Oral         | 10 Mg, Qd          |                 | King         |
| Deterioration;          | Escitalopram Oxalate       |              |            | S           | Oral         | Unk, Unk           |                 | Not Reported |
| Hyponatraemia           | Aldactone                  |              |            | S           | Oral         |                    | 5 DAY           | Not Reported |
|                         | Aceprometazine\Meprobamate |              |            | C           |              |                    |                 | Not Reported |
|                         | Sulpiride                  |              |            | C           |              |                    |                 | Not Reported |
|                         | Aldactazine                |              |            | C           |              |                    |                 | Not Reported |
|                         | Flecainide Acetate         |              |            | C           |              |                    |                 | Not Reported |
|                         | Cordarone                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2008              | 6691696       | DIRECT           | N                  | LT              |                      |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|------------|
| Condition Aggravated;<br>Crying; Depression;<br>Irritability; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg Tablet Daily Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jun-2008              | 6647275       | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-01628-01     |                      | 63 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                        |   |      |              |              |
|-------------------|------------------------|---|------|--------------|--------------|
| Anal Incontinence | Ciprallex              | S | Oral | 15 Mg Qd Po  | Not Reported |
|                   | Ciprallex              | S | Oral | 7.5 Mg Qd Po | Not Reported |
|                   | Unspecified Ingredient | C |      |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jun-2008              | 6693908       | DIRECT           | N                  | DE              |                      |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asphyxia; Completed Suicide; Insomnia | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        | 30 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2008              | 6692214       | DIRECT           | N                  | HO, LT          |                      |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Major Depression; Suicidal Ideation; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 20mg Daily Po      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2008              | 6693846       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02145-01     |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Affective Disorder;<br>Aggression; Agitation;<br>Alopecia; Anxiety;<br>Asthenia; Bulimia<br>Nervosa; Chest<br>Discomfort; Constipation;<br>Crying; Decreased<br>Appetite; Disorientation;<br>Drug Hypersensitivity; Eye<br>Pain; Fatigue; Feeling<br>Cold; Gastrointestinal<br>Disorder; General Physical | Escitalopram Oxalate   |              |            | S           | Oral         | 5 Mg Qd; Po        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Clonazepam             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Acetaminophen\Caffeine |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                  | Vastarel               |              |            | S           | Oral         | 35 Mg Bid; Po      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Health Deterioration;  
Headache; Hyperhidrosis;  
Hypoglycaemia; Influenza  
Like Illness; Insomnia;  
Musculoskeletal Pain;  
Nasal Congestion;  
Nausea; Renal Pain;  
Respiratory Failure;  
Screaming; Skin Reaction;  
Sleep Disorder; Tinnitus;  
Visual Impairment

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 26-Jun-2008              | 6684815       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2008050439 |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crohn'S Disease;           | Chantix                    |              |            | S           |              |                    |                 | Not Reported |
| Depression; Feeling        | Diflucan                   |              |            | S           |              |                    |                 | Not Reported |
| Abnormal; Fungal           | Lexapro                    |              |            | S           |              |                    |                 | Not Reported |
| Infection; Product         | Valium                     |              |            | C           |              |                    |                 | Not Reported |
| Administration Error;      | Colace                     |              |            | C           |              |                    |                 | Not Reported |
| Suicidal Ideation; Urinary | Tylenol                    |              |            | C           |              |                    |                 | Not Reported |
| Tract Infection; Vomiting  | Ambien                     |              |            | C           |              |                    |                 | Not Reported |
|                            | Hydrocodone                |              |            | C           |              |                    |                 | Not Reported |
|                            | Buprenorphine              |              |            | C           |              |                    |                 | Not Reported |
|                            | Hydrochloride\Naloxone     |              |            |             |              |                    |                 |              |
|                            | Hydrochloride              |              |            |             |              |                    |                 |              |
|                            | Asacol                     |              |            | C           |              |                    |                 | Not Reported |
|                            | Maxalt                     |              |            | C           |              |                    |                 | Not Reported |
|                            | Levonorgestrel And Ethinyl |              |            | C           |              |                    |                 | Not Reported |
|                            | Estradiol                  |              |            |             |              |                    |                 |              |
|                            | Acyclovir Sodium           |              |            | C           |              |                    |                 | Not Reported |
|                            | Compazine                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jun-2008              | 6662500       | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-H04368308     |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                        |   |      |              |       |              |
|----------------------------------------------------------|------------------------|---|------|--------------|-------|--------------|
| Fall; Inappropriate<br>Antidiuretic Hormone<br>Secretion | Eupantol               | S | Oral | Unknown Dose | 8 DAY | Wyeth        |
|                                                          | Prozac                 | S |      |              |       | Not Reported |
|                                                          | Escitalopram Oxalate   | S |      |              |       | Lundbeck     |
|                                                          | Previscan (Fluindione) | C |      |              |       | Not Reported |
|                                                          |                        |   |      | Unknown      |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Jun-2008              | 6687262       | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-<br>2008052281 |                      | 84 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death; Medication Error | Tikosyn                 |              |            | S           |              |                    |                 | Not Reported |
|                         | Cardizem                |              |            | S           |              |                    |                 | Not Reported |
|                         | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                         | Methadone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                         | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
|                         | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
|                         | Senokot                 |              |            | S           |              |                    |                 | Not Reported |
|                         | Senokot                 |              |            | S           |              |                    |                 | Not Reported |
|                         | Lidoderm                |              |            | S           |              |                    |                 | Not Reported |
|                         | Lidoderm                |              |            | S           |              |                    |                 | Not Reported |
|                         | Ms Contin               |              |            | C           |              |                    |                 | Not Reported |
|                         | Levothyroxine           |              |            | C           |              |                    |                 | Not Reported |
|                         | Digoxin                 |              |            | C           |              |                    |                 | Not Reported |
|                         | Prilosec                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2008              | 6696950       | EXPEDITED (15-DAY) | Y                  | HO              | S08-IRL-02180-01     |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Intentional<br>Self-Injury; Overdose;<br>Therapeutic Product Effect<br>Decreased | Lexapro        |              |            | S           | Oral         | 200 Mg Once Po     |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                               | Alcohol        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2008              | 6697709       | EXPEDITED (15-DAY) | N                  | DS              | S08-USA-02077-01     |                      | 56 YR      | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|--------------|----------------------|----------------------|--------------|------------|----------------|
| Abdominal Pain Upper;<br>Abnormal Dreams;<br>Anxiety; Asthenia; Blister;<br>Breath Odour; Diarrhoea;<br>Dizziness; Dry Mouth;<br>Dysgeusia; Dyspepsia;<br>Dysphonia; Energy<br>Increased; Epistaxis;<br>Fatigue; Feeling Hot;<br>Gastroenteritis<br>Salmonella; Hallucination,<br>Visual; Headache;<br>Hyperhidrosis;<br>Hyperphagia;<br>Hyporeflexia; Impaired<br>Work Ability; Increased<br>Appetite; Influenza; Middle<br>Insomnia; Nausea;<br>Nervousness;<br>Oropharyngeal Pain;<br>Serotonin Syndrome;<br>Tremor; Vertigo; Yawning | Lexapro                    |                    |                    | S               | Oral         | 10 Mg Qd Po          |                      | Not Reported |            |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 6697798                    | EXPEDITED (15-DAY) | Y                  | HO              |              | S08-FRA-02138-01     |                      | 82 YR        | Male       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u>      | <u>Mfr</u>   |            |                |
| Aortic Valve                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate       |                    |                    | S               | Oral         | 20 Mg Qd Po          |                      | Not Reported |            |                |
| Incompetence; Atrial<br>Fibrillation;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Aldactone                  |                    |                    | S               | Oral         | 50 Mg Qd Po          |                      | Not Reported |            |                |
| Electrocardiogram Qt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Aldactone                  |                    |                    | S               | Oral         | 50 Mg Qd Po          |                      | Not Reported |            |                |
| Prolonged; General<br>Physical Health                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Ramipril                   |                    |                    | S               | Oral         | 10 Mg Qd Po          |                      | Not Reported |            |                |
| Deterioration;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Flecainide Acetate         |                    |                    | S               | Oral         | 100 Mg Qd Po         |                      | Not Reported |            |                |
| Hyponatraemia; Mitral                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cordarone                  |                    |                    | S               |              |                      |                      | Not Reported |            |                |
| Valve Incompetence;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Aldactazine                |                    |                    | C               |              |                      |                      | Not Reported |            |                |
| Nausea; Palpitations;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Aceprometazine\Meprobamate |                    |                    | C               |              |                      |                      | Not Reported |            |                |
| Vomiting                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Dogmatil (Sulpiride)       |                    |                    | C               |              |                      |                      | Not Reported |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 02-Jul-2008                                                                                             | 6586877              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00781-01     |                         |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Micturition Disorder;<br>Urinary Retention                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2008                                                                                             | 6615898              | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-01213-02     |                         |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Disorder; Foetal<br>Disorder; Maternal Drugs<br>Affecting Foetus                                | Lexapro              |                    |                    | S               | Transplacental       | 20 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                         | Lexapro              |                    |                    | S               | Transplacental       | 10 Mg Qd Transplacental |                 | Not Reported |                |
|                                                                                                         | Folic Acid           |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                         | Clonazepam           |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2008                                                                                             | 6631473              | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01420-01     |                         | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Eclampsia; Maternal<br>Exposure During<br>Pregnancy; Pregnancy;<br>Premature Baby | Ciprallex            |                    |                    | S               | Oral                 | 20 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                         | Ciprallex            |                    |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2008                                                                                             | 6681239              | EXPEDITED (15-DAY) | Y                  | DE              | S08-MYS-01959-01     |                         | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Steatosis; Toxicity<br>To Various Agents                                                        | Lexapro              |                    |                    | S               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 02-Jul-2008                                                                  | 6689275                         | EXPEDITED (15-DAY) | N                  | OT              | A0734542A            |                      | 50 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Overdose;<br>Hyperthyroidism; Vision<br>Blurred; Weight Increased | Lamictal                        |                    |                    | S               | Oral                 | 350mg Per Day        | 143 WEEK        | Glaxosmithkline |                |
|                                                                              | Lexapro                         |                    |                    | S               | Unknown              | 5mg Per Day          |                 | Not Reported    |                |
|                                                                              | Lithium                         |                    |                    | S               | Unknown              | 2700mg Per Day       |                 | Glaxosmithkline |                |
|                                                                              | Synthroid                       |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                                              | Klonopin                        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                              | Topamax                         |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Jul-2008                                                                  | 6699577                         | EXPEDITED (15-DAY) | Y                  | HO              | S08-GER-02218-01     |                      | 71 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Dyskinesia                                                                   | Ciprallex                       |                    |                    | S               | Oral                 | 15 Mg Qd Po          |                 | Not Reported    |                |
|                                                                              | Ciprallex                       |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported    |                |
|                                                                              | Ciprallex                       |                    |                    | S               | Oral                 | 5 Mg Qd Po           |                 | Not Reported    |                |
|                                                                              | Ciprallex                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |
|                                                                              | Seroquel                        |                    |                    | S               | Oral                 | 200 Mg Qd Po         |                 | Not Reported    |                |
|                                                                              | Seroquel                        |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                                              | Ramipril                        |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                              | Tavor (Lorazepam)               |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                              | Hct Hexal (Hydrochlorothiazide) |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                              | L-Thyroxin (Levothyroxine)      |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 02-Jul-2008                                                                  | 6699578                         | EXPEDITED (15-DAY) | Y                  | OT              | S08-GRC-02230-01     |                      | 78 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Catatonia; Nervous<br>System Disorder                                        | Ciprallex                       |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                                                                                         | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Jul-2008                                                                                                                                                                               | 6699584                     | EXPEDITED (15-DAY)        | Y                           | HO                       | S08-FRA-01822-01              |                               | 47 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                            | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthenia; Panic Attack;<br>Suicidal Ideation                                                                                                                                              | Escitalopram Oxalate        |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
|                                                                                                                                                                                           | Alprazolam                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                                                           | Bion (Multivitamin Complex) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                         | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jul-2008                                                                                                                                                                               | 6699586                     | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-FRA-02226-01              |                               | 60 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                            | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Disorientation; Memory<br>Impairment                                                                                                                                                      | Escitalopram Oxalate        |                           |                             | S                        | Oral                          | 10 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                         | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jul-2008                                                                                                                                                                               | 6700113                     | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-FRA-00474-01              |                               | 71 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                            | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyskinesia                                                                                                                                                                                | Escitalopram Oxalate        |                           |                             | S                        | Oral                          | 20 Mg Qd Po                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                         | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jul-2008                                                                                                                                                                               | 6670462                     | EXPEDITED (15-DAY)        | Y                           | DE, HO                   | S08-TUR-01850-01              |                               | 26 YR                    | Female              | TUR                     |
| <a href="#">Preferred Term</a>                                                                                                                                                            | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Activated Partial<br>Thromboplastin Time<br>Prolonged; Blood Sodium<br>Increased; Coma;<br>International Normalised<br>Ratio Increased;<br>Leukocytosis; Liver<br>Function Test Abnormal; | Cipralext                   |                           |                             | S                        | Oral                          | 5 Mg Qd Po                    |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Prothrombin Time  
Prolonged; Pupillary  
Reflex Impaired;  
Respiratory Arrest

| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2008                                            | 6622538                        | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01316-01     |                      | 68 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysstasia; Fall; Gait<br>Disturbance;<br>Hydrocephalus | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Voltaren                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Katadolon (Flupirtine Maleate) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2008                                            | 6700576                        | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-02256-01     |                      | 28 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Drug<br>Interaction; Malaise              | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                        | Lithium Carbonate              |                    |                    | S               | Oral                 | 1000 Mg Qd Po        |                 | Not Reported |                |
|                                                        | Lamictal                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Clonazepam                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Nozinan (Levomepromazine)      |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Imovane (Zopiclone)            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2008                                            | 6700579                        | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-02228-01     |                      | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ovarian Cyst Ruptured                                  | Escitalopram Oxalate           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                        | Lexomil (Bromazepam)           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                        | Jasminelle                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2008                                            | 6701768                        | EXPEDITED (15-DAY) | Y                  | LT              | S08-SWI-02243-01     |                      | 42 YR           | Male         | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| Depression; Drug Level Decreased;<br>Electrocardiogram Repolarisation Abnormality;<br>Electrocardiogram St Segment Abnormal;<br>Electrocardiogram T Wave Inversion; Schizoaffective Disorder | Cipralax                     |                    |                    | S               | Oral                 | 10 Mg Qd Po                            |                 | Not Reported |                |
|                                                                                                                                                                                              | Clozapine                    |                    |                    | S               | Oral                 | 300 Mg Qd Po                           |                 | Not Reported |                |
|                                                                                                                                                                                              | Candesartan Cilexetil        |                    |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                                                                                                                                                              | Concor (Bisoprolol Fumarate) |                    |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                                                                                                                                                              |                              |                    |                    |                 |                      |                                        |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2008                                                                                                                                                                                  | 6701735                      | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-02210-01     |                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia; Diarrhoea; Headache; Impaired Work Ability; Mood Swings; Nausea; Nightmare; Paraesthesia; Screaming; Sleep Terror; Withdrawal Syndrome                                  | Lexapro                      |                    |                    | S               |                      |                                        |                 | Not Reported |                |
|                                                                                                                                                                                              | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Qd Po                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2008                                                                                                                                                                                  | 6703745                      | DIRECT             | Y                  | HO              |                      |                                        | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels                                                                                                                          | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg Daily Po, During First Trimester |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2008                                                                                                                                                                                  | 6704039                      | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02251-01     |                                        |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                  |                       |                      |                    |                 |                      |                         |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Dry Eye                                                                                                                                                                          |                       | Escitalopram Oxalate |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2008                                                                                                                                                                      | 6704128               | EXPEDITED (15-DAY)   | Y                  | HO              | S08-ESP-02261-01     |                         | 65 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Melaena; Upper Gastrointestinal Haemorrhage                                                                                                                    | Ciprallex             |                      |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                  | Aspirin               |                      |                    | S               | Oral                 | 100 Mg Qd Po            |                 | Not Reported |                |
|                                                                                                                                                                                  | Sinemet               |                      |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                  | Rivastigmine Tartrate |                      |                    | C               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                                  | Cozaar                |                      |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2008                                                                                                                                                                      | 6704508               | EXPEDITED (15-DAY)   | Y                  | CA              | S08-FRA-00093-02     |                         |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur; Foetal Cardiac Disorder; Foetal Distress Syndrome; Foetal Growth Restriction; Foetal Heart Rate Decreased; Maternal Drugs Affecting Foetus; Small For Dates Baby | Escitalopram Oxalate  |                      |                    | S               | Transplacental       | 5 Mg Qd, Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                  | Lexomil (Bromazepam)  |                      |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2008                                                                                                                                                                      | 6704513               | EXPEDITED (15-DAY)   | Y                  | OT              | S08-FRA-00093-01     |                         | 29 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>        | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Pregnancy; Suicidal Ideation                                                                                                                 | Escitalopram Oxalate  |                      |                    | S               | Oral                 | 10 Mg Qd Po             |                 | Not Reported |                |
|                                                                                                                                                                                  | Escitalopram Oxalate  |                      |                    | S               | Oral                 | 5 Mg Qd Po              |                 | Not Reported |                |
|                                                                                                                                                                                  | Lexomil (Bromazepam)  |                      |                    | C               |                      |                         |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                                                                                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|------------------------------------|--------------------------|---------------------|-------------------------|
| 09-Jul-2008                                                                                                                                                           | 6704764                 | DIRECT                    |                             | DE                       |                               |                                    | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Balance Disorder;<br>Congenital Anomaly;<br>Dizziness; Feeling<br>Abnormal;<br>Holoprosencephaly;<br>Maternal Drugs Affecting<br>Foetus; Pregnancy; Vision<br>Blurred | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Daily Po                     | 9 MTH                    | Not Reported        |                         |
|                                                                                                                                                                       | Albuterol               |                           |                             | S                        | Respiratory<br>(inhalation)   | 2 Puffs Every 4 Hr/As<br>Needed Po |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2008                                                                                                                                                           | 6706234                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-UKI-01419-02              |                                    |                          | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Distress Syndrome;<br>Maternal Drugs Affecting<br>Foetus                                                                                                       | Ciprallex               |                           |                             | S                        | Transplacental                | 20 Mg Qd Transplacental            |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2008                                                                                                                                                           | 6706344                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-ESP-02260-01              |                                    | 51 YR                    | Male                | ESP                     |
| <a href="#">Preferred Term</a>                                                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ocular Hypertension                                                                                                                                                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg Qd Po                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2008                                                                                                                                                           | 6706453                 | EXPEDITED (15-DAY)        | Y                           | DS                       | S08-UKI-02311-01              |                                    | 67 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                                                                                                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Behaviour;<br>Aggression; Antisocial<br>Behaviour; Diarrhoea;                                                                                                | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                        |                          | Not Reported        |                         |
|                                                                                                                                                                       | Ciprallex               |                           |                             | S                        | Oral                          | 10 Mg Qd Po                        |                          | Not Reported        |                         |



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|                                                                             |                               |   |      |             |              |
|-----------------------------------------------------------------------------|-------------------------------|---|------|-------------|--------------|
| Drug Interaction; Eye Disorder; Mania; Mood Swings; Nervous System Disorder | Ciprallex                     | S | Oral | 10 Mg Qd Po | Not Reported |
|                                                                             | Mirtazapine                   | S | Oral | 30 Mg Qd Po | Not Reported |
|                                                                             | Flucloxacillin                | C |      |             | Not Reported |
|                                                                             | Amias (Candesartan Cilexetil) | C |      |             | Not Reported |
|                                                                             | Carbocisteine                 | C |      |             | Not Reported |
|                                                                             | Doxycycline                   | C |      |             | Not Reported |
|                                                                             | Lansoprazole                  | C |      |             | Not Reported |
|                                                                             | Bendrofluazide                | C |      |             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2008              | 6306981       | EXPEDITED (15-DAY) | Y                  | OT              | S07-USA-01512-01     |                      | 64 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Diastolic Increased; Depression; Drug Ineffective; Ejaculation Failure; Optic Ischaemic Neuropathy; Papilloedema; Somnolence; Visual Impairment; Weight Increased | Lexapro                        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                  | Lexapro                        |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                                                                  | Lexapro                        |              |            | S           | Oral         | 5 Mg Qd Po         |                 | Not Reported |
|                                                                                                                                                                                  | Ambien                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Cymbalta                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Clonazepam                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Hyzaar                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | (Losartan/Hydrochlorothiazide) |              |            |             |              |                    |                 |              |
|                                                                                                                                                                                  | Aspirin                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                  | Klonopin                       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2008              | 6654536       | EXPEDITED (15-DAY) | Y                  | OT              | S08-SAF-01777-01     |                      | 16 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Confusional State; Disorientation; Feeling Abnormal; Panic Attack; Repetitive Speech; Restlessness; Tooth Impacted; Weight Increased | Ciprallex                    |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                                                                                                               | Livox (Fluovaxamine Maleate) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Dormicum (Nitrazepam)        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Propafol                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Sufentanil Citrate           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Esmaron (Trichlormethiazide) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Toradol                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               | Dexamethasone                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                               |                              |              |            |             |              |                    |                 |              |

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|                                                       |                        | Augmentin          |                    | C               |                            |                                            |                 |              | Not Reported   |
|-------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------------------------|-----------------|--------------|----------------|
|                                                       |                        | Neostigmine        |                    | C               |                            |                                            |                 |              | Not Reported   |
|                                                       |                        | Atropine           |                    | C               |                            |                                            |                 |              | Not Reported   |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2008                                           | 6674451                | EXPEDITED (15-DAY) | Y                  | OT              | S08-CAN-02031-01           |                                            |                 | Male         | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Steatosis; Weight Increased                   | Ciprallex              |                    |                    | S               | Oral                       | 15 Mg Qd Po                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2008                                           | 6696897                | EXPEDITED (15-DAY) | Y                  | OT              | ES-ASTRAZENECA-2008AC01732 |                                            | 53 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Dyskinesia       | Seroquel               |                    |                    | S               | Oral                       |                                            |                 | Zeneca       |                |
|                                                       | Lithium Carbonate      |                    |                    | C               | Oral                       |                                            |                 | Not Reported |                |
|                                                       | Seroquel               |                    |                    | S               | Oral                       |                                            | 1 MTH           | Zeneca       |                |
|                                                       | Seroquel               |                    |                    | S               |                            |                                            |                 | Zeneca       |                |
|                                                       | Lorazepam              |                    |                    | S               | Oral                       | 0.1 % 30 ML Solution                       |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate   |                    |                    | S               | Oral                       |                                            |                 | Not Reported |                |
|                                                       | Tiapride               |                    |                    | S               | Oral                       |                                            | 0 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2008                                           | 6697280                | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ROCHE-544089            |                                            | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Naproxen               |                    |                    | S               | Oral                       | Route Reported As Ingestion.               |                 | Roche        |                |
|                                                       | Quetiapine             |                    |                    | S               | Oral                       | Route Reported As Ingestion.               |                 | Not Reported |                |
|                                                       | Unspecified Ingredient |                    |                    | S               | Oral                       | Route Reported As Ingestion. Drug Reported |                 | Not Reported |                |

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|                      |   |      |                                  |              |
|----------------------|---|------|----------------------------------|--------------|
| Butalbital\Caffeine  | S | Oral | As Angiotensin Receptor Blocker. | Not Reported |
| Aspirin              | S | Oral | Route Reported As Ingestion.     | Not Reported |
| Acetaminophen        | S | Oral | Route Reported As Ingestion.     | Roche        |
| Ibuprofen            | S | Oral | Route Reported As Ingestion.     | Roche        |
| Escitalopram Oxalate | S | Oral | Route Reported As Ingestion.     | Not Reported |
| Caffeine             | S | Oral | Route Reported As Ingestion.     | Roche        |
| Fexofenadine         | S | Oral | Route Reported As Ingestion.     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2008              | 6707921       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02312-01     |                      | 39 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal;<br>Inappropriate Affect;<br>Speech Disorder | Escitalopram Oxalate  |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Not Reported |
|                                                               | Zopiclone             |              |            | C           |              |                    |                 | Not Reported |
|                                                               | Trophicreme (Estriol) |              |            | C           |              |                    |                 | Not Reported |
|                                                               | Cyproterone           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2008              | 6707932       | EXPEDITED (15-DAY) | Y                  | OT              | S08-ESP-02318-01     |                      | 61 YR      | Male       | ESP            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dry Mouth; Oral<br>Candidiasis; Poor Dental<br>Condition | Cipralext      |              |            | S           | Oral         | 20 Mg Qd Po        |                 | Not Reported |
|                                                          | Cymbalta       |              |            | S           | Oral         | 60 Mg Qd Po        |                 | Not Reported |

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| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jul-2008                                                | 6707969                       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02317-01                 |                      | 80 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Enuresis                             | Escitalopram Oxalate          |                    |                    | S               | Oral                             | 10 Mg Qd Po          |                 | Not Reported |                |
|                                                            | Levofloxacin                  |                    |                    | S               |                                  |                      |                 | Not Reported |                |
|                                                            | Unspecified Ingredient        |                    |                    | C               |                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jul-2008                                                | 6711141                       | EXPEDITED (15-DAY) | N                  | DE              | S08-USA-02339-01                 |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun<br>Shot Wound; Head Injury          | Lexapro                       |                    |                    | S               |                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2008                                                | 6698533                       | EXPEDITED (15-DAY) |                    | HO              | US-ABBOTT-08P-163-<br>0460934-00 |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Intentional<br>Overdose | Lexapro                       |                    |                    | S               |                                  |                      |                 | Not Reported |                |
|                                                            | Lexapro                       |                    |                    | S               |                                  |                      |                 | Not Reported |                |
|                                                            | Aripiprazole                  |                    |                    | C               |                                  | Not Reported         |                 | Not Reported |                |
|                                                            | Methylphenidate Hydrochloride |                    |                    | C               |                                  | Not Reported         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2008                                                | 6699614                       | EXPEDITED (15-DAY) | Y                  | HO              | DE-ASTRAZENECA-<br>2008PK01539   |                      | 45 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Generalised                                           | Quetiapine Fumarate           |                    |                    | S               | Oral                             |                      | 7 DAY           | Not Reported |                |
|                                                            | Cipralex                      |                    |                    | S               |                                  |                      | 7 DAY           | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 16-Jul-2008                                                                                                                                                    | 6712428              | DIRECT             | Y                  | HO              |                      |                        | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria; Hallucination, Visual; Myocardial Necrosis Marker Increased                                                                                        | Escitalopram Oxalate |                    |                    | S               |                      | See Above              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2008                                                                                                                                                    | 6712915              | DIRECT             | Y                  |                 |                      |                        | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Erectile Dysfunction; Sexual Dysfunction                                                                                                           | Sertraline           |                    |                    | S               | Oral                 | 100mg Daily Po         |                 | Watson       |                |
|                                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg Daily Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2008                                                                                                                                                    | 6692919              | EXPEDITED (15-DAY) | Y                  | HO              | FR-AMGEN-US291390    |                        | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Depressed Mood; Diarrhoea; Headache; Hepatitis Acute; Hyperhidrosis; Neuropathy Peripheral; Pyrexia; Shock; Skin Burning Sensation; Tremor; Vomiting | Enbrel               |                    |                    | S               | Subcutaneous         |                        |                 | Not Reported |                |
|                                                                                                                                                                | Rifadine             |                    |                    | S               | Unknown              | Unknown                |                 | Not Reported |                |
|                                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1.5 Tablet Total Daily |                 | Not Reported |                |
|                                                                                                                                                                | Rimifon              |                    |                    | S               | Unknown              | Unknown                |                 | Not Reported |                |
|                                                                                                                                                                | Pyrazinamide         |                    |                    | S               | Unknown              |                        |                 | Not Reported |                |
|                                                                                                                                                                | Xanax                |                    |                    | C               | Unknown              | 2 Mg Total Daily       |                 | Not Reported |                |
|                                                                                                                                                                | Cortancyl            |                    |                    | C               | Unknown              | 7 Mg Total Daily       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2008                                                                                                                                                    | 6699570              | EXPEDITED (15-DAY) | Y                  | HO              | S08-GER-02208-01     |                        | 67 YR           | Male         | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Dermatitis Allergic                                                                                                                                      | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                          | Remergil                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Metoprolol                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Aspirin                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Delix                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Seroquel                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2008                                                                                                                                              | 6714041                   | EXPEDITED (15-DAY) | Y                  | DS              | 1000000013           |                                  | 60 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness                                                                                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 20 Mg, Oral                      |                 | Not Reported |                |
|                                                                                                                                                          | Metformin (500 Milligram) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Adizem-XI (300 Milligram) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Coaprovel                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Lipitor (10 Milligram)    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jul-2008                                                                                                                                              | 6717475                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000000018           |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Extrapyramidal Disorder;<br>Fatigue; General Physical<br>Health Deterioration;<br>Parkinsonian Gait;<br>Psychomotor Retardation | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5 Mg, (5 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                          | Exelon                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | L-Dopa                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Unspecified Ingredient    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Previscan (Fluindione)    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Rivotril                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Oxazepam                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Haloperidol               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Motilium                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                          | Comtan                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Jul-2008              | 8702247       | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-08P-163-0462145-00 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|---------------|------------------------------|-----------------|--------------|
| Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome | Humira                                |              |            | S           | Other         |                              |                 | Not Reported |
|                                                                                                                                                                                     | Vicodin                               |              |            | S           | Oral          | 5/500, 3 In 1 D, As Required |                 | Not Reported |
|                                                                                                                                                                                     | Lexapro                               |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Chlormezanone                         |              |            | S           |               |                              |                 | Not Reported |
|                                                                                                                                                                                     | Amitriptyline                         |              |            | S           | Oral          | 75mg Qhs                     |                 | Not Reported |
|                                                                                                                                                                                     | Rizatriptan Benzoate                  |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Pregabalin                            |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Celecoxib                             |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Cyclobenzaprine Hydrochloride         |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Bupropion                             |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Minocycline\Minocycline Hydrochloride |              |            | S           | Oral          |                              |                 | Not Reported |
|                                                                                                                                                                                     | Clindamycin                           |              |            | S           | Oral          |                              | 7 DAY           | Not Reported |
|                                                                                                                                                                                     | Tetanus Toxoid Nos                    |              |            | S           | Intramuscular |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2008              | 6632456       | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-01420-02     |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|----------------------------------------------------------------------------------|-----------------|--------------|
| Caesarean Section; Eclampsia; Maternal Drugs Affecting Foetus; Pre-Eclampsia; Premature Baby; Small For Dates Baby | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D), Transplacental; 10 Mg (10 Mg, 1 In 1 D), Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|-------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|------------------|--------------------------|-----------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 21-Jul-2008                                                                   | 6654239                                                     | EXPEDITED (15-DAY) | Y                  | DE               | S08-USA-01732-01         |                                               |                 | Male                                                         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Completed Suicide                                                             | Lexapro                                                     |                    |                    | S                | Oral                     | Oral                                          |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 21-Jul-2008                                                                   | 6705192                                                     | EXPEDITED (15-DAY) | Y                  | HO, OT           | FR-PFIZER INC-2008057439 |                                               | 27 YR           | Female                                                       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Child Abuse; Delirium; Depression; Dissociation; Hallucination; Schizophrenia | Champix<br>Prazepam<br>Escitalopram Oxalate<br>Triphasil-21 |                    |                    | S<br>S<br>S<br>C |                          |                                               |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 21-Jul-2008                                                                   | 6718182                                                     | EXPEDITED (15-DAY) | Y                  | OT               | SPV1-2008-01455          |                                               | 45 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Bipolar I Disorder; Drug Ineffective                                          | Vyvanse<br>Lexapro                                          |                    |                    | S<br>S           | Oral<br>Oral             | 70 Mg, 1x/Day:Qd, Oral<br>Mg, 1x/Day:Qd, Oral |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 21-Jul-2008                                                                   | 6718630                                                     | EXPEDITED (15-DAY) | Y                  | OT               | 1000000116               |                                               |                 | Male                                                         | DNK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Urinary Retention                                                             | Escitalopram Oxalate                                        |                    |                    | S                | Oral                     | Oral                                          |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 22-Jul-2008                                                                   | 6640571                                                     | EXPEDITED (15-DAY) | Y                  | OT               | S08-FRA-01538-01         |                                               | 16 YR           | Female                                                       | DNK            |



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| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Bladder Dilatation; Urinary Retention | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; Oral |                 | Not Reported |
|                                       |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; Oral |                 |              |
|                                       | Xanax                |              |            | C           |              |                                     |                 | Not Reported |
|                                       | Atarax               |              |            | C           |              |                                     |                 | Not Reported |
|                                       | Tercian (Drops)      |              |            | C           |              |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2008              | 6670463       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S08-FRA-01965-01     |                      | 82 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------|-----------------|--------------|
| Cognitive Disorder; Condition Aggravated; Decreased Appetite; Depression; Drug Interaction; Gastrointestinal Disorder; General Physical Health Deterioration; Hypochloroemia; Hypokalaemia; Hyponatraemia; Intentional Overdose; Intentional Self-Injury; Loss Of Personal Independence In Daily Activities; Suicide Attempt | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral |                 |              |
|                                                                                                                                                                                                                                                                                                                              | Fludex (Indapamide)  |              |            | S           | Oral         | 1.5 Mg (1.5 Mg), Oral                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Flecainide Acetate   |              |            | S           |              | (100 Mg,1 In 1 Id)                                       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Uvimag B6            |              |            | C           |              |                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Temerit              |              |            | C           |              |                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Odrik                |              |            | C           |              |                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Pariet               |              |            | C           |              |                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              | Zestoretic           |              |            | C           |              |                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                              |                      |              |            |             |              |                                                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2008              | 6689430       | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2008DE11459      |                      | 51 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Fatigue; Intentional Overdose; Suicide Attempt | Estradiol Valerate   |              |            | S           |              | 4 Mg, Unk          |                 | Novartis     |
|                                                           | Escitalopram Oxalate |              |            | S           |              | Unk                |                 | Not Reported |

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|                |   |     |              |
|----------------|---|-----|--------------|
| Mirtazapine    | S | Unk | Not Reported |
| Quetiapine     | S | Unk | Not Reported |
| Lorazepam      | S | Unk | Not Reported |
| Metoclopramide | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 22-Jul-2008              | 6717554              | EXPEDITED (15-DAY) | Y                  | DS              | 1000000126           |                             | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia Areata          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In1 D),Oral |                 | Not Reported |                |
|                          | Valium               |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                          | Subutex              |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                          | Cannabis             |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2008                 | 6719830              | EXPEDITED (15-DAY) | Y                  | HO              | 1000000045           |                      | 35 YR           | Male         | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Drug Dependence | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                             | Rivotril             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 23-Jul-2008                                                                | 6671036                            | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-01895-01     |                               | 81 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Benign Prostatic Hyperplasia; Memory Impairment; Renal Failure; Somnolence | Lexapro                            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                            | Lisinopril                         |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                            | Metoprolol Tartrate                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                            | Prilosec (Omeprazole) (Omeprazole) |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2008              | 6701141       | EXPEDITED (15-DAY) | N                  | OT              | A0737779A            |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anxiety; Blood Cholesterol Increased; Blood Pressure Increased; Blood Triglycerides Increased; Bruxism; Depression; Dyskinesia; Feeling Abnormal; Hallucination; Headache; Hyperhidrosis; Insomnia; Intentional Overdose; Nightmare; Pain; Performance Status Decreased; Renal Failure; Road Traffic Accident; Sedation; Seizure; Sleep Apnoea Syndrome; Stress; Suicidal Ideation; Suicide Attempt; Tardive Dyskinesia; Thyroid Disorder; Weight Decreased | Wellbutrin             |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Xanax                  |              |            | S           | Oral         |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Seroquel               |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Lexapro                |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Restoril               |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Cymbalta               |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2008              | 6638832       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-01516-01     |                      | 13 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------|-----------------|--------------|
| Amnesia; Seizure; Staring | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                           |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                |                             |                                                   |                    |                 |                           |                                  |                 |                                                                                                  |                |              |  |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------------------------------|--------------------|-----------------|---------------------------|----------------------------------|-----------------|--------------------------------------------------------------------------------------------------|----------------|--------------|--|
|                                                                                                                                |                             | Nasacort (Nasal Drops<br>(Including Nasal Spray)) |                    | C               |                           | Oral                             |                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral; 5 Mg (5 Mg, 1 In<br>1 D), Oral |                | Not Reported |  |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>               | <u>Case Type</u>                                  | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                                                       | <u>Country</u> |              |  |
| 25-Jul-2008                                                                                                                    | 6720370                     | EXPEDITED (15-DAY)                                | Y                  | OT              | 1000000148                |                                  | 45 YR           | Male                                                                                             | USA            |              |  |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>              | <u>Comp.</u>                                      | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                       |                |              |  |
| Bipolar I Disorder; Drug<br>Ineffective                                                                                        | Lexapro                     |                                                   |                    | S               | Oral                      | 1 In 1 D, Oral                   |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Vyvanse                     |                                                   |                    | S               | Oral                      | 70 Mg (70 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                                                                     |                |              |  |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>               | <u>Case Type</u>                                  | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                                                       | <u>Country</u> |              |  |
| 28-Jul-2008                                                                                                                    | 6711607                     | EXPEDITED (15-DAY)                                | N                  | HO              | US-JNJFOC-<br>20080704816 |                                  | 44 YR           | Female                                                                                           | USA            |              |  |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>              | <u>Comp.</u>                                      | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                       |                |              |  |
| Anaemia; Breakthrough<br>Pain; Depression;<br>Exostosis; Sepsis;<br>Somnolence; Wrong<br>Technique In Product<br>Usage Process | Fentanyl Transdermal System |                                                   |                    | S               | Transdermal               |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Fentanyl Transdermal System |                                                   |                    | S               | Transdermal               |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Buspar                      |                                                   |                    | S               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Geodon                      |                                                   |                    | S               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Lexapro                     |                                                   |                    | S               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Effexor Xr                  |                                                   |                    | C               | Oral                      | 3x 75 Mg                         |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Caduet                      |                                                   |                    | C               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Premarin                    |                                                   |                    | C               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Nexium                      |                                                   |                    | C               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Reglan                      |                                                   |                    | C               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |
|                                                                                                                                | Norvasc                     |                                                   |                    | C               | Oral                      |                                  |                 | Not Reported                                                                                     |                |              |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 28-Jul-2008                                                                                                                                                                       | 6711743                            | EXPEDITED (15-DAY) | N                  | HO              | US-TEVA-174573USA    |                               | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Diabetic Ketoacidosis;<br>Pain; Restless Legs<br>Syndrome                                                                                                   | Trazodone                          |                    |                    | S               | Oral                 |                               |                 | Teva         |                |
|                                                                                                                                                                                   | Gatifloxacin                       |                    |                    | S               |                      |                               | 10 DAY          | Not Reported |                |
|                                                                                                                                                                                   | Famciclovir                        |                    |                    | S               |                      |                               | 7 DAY           | Not Reported |                |
|                                                                                                                                                                                   | Clarithromycin                     |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Oxycodone Hydrochloride            |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Tylox                              |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Quinapril Hydrochloride            |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Escitalopram Oxalate               |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Repaglinide                        |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Rosiglitazone Maleate              |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Omeprazole                         |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2008                                                                                                                                                                       | 6720220                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000000229           |                               | 88 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diabetes Mellitus<br>Inadequate Control; Drug<br>Interaction; Haemolysis;<br>Hyponatraemia; Malaise;<br>Platelet Count Increased;<br>White Blood Cell Count<br>Increased | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral     |                 | Not Reported |                |
|                                                                                                                                                                                   | Hydrochlorothiazide/Irbesartan     |                    |                    | S               | Oral                 | 300 Mg (300 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                   | Pantoprazole                       |                    |                    | S               | Oral                 | 200 Mg (200 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                   | Glimepiride                        |                    |                    | S               | Oral                 | 4 Mg (4 Mg,1 In 1 D),Oral     |                 | Not Reported |                |
|                                                                                                                                                                                   | Escitalopram(Escitalopram Oxalate) |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Coaprovel                          |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Inipomp                            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                   | Amaryl                             |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2008                                                                                                                                                                       | 6650935                            | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01714-01     |                               | 36 YR           | Male         | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| Overdose; Pollakiuria                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                           | 30 Mg (30 Mg, 1 In 1 D),<br>Oral                                 |                 | Not Reported |                |
|                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                           | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                 |                 | Not Reported |                |
|                                                                                   | Tranxene T-Tab          |                    |                    | C               |                                |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2008                                                                       | 6700474                 | EXPEDITED (15-DAY) | Y                  | DE              | S08-FRA-02213-01               |                                                                  | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Craniocerebral Injury;<br>Ecchymosis;<br>Meningorrhagia;<br>Periorbital Haematoma | Escitalopram Oxalate    |                    |                    | S               | Oral                           | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                   |                         |                    |                    |                 | Oral                           | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                                   | Aotal (Acamprosate)     |                    |                    | C               |                                |                                                                  |                 | Not Reported |                |
|                                                                                   | Stresam (Etifoxine)     |                    |                    | C               |                                |                                                                  |                 | Not Reported |                |
|                                                                                   | Zolpidem Tartrate       |                    |                    | C               |                                |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2008                                                                       | 6712748                 | EXPEDITED (15-DAY) | Y                  | HO              | CA-PURDUE-<br>GBR_2008_0004252 |                                                                  | 52 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Interval; Overdose                                        | Morphine Sulfate        |                    |                    | S               | Unknown                        | 30 Mg, Daily                                                     |                 | Not Reported |                |
|                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Unknown                        | 10 Mg, Daily                                                     |                 | Not Reported |                |
|                                                                                   | Zopiclone               |                    |                    | S               | Unknown                        | 15 Mg, Daily                                                     |                 | Not Reported |                |
|                                                                                   | Oxycodone Hydrochloride |                    |                    | S               | Unknown                        | Unk, Unk                                                         |                 | Not Reported |                |
|                                                                                   | Lorazepam               |                    |                    | S               | Unknown                        |                                                                  |                 | Not Reported |                |
|                                                                                   | Diazepam                |                    |                    | S               | Unknown                        |                                                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------|-----------------|----------------------|----------------|
| 29-Jul-2008                                                                                                     | 6722427                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000000187                                      |                                                       | 48 YR           | Female               | DNK            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Amenorrhoea                                                                                                     | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | 20 Mg (10 Mg, 2 In 1 D),<br>Oral                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Jul-2008                                                                                                     | 6722435                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000000175                                      |                                                       | 55 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Pulmonary<br>Oedema; Anaemia;<br>Cardiac Failure; Epistaxis;<br>Heart Transplant;<br>Respiratory Distress | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported         |                |
|                                                                                                                 | Sintrom                 |                    |                    | C               |                                                 |                                                       |                 | Not Reported         |                |
|                                                                                                                 | Hemigoxine              |                    |                    | C               |                                                 |                                                       |                 | Not Reported         |                |
|                                                                                                                 | Cordarone               |                    |                    | C               |                                                 |                                                       |                 | Not Reported         |                |
|                                                                                                                 | Lasix                   |                    |                    | C               |                                                 |                                                       |                 | Not Reported         |                |
|                                                                                                                 | Ramipril                |                    |                    | C               |                                                 |                                                       |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 31-Jul-2008                                                                                                     | 6416424                 | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13909163 |                                                       | 71 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>           |                |
| Adrenal Insufficiency;                                                                                          | Paclitaxel              |                    |                    | S               |                                                 |                                                       |                 | Bristol Myers Squibb |                |
| Androgen Deficiency;                                                                                            | Carboplatin             |                    |                    | S               |                                                 |                                                       |                 | Bristol Myers Squibb |                |
| Blood Testosterone                                                                                              | Megestrol Acetate       |                    |                    | S               |                                                 |                                                       |                 | Bristol Myers Squibb |                |
| Decreased; Blood Thyroid                                                                                        | Oxycodone Hydrochloride |                    |                    | S               |                                                 |                                                       |                 | Endo                 |                |
| Stimulating Hormone                                                                                             | Fludrocortisone Acetate |                    |                    | S               |                                                 |                                                       |                 | King                 |                |
| Decreased; Cortisol                                                                                             | Capecitabine            |                    |                    | S               |                                                 |                                                       |                 | Not Reported         |                |
| Decreased; Dyspnoea                                                                                             | Enoxaparin Sodium       |                    |                    | S               |                                                 |                                                       |                 | Not Reported         |                |
| Exertional; Erythema;                                                                                           | Radiation Therapy       |                    |                    | S               |                                                 |                                                       |                 | Not Reported         |                |
| Fatigue; Hyperhidrosis;                                                                                         | Escitalopram Oxalate    |                    |                    | S               |                                                 |                                                       |                 | Not Reported         |                |
| Nocturia; Somnolence                                                                                            | Levothyroxine           |                    |                    | S               |                                                 |                                                       |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------|-------------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------|----------------|
| 31-Jul-2008                                                                                                                                                                         | 6461615                                                                                                          | EXPEDITED (15-DAY) | Y                  | OT                    | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13971080 |                      | 71 YR           | Male                                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Adrenal Insufficiency;<br>Androgen Deficiency;<br>Dyspnoea Exertional;<br>Erythema; Hyperhidrosis;<br>Nocturia; Somnolence                                                          | Megestrol Acetate<br>Oxycodone Hydrochloride<br>Fludrocortisone Acetate<br>Escitalopram Oxalate<br>Levothyroxine |                    |                    | S<br>S<br>S<br>S<br>S |                                                 |                      |                 | Bristol Myers Squibb<br>Endo<br>King<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 31-Jul-2008                                                                                                                                                                         | 6722509                                                                                                          | DIRECT             | N                  | OT                    |                                                 |                      | 48 YR           | Female                                                               | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Abdominal Pain Upper;<br>Asthenia; Bronchospasm;<br>Constipation; Diarrhoea;<br>Drug Withdrawal<br>Syndrome; Dyspnoea;<br>Laryngospasm; Muscle<br>Spasms; Tongue Spasm;<br>Wheezing | Lexapro                                                                                                          |                    |                    | S                     | Oral                                            | 5mg Daily Po         | 2 YR            | Not Reported                                                         |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 31-Jul-2008                                                                                                                                                                         | 6724362                                                                                                          | EXPEDITED (15-DAY) | N                  | CA                    | 1000000296                                      |                      | < 1 DAY         | Male                                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                           |                |
| Anomalous Pulmonary<br>Venous Connection; Atrial<br>Septal Defect; Maternal<br>Drugs Affecting Foetus                                                                               | Lexapro                                                                                                          |                    |                    | S                     | Transplacental                                  | Transplacental       |                 | Not Reported                                                         |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                           | <u>Country</u> |
| 31-Jul-2008                                                                                                                                                                         | 6724398                                                                                                          | EXPEDITED (15-DAY) | N                  | CA                    | 1000000264                                      |                      | < 1 DAY         | Male                                                                 | USA            |



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| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Congenital Pulmonary Valve Atresia; Fallot'S Tetralogy; Maternal Drugs Affecting Foetus  | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2008                                                                              | 6724403        | EXPEDITED (15-DAY) | N                  | CA              | 1000000291           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Disease Congenital; Maternal Drugs Affecting Foetus; Persistent Foetal Circulation | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2008                                                                              | 6724409        | EXPEDITED (15-DAY) | N                  | CA              | 1000000295           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur                                                                           | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2008                                                                              | 6724414        | EXPEDITED (15-DAY) | N                  | CA              | 1000000293           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fallot'S Tetralogy; Maternal Drugs Affecting Foetus                                      | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jul-2008                                                                              | 6724448        | EXPEDITED (15-DAY) | N                  | CA              | 1000000290           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                     |                     |                    |                    |                 |                                          |                      |                 |            |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|------------|--------------------------------------|
| Maternal Drugs Affecting Foetus; Persistent Foetal Circulation                                                                                                      |                     |                    | Lexapro            |                 | S                                        | Transplacental       | Transplacental  |            | Not Reported                         |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                       |
| 31-Jul-2008                                                                                                                                                         | 6724688             | EXPEDITED (15-DAY) | N                  | CA              | 1000000294                               |                      | < 1 DAY         | Female     | USA                                  |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                                      |
| Congenital Tricuspid Valve Atresia; Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels                                                             | Lexapro             |                    |                    | S               |                                          | Transplacental       |                 |            | Not Reported                         |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                       |
| 31-Jul-2008                                                                                                                                                         | 6724692             | EXPEDITED (15-DAY) | N                  | CA              | 1000000292                               |                      | < 1 DAY         | Male       | USA                                  |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                                      |
| Atrial Septal Defect; Dextrocardia; Double Outlet Right Ventricle; Maternal Drugs Affecting Foetus; Pulmonary Artery Stenosis Congenital; Ventricular Septal Defect | Lexapro             |                    |                    | S               | Transplacental                           | Transplacental       |                 |            | Not Reported                         |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                       |
| 01-Aug-2008                                                                                                                                                         | 6716245             | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-13819560 |                      |                 | Female     | USA                                  |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                                      |
| Drug Interaction; Drug Level Fluctuating                                                                                                                            | Coumadin<br>Lexapro |                    |                    | S<br>S          |                                          |                      |                 |            | Bristol Myers Squibb<br>Not Reported |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u>                       |
| 01-Aug-2008                                                                                                                                                         | 6726645             | EXPEDITED (15-DAY) | Y                  | OT              | 1000000287                               |                      | 36 YR           | Female     | DNK                                  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| Dysgeusia; Urticaria;<br>Vaginal Haemorrhage                                           | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                                        | Omeprazole              |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                            | 6726646                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000000288                    |                                  | 70 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Coma; Seizure                                                                          | Escitalopram Oxalate    |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                            | 6727512                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000000297                    |                                  | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Craniosynostosis;<br>Maternal Drugs Affecting<br>Foetus                                | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                            | 6727517                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000000299                    |                                  | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy;<br>Maternal Drugs Affecting<br>Foetus; Pulmonary Artery<br>Atresia | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                            | 6727524                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000000279                    |                                  |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Maternal Exposure During                                                               | Lexapro                 |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Pregnancy;  
Premature Labour

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2008              | 6727528       | EXPEDITED (15-DAY) | N                  | CA, OT          | 1000000300           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Maternal Drugs Affecting Foetus; Persistent Foetal Circulation; Premature Baby; Respiratory Disorder; Respiratory Distress | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2008              | 6727530       | EXPEDITED (15-DAY) | N                  | CA              | 1000000301           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Anomalous Pulmonary Venous Connection; Maternal Drugs Affecting Foetus | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Aug-2008              | 6727541       | EXPEDITED (15-DAY) | N                  | CA, OT          | 1000000302           |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Amnesia; Double Outlet Right Ventricle; Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus; Pulmonary Valve Stenosis | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Aug-2008                                                                                                 | 6727555                 | EXPEDITED (15-DAY)        | Y                           | CA                       | 1000000303                    |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy;<br>Maternal Drugs Affecting<br>Foetus; Pulmonary Artery<br>Atresia                      | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                                                 | 6727578                 | EXPEDITED (15-DAY)        | Y                           | CA                       | 1000000304                    |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy;<br>Maternal Drugs Affecting<br>Foetus; Multiple<br>Congenital Abnormalities             | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                                                 | 6727594                 | EXPEDITED (15-DAY)        | N                           | CA, DE                   | 1000000305                    |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypoplastic Left Heart<br>Syndrome; Maternal<br>Drugs Affecting Foetus;<br>Persistent Foetal<br>Circulation | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2008                                                                                                 | 6727597                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000000306                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Arterial Disorder; Atrial<br>Septal Defect; Maternal                                                        | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drugs Affecting Foetus;  
Pulmonary Valve Stenosis

| <a href="#">FDA Received Date</a>                                                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Aug-2008                                                                                       | 6727611                 | EXPEDITED (15-DAY)        | N                           | CA, DE                   | 1000000307                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Heart Disease Congenital;<br>Maternal Drugs Affecting<br>Foetus; Persistent Foetal<br>Circulation | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Aug-2008                       | 6729746                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000000298                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Craniosynostosis                  | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                                                                                                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 04-Aug-2008                                                                                                                                                | 6724687                 | DIRECT                    | N                           | RI                       |                               |                               | 22 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Altered State Of<br>Consciousness; Anger;<br>Crying; Drug Withdrawal<br>Syndrome; Fatigue;<br>Headache; Influenza Like<br>Illness; Nonspecific<br>Reaction | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg Po                      |                          | Forest              |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 04-Aug-2008                       | 6730324                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000000344                    |                               | 20 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                          |   |      |                                  |              |
|-------------------|--------------------------|---|------|----------------------------------|--------------|
| Breast Mass; Cyst | Lexapro                  | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                   | Trazodone (75 Milligram) | C |      |                                  | Not Reported |
|                   | Concerta (18 Milligram)  | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2008              | 6730325       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000361           |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Alcohol Interaction;<br>Impaired Driving Ability;<br>Imprisonment | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                                   |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2008              | 6592651       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00892-01     |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Dermatitis Exfoliative;<br>Photosensitivity Reaction | Escitalopram Oxalate              |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D);<br>Oral |                 | Not Reported |
|                                                                               | Paroxetine                        |              |            | C           |              |                                  |                 | Not Reported |
|                                                                               | Methotrexate                      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                               | Soriatane (Acitretin) (Acitretin) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2008              | 6642513       | EXPEDITED (15-DAY) | N                  | HO              | S08-USA-01542-01     |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Asthenia; Blood Iron<br>Decreased; Haemoglobin<br>Decreased; Miosis; Pallor;<br>Somnolence | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, Once A Day)<br>Oral   |                 | Not Reported |
|                                                                                            | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, Once A<br>Day) Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |                                 |              |
|---------|---|------|---------------------------------|--------------|
| Lexapro | S | Oral | 5 Mg (5 Mg, Once A Day)<br>Oral | Not Reported |
|---------|---|------|---------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2008              | 6728934       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000378           |                      | 69 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Gastric Haemorrhage   | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2008              | 6720687       | EXPEDITED (15-DAY) | Y                  | DS              | GB-TEVA-175222ISR    |                      | 66 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Diarrhoea;<br>Drug Interaction; Mania;<br>Mood Swings; Social<br>Problem; Visual<br>Impairment | Mirtazapine          |              |            | S           | Oral         |                    |                 | Teva         |
|                                                                                                                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2008              | 6727083       | DIRECT           | N                  | LT, RI          |                      |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Butterfly Rash; Cardiac<br>Disorder; Dizziness;<br>Hyperhidrosis; Influenza<br>Like Illness; Irritable Bowel<br>Syndrome; Muscle Injury;<br>Musculoskeletal Pain;<br>Neck Pain; Pain In<br>Extremity; Palpitations;<br>Temperature Intolerance;<br>Tremor; Wheelchair User | Lexapro        |              |            | S           | Oral         | 1 Pid Po           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                     | Lexapro        |              |            | S           | Oral         | 1 Pid Po           |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|----------------------------------------------|----------------|
| 07-Aug-2008                                                                                                                                                                                  | 6728925                                         | DIRECT             | N                  | RI              |                      |                      | 46 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Condition Aggravated;<br>Depression; Feeling<br>Abnormal; Pulmonary<br>Hypertension                                                                                                          | Lexapro                                         |                    |                    | S               |                      | 1 Daily              | 1 YR            | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 07-Aug-2008                                                                                                                                                                                  | 6728940                                         | DIRECT             | N                  |                 |                      |                      | 40 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Drug Dependence; Drug<br>Detoxification; Drug<br>Withdrawal Syndrome;<br>Headache; Ill-Defined<br>Disorder; Insomnia;<br>Nausea                                                              | Lexapro                                         |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 07-Aug-2008                                                                                                                                                                                  | 6732512                                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000000373           |                      | 31 YR           | Unknown                                      | IND            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anger; Condition<br>Aggravated; Depression;<br>Disorientation;<br>Disturbance In Attention;<br>Feeling Abnormal;<br>Hunger; Irritability;<br>Photosensitivity Reaction;<br>Suicidal Ideation | Escitalopram Oxalate<br>Clozapam<br>Milnacipran |                    |                    | S<br>C<br>C     | Oral                 | Oral                 | 4 YR            | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 08-Aug-2008                                                                                                                                                                                  | 6721847                                         | NON-EXPEDITED      | N                  |                 | A0715016A            |                      | 52 YR           | Male                                         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|-----------------|----------------|
| Middle Insomnia; Restless<br>Legs Syndrome                                                                                             | Paxil                |                    |                    | S               | Oral                 |                                  |                 | Glaxosmithkline |                |
|                                                                                                                                        | Lunesta              |                    |                    | S               | Oral                 | 1va Per Day                      |                 | Glaxosmithkline |                |
|                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                 |                                  |                 | Not Reported    |                |
|                                                                                                                                        | Zetia                |                    |                    | C               |                      |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Aug-2008                                                                                                                            | 6721911              | NON-EXPEDITED      | N                  |                 | A0732266A            |                                  |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Drug Reaction;<br>Panic Attack                                                                                                 | Paxil                |                    |                    | S               | Oral                 | 80mg Unknown                     |                 | Glaxosmithkline |                |
|                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                 | 20mgd Per Day                    |                 | Not Reported    |                |
|                                                                                                                                        | Seroquel             |                    |                    | C               |                      |                                  |                 | Not Reported    |                |
|                                                                                                                                        | Ativan               |                    |                    | C               |                      |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Aug-2008                                                                                                                            | 6734049              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02328-01     |                                  | 24 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Clonus; Decreased<br>Appetite; Hyperhidrosis;<br>Weight Decreased                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Aug-2008                                                                                                                            | 6735351              | EXPEDITED (15-DAY) | Y                  | HO, LT          | GXKR2008CA07241      |                                  | 52 YR           | Male            | CAN            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Activated Partial<br>Thromboplastin Time<br>Prolonged; Blood Calcium<br>Decreased; Blood<br>Creatine Phosphokinase<br>Increased; Blood | Diazepam             |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported    |                |
|                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported    |                |
|                                                                                                                                        | Zopiclone            |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported    |                |
|                                                                                                                                        | Morphine             |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                    |                                      |        |              |              |                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------|--------------|--------------|------------------------------|
| Creatinine Increased;<br>Blood Pressure<br>Decreased; Coma; Drug<br>Screen Positive;<br>Electrocardiogram Qt<br>Prolonged; Heart Rate<br>Decreased;<br>Hyperkalaemia; Intentional<br>Overdose; International<br>Normalised Ratio<br>Decreased; Nodal<br>Rhythm; Oxygen<br>Saturation Decreased;<br>Suicide Attempt | Lorazepam<br>Oxycodone Hydrochloride | S<br>S | Oral<br>Oral | Oral<br>Oral | Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------|--------------|--------------|------------------------------|

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 08-Aug-2008                 | 6737050              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02161-01     |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Ecchymosis;<br>Hypokalaemia | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>                                                                                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>                    | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>                                                                                                           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|-----------------------------------------|----------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------|----------------|
| 11-Aug-2008                                                                                                                                                                             | 6723435                                                                                                                                      | EXPEDITED (15-DAY) | Y                  | HO, LT                               | CA-<br>KINGPHARMUSA00001<br>-K200800876 |                                                                                              |                 | Unknown                                                                                                              | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>                                                                                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                            | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>                                                                                                           |                |
| Bradycardia; Drug<br>Interaction;<br>Electrocardiogram<br>Abnormal;<br>Electrocardiogram Qt<br>Prolonged;<br>Hyperkalaemia; Loss Of<br>Consciousness;<br>Overdose; Sinus<br>Tachycardia | Avinza<br>Escitalopram Oxalate<br>Diazepam<br>Zopiclone<br>Lorazepam<br>Acetaminophen W/Oxycodone<br>Citalopram<br>Oxycodone Hcl Controlled- |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S |                                         | Unk, Unk<br>Unk, Unk<br>Unk, Unk<br>Unk, Unk<br>Unk, Unk<br>Unk, Unk<br>Unk, Unk<br>Unk, Unk |                 | King<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |   |          |              |
|-------------------------------------------------|---|----------|--------------|
| Release<br>Oxycodone Hcl Controlled-<br>Release | S | Unk, Unk | Not Reported |
| Altace                                          | C | 5 Mg, Qd | King         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2008              | 6728826       | DIRECT           | N                  |                 |                      |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Loss Of Personal Independence In Daily Activities; Malaise; Middle Insomnia; Tremor | Lexapro                 |              |            | S           | Oral         | 20 Mg Po           |                 | Not Reported |
|                                                                                     | Trazodone Hydrochloride |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2008              | 6728961       | DIRECT           | N                  | OT              |                      |                      | 13 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity; Rash Generalised | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2008              | 6735291       | EXPEDITED (15-DAY) | Y                  | DS              | GXKR2008GB07118      |                      | 66 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Aggression; Diarrhoea; Drug Interaction; Mania; Mood Swings; Negativism; Social Problem; Visual Impairment | Mirtazapine                          |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
|                                                                                                                                | Cipralex                             |              |            | S           | Oral         | 10 Mg, Oral        |                 | Not Reported |
|                                                                                                                                |                                      |              |            |             | Oral         | 10 Mg, Oral        |                 |              |
|                                                                                                                                |                                      |              |            |             | Oral         | 10 Mg, Oral        |                 |              |
|                                                                                                                                | Amias (Candesartan Cilexetil)        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Bendrofluazide (Bendroflumethiazide) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Carbocysteine                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Flucloxacillin Sodium                |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Monohydrate  
Lansoprazole

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2008              | 6737562       | EXPEDITED (15-DAY) | Y                  | DS              | 107-#03#2008-03897   |                      | 66 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Diarrhoea;<br>Drug Interaction; Mania;<br>Mood Swings; Social<br>Problem; Visual<br>Impairment | Mirtazapine (Mirtazapine)       |              |            | S           | Oral         | 30 Mg Oral         | 1 YR            | Not Reported |
|                                                                                                                                   | Ciprallex                       |              |            | S           | Oral         | 10 Mg Oral         | 11 MTH          | Not Reported |
|                                                                                                                                   | Amias (Candesartan Cilexetil)   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Bendrofluazide (Bendrofluazide) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Carbocysteine                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Doxycycline                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Flucloxacillin Sodium           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Monohydrate<br>Lansoprazole     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2008              | 6737976       | EXPEDITED (15-DAY) | Y                  | DS              | 2008S1013585         |                      | 66 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Aggression; Diarrhoea;<br>Drug Interaction; Mania;<br>Mood Swings; Social<br>Problem; Visual<br>Impairment | Mirtazapine (Mirtazapine) |              |            | S           |              | 30 Mg;             |                 | Not Reported |
|                                                                                                                                   | Ciprallex                 |              |            | S           | Oral         | 10 Mg; ; Oral      |                 | Not Reported |
|                                                                                                                                   |                           |              |            |             | Oral         | 10 Mg; ; Oral      |                 |              |
|                                                                                                                                   |                           |              |            |             | Oral         | 10 Mg; ; Oral      |                 |              |
|                                                                                                                                   | Amias                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Bendrofluazide            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Carbocisteine             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                   | Doxycycline               |              |            | C           |              |                    |                 | Not Reported |
| Flucloxacillin                                                                                                                    |                           |              | C          |             |              |                    | Not Reported    |              |
| Lansoprazole                                                                                                                      |                           |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Aug-2008              | 6738991       | EXPEDITED (15-DAY) | Y                  | DE              | 1000000430           |                      | 87 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| Brain Scan Abnormal;<br>Cerebral Haemorrhage;<br>Coma; Loss Of<br>Consciousness; Mydriasis | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                            | Kardegic (Acetylsalicylate<br>Lysine) |                    |                    | S               | Oral                 | 75 Mg, (75mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |                |
|                                                                                            | Cyamemazine                           |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Prazepam                              |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Zolpidem                              |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Levothyrox                            |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Acebutolol Hydrochloride              |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Colpotrophine                         |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| Diprosone (Cream)                                                                          |                                       |                    | C                  |                 |                      |                                                       | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2008                                                                                | 6732604                               | DIRECT             | Y                  |                 |                      |                                                       |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Product<br>Quality Issue                                                         | Lexapro                               |                    |                    | S               | Oral                 | 10mg Daily Po                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2008                                                                                | 6734204                               | DIRECT             | N                  | OT              |                      |                                                       | 77 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Libido Increased; Memory<br>Impairment                                                     | Lexapro                               |                    |                    | S               |                      | 1 Tablet Per Day                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2008                                                                                | 6738111                               | EXPEDITED (15-DAY) | Y                  | OT              | 2008S1012414         |                                                       |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;<br>Condition Aggravated;<br>Dizziness; Drug                           | Fluoxetine                            |                    |                    | S               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Paroxetine Hydrochloride              |                    |                    | S               |                      |                                                       |                 | Not Reported |                |
|                                                                                            | Sertraline                            |                    |                    | S               |                      |                                                       |                 | Not Reported |                |

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|                                                                                                                                                                                             |           |   |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|--------------|
| Withdrawal Syndrome;<br>Eye Disorder; Headache;<br>Intentional Overdose;<br>Irritability; Migraine; Mood<br>Altered; Nausea; Self-<br>Injurious Ideation; Suicidal<br>Ideation; Tearfulness | Ciprallex | S | Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---|--------------|

| <u>FDA Received Date</u>                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2008                                                                           | 6729557                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-MERCK-0808FRA00015 |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                         | Zocor                   |                    |                    | S               | Oral                  |                      | 11 DAY          | Merck        |                |
|                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                       | Indapamide\Perindopril  |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                       | Erbumine                |                    |                    |                 |                       |                      |                 |              |                |
|                                                                                       | Bromazepam              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2008                                                                           | 6729581                 | EXPEDITED (15-DAY) | Y                  | DE              | DSA_32196_2008        |                      | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To<br>Product; Medication Error;<br>Wrong Product<br>Administered | Cardizem La             |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Tikosyn                 |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Methadone Hydrochloride |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Lexapro                 |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Senokot                 |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Lidoderm                |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Prilosec                |                    |                    | S               |                       | (Df)                 |                 | Not Reported |                |
|                                                                                       | Ms Contin               |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                       | Levothyroxine           |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                                                       | Digoxin                 |                    |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| 18-Aug-2008                                                                                                                                                                                                | 6729684                               | EXPEDITED (15-DAY) | Y                  | DS, LT          | 1000000332                   |                                  | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Asthenia; Crying;<br>Decreased Appetite;<br>Fatigue; Insomnia; Loss<br>Of Libido; Performance<br>Status Decreased;<br>Restlessness; Skin<br>Burning Sensation;<br>Suicidal Ideation | Escitalopram Oxalate                  |                    |                    | S               | Oral                         | 10 Mg (10 Mg,L In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                            | Alprazolam(0.5 Milligram,<br>Tablets) |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2008                                                                                                                                                                                                | 6745779                               | EXPEDITED (15-DAY) | Y                  | OT              | 100000378                    |                                  | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Haemorrhage                                                                                                                                                                                        | Escitalopram Oxalate                  |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                            | Escitalopram Oxalate                  |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                            | Unspecified Ingredient                |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Aug-2008                                                                                                                                                                                                | 6760719                               | NON-EXPEDITED      | Y                  |                 | TPA2008A00795                |                                  | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                      | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dizziness;<br>Nausea; Tremor                                                                                                                                                                      | Rozerem                               |                    |                    | S               | Oral                         | Per Oral                         |                 | Not Reported |                |
|                                                                                                                                                                                                            | Lexapro                               |                    |                    | S               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                   | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Aug-2008                                                                                                                                                                                                | 6731085                               | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2008065734 |                                  | 84 YR           | Female       | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| Epilepsy; Postictal State; Seizure                                                                                          | Lyrica                 |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
|                                                                                                                             | Tramadol Hydrochloride |                    |                    | S               | Oral                 |                                   |                 | Not Reported |                |
|                                                                                                                             | Escitalopram Oxalate   |                    |                    | S               | Oral                 | Daily Dose:10mg-Freq:Every Day    |                 | Not Reported |                |
|                                                                                                                             | Nifedipine             |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Hyzaar                 |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Nitroglycerin          |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Clopidogrel            |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Omeprazole             |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Simvastatin            |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| Zolpidem                                                                                                                    |                        |                    | C                  |                 |                      |                                   | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Aug-2008                                                                                                                 | 6736793                | DIRECT             | Y                  | HO              |                      |                                   | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Magnesium Decreased; Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Palpitations; Ventricular Tachycardia | Risperidone            |                    |                    | S               | Oral                 | 1mg Qhs Po (Duration: Chronic)    |                 | Not Reported |                |
|                                                                                                                             | Lexapro                |                    |                    | S               | Oral                 | 10mg Daily Po (Duration: Chronic) |                 | Not Reported |                |
|                                                                                                                             | Asa                    |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Hctz                   |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Lisinopril             |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Actos                  |                    |                    | C               |                      |                                   |                 | Not Reported |                |
| Trazodone Hydrochloride                                                                                                     |                        |                    | C                  |                 |                      |                                   | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Aug-2008                                                                                                                 | 6743897                | EXPEDITED (15-DAY) | Y                  | DS              | 1000000510           |                                   | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Headache; Memory Impairment; Photophobia; Visual Impairment                                             | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg )5 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |
|                                                                                                                             | Plavix                 |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Lexomil                |                    |                    | C               |                      |                                   |                 | Not Reported |                |
|                                                                                                                             | Zopiclone              |                    |                    | C               |                      |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                      |                         |                    |                    |                 |                                                   |                                              |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------------------------------|-----------------|--------------|----------------|
| Ideos                                                                                                                                |                         | C                  |                    | Not Reported    |                                                   |                                              |                 |              |                |
| Actonel                                                                                                                              |                         | C                  |                    | Not Reported    |                                                   |                                              |                 |              |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Aug-2008                                                                                                                          | 6747833                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000000496                                        |                                              | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Intolerance;<br>Gastroenteritis; Headache;<br>Seizure                                                                           | Lexapro                 |                    |                    | S               |                                                   |                                              |                 | Not Reported |                |
|                                                                                                                                      | Pegintron               |                    |                    | S               | Subcutaneous                                      | 120 Mcg Qw (120 Mcg, 1 In 1 Wk),Subcutaneous |                 | Not Reported |                |
|                                                                                                                                      | Rebetol                 |                    |                    | S               | Oral                                              | Oral                                         |                 | Not Reported |                |
|                                                                                                                                      | Advair Diskus           |                    |                    | S               |                                                   |                                              |                 | Not Reported |                |
|                                                                                                                                      | Trazodone Hydrochloride |                    |                    | S               |                                                   |                                              |                 | Not Reported |                |
|                                                                                                                                      | Valium                  |                    |                    | S               |                                                   |                                              |                 | Not Reported |                |
|                                                                                                                                      | Methadone Hydrochloride |                    |                    | S               |                                                   |                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Aug-2008                                                                                                                          | 6731673                 | EXPEDITED (15-DAY) | Y                  | HO              | CA-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200801270 |                                              |                 | Unknown      | CAN            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qrs<br>Complex Abnormal;<br>Electrocardiogram Qt<br>Prolonged; Loss Of<br>Consciousness; Nodal<br>Rhythm; Overdose | Morphine                |                    |                    | S               |                                                   | Maximum 9500 Mg<br>Possible Ingestion        |                 | Tyco         |                |
|                                                                                                                                      | Morphine                |                    |                    | S               |                                                   | Maximum 2640 Mg<br>Possible Ingestion        |                 | Tyco         |                |
|                                                                                                                                      | Morphine                |                    |                    | S               |                                                   | Maximum Of 2640 Mg<br>Ingested               |                 | Tyco         |                |
|                                                                                                                                      | Morphine                |                    |                    | S               |                                                   | Maximum 420 Mg<br>Possible Ingestion         |                 | Tyco         |                |
|                                                                                                                                      | Oxycodone               |                    |                    | S               |                                                   | 10 Mg Extended Release                       |                 | Tyco         |                |
|                                                                                                                                      | Oxycodone               |                    |                    | S               |                                                   | Unk, Unk                                     |                 | Tyco         |                |
|                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               |                                                   | Maximum 140 Mg<br>Possible Ingestion         |                 | Not Reported |                |
|                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               |                                                   | Maximum Of 140 Mg                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |                                        |              |
|---------------------------|---|----------------------------------------|--------------|
| Diazepam                  | S | Ingested                               | Not Reported |
| Zopiclone                 | S | Maximum 1800 Mg<br>Possible Ingestion  | Not Reported |
| Zopiclone                 | S | Maximum 187.5 Mg<br>Possible Ingestion | Not Reported |
| Lorazepam                 | S | Maximum Of 187.5 Mg<br>Ingested        | Not Reported |
| Acetaminophen W/Oxycodone | S | Maximum 30 Mg Possible<br>Ingestion    | Not Reported |
| Citalopram                | S | Unlikley This Was<br>Ingested          | Not Reported |
| Ramipril                  | C | Possible That Ingested                 | Not Reported |
|                           |   | 5 Mg, Qd                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Aug-2008              | 6731776       | EXPEDITED (15-DAY) |                    | HO              | GB-EISAI MEDICAL<br>RESEARCH-A044-002-<br>005675 |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Drug<br>Interaction;<br>Electrocardiogram Qt<br>Prolonged; Syncope;<br>Torsade De Pointes | Omeprazole           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Prochlorperazine     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Ferrous Sulfate      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Aricept              |              |            | S           | Oral         |                    | 2 YR            | Not Reported |
|                                                                                                        | Inderal              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                        | Inderal              |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                        | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Aug-2008                                 | 6744118              | EXPEDITED (15-DAY) | Y                  | OT              | 1000000364           |                      | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Headache; Hypotension; Loss Of | Escitalopram Oxalate |                    |                    | S               | Oral                 | (5 Mg,Once), Oral    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                         |   |              |
|------------------------------------|-------------------------|---|--------------|
| Consciousness; Malaise;<br>Vertigo | Lysanxia (10 Milligram) | C | Not Reported |
|------------------------------------|-------------------------|---|--------------|

| <u>FDA Received Date</u>                                                 | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 21-Aug-2008                                                              | 6711142                         | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-02321-01     |                                  | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Schedule Of<br>Product Administration;<br>Pyrexia; Seizure | Lexapro                         |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                          | Xanax (0.25 Milligram, Tablets) |                    |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|-----------------|----------------|
| 21-Aug-2008                                                             | 6732631                 | EXPEDITED (15-DAY) | N                  | HO              | A0743752A                   |                      | 51 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cervicogenic Headache;<br>Drug Intolerance;<br>Gastroenteritis; Seizure | Advair Diskus           |                    |                    | S               | Respiratory<br>(inhalation) |                      |                 | Glaxosmithkline |                |
|                                                                         | Peginterferon Alfa-2b   |                    |                    | S               | Subcutaneous                | 120mcg Weekly        |                 | Not Reported    |                |
|                                                                         | Rebetol                 |                    |                    | S               | Oral                        |                      |                 | Not Reported    |                |
|                                                                         | Trazodone Hydrochloride |                    |                    | S               | Unknown                     |                      |                 | Not Reported    |                |
|                                                                         | Lexapro                 |                    |                    | S               | Unknown                     |                      |                 | Not Reported    |                |
|                                                                         | Valium                  |                    |                    | S               | Unknown                     |                      |                 | Glaxosmithkline |                |
|                                                                         | Methadone Hydrochloride |                    |                    | S               | Unknown                     |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 21-Aug-2008                                     | 6733173                                                | EXPEDITED (15-DAY) | Y                  | HO              | AU-MERCK-<br>0808AUS00075 |                      | 70 YR           | Female       | AUS            |
| <u>Preferred Term</u>                           | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Chromaturia;<br>Hepatitis; Jaundice | Zocor                                                  |                    |                    | S               | Oral                      |                      |                 | Merck        |                |
|                                                 | Escitalopram Oxalate                                   |                    |                    | S               | Unknown                   |                      | 12 DAY          | Not Reported |                |
|                                                 | Influenza Virus Split Virion 3v<br>Vaccine Inactivated |                    |                    | C               | Subcutaneous              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| 21-Aug-2008                                                     | 6746752                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000000540           |                                                 | 78 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Condition Aggravated; Hyponatraemia; Weight Decreased | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral                    |                 | Not Reported |                |
|                                                                 | Indapamide\Perindopril            |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                 | Bromazepam                        |                    |                    | S               | Oral                 | 3 Mg (3 Mg, 1 In 1 D), Oral                     |                 | Not Reported |                |
|                                                                 | Zocor                             |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),Oral                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2008                                                     | 6746790                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000000512           |                                                 | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Loss Of Consciousness; Seizure; Tongue Biting         | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg, (10 Mg, 1 In 1 D), Oral                  |                 | Not Reported |                |
|                                                                 | Tramadol                          |                    |                    | S               | Oral                 | 300 Mg, (150mg, 2 In 1 D), Oral                 |                 | Not Reported |                |
|                                                                 | Lyrica                            |                    |                    | S               | Oral                 | 300 Mg, (150 Mg, 2 In 1 D), Oral                |                 | Not Reported |                |
|                                                                 | Lyrica                            |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                 | Topalgic [Tramadol Hydrochloride] |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Aug-2008                                                     | 6746960                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000000558           |                                                 | 78 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression;                                                     | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                 |                                   |   |      |      |  |                                                                  |              |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---|------|------|--|------------------------------------------------------------------|--------------|
| Craniocerebral Injury;<br>Disturbance In Attention;<br>Fall; Psychomotor<br>Retardation;<br>Restlessness; Subdural<br>Haematoma |                                   |   |      |      |  | Oral; 20 Mg (20 Mg, 1 In 1 D), Oral                              |              |
|                                                                                                                                 |                                   |   |      | Oral |  | 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral     |              |
|                                                                                                                                 | Memantine Hydrochloride           | S | Oral |      |  | 5 Mg, 5 Mg, 1 In 1 D), Oral                                      | Not Reported |
|                                                                                                                                 | Valproic Acid                     | S | Oral |      |  | 500 Mg (250 Mg, 2 In 1 D), Oral; 750 Mg (750 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                                                 |                                   |   | Oral |      |  | 500 Mg (250 Mg, 2 In 1 D), Oral; 750 Mg (750 Mg, 1 In 1 D), Oral |              |
|                                                                                                                                 | Loxapac                           | S | Oral |      |  | 25 Gtt (25 Gtt, 1 In 1 D), Oral                                  | Not Reported |
|                                                                                                                                 | Unspecified Ingredient            | S |      |      |  |                                                                  | Not Reported |
|                                                                                                                                 | Aspegic [Acetylsalicylate Lysine] | S |      |      |  | 100 Mg (100 Mg, 1 In 1 D)                                        | Not Reported |
|                                                                                                                                 | Rivotril (Drops (For Oral Use))   | C |      |      |  |                                                                  | Not Reported |
|                                                                                                                                 | Risperidone                       | C |      |      |  |                                                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2008              | 6733935       | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-580552      |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastroenteritis; Post<br>Lumbar Puncture<br>Syndrome; Seizure | Diazepam                |              |            | S           | Unknown      |                    |                 | Roche        |
|                                                               | Peginterferon Alfa-2b   |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                               | Ribavirin               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                               | Advair Diskus           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Trazodone Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Lexapro                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Methadone Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                               | Provigil                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 22-Aug-2008              | 6734290       | NON-EXPEDITED    | N                  |                 | US-ABBOTT-07P-163-0417170-00 |                      | 47 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Fatigue                                    | Synthroid                   |                    |                    | S               | Oral                         |                                |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate        |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Zolpidem Tartrate           |                    |                    | C               |                              |                                |                 | Not Reported |                |
|                                                              | Calcium                     |                    |                    | C               |                              |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2008                                                  | 6734454                     | NON-EXPEDITED      | N                  |                 | US-ABBOTT-07P-163-0430162-00 |                                |                 | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Drug Screen Positive; Urine Odour Abnormal | Synthroid                   |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Lexapro                     |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Lamotrigine                 |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Modafinil                   |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Levetiracetam               |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Aripiprazole                |                    |                    | S               |                              |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Aug-2008                                                  | 6734537                     | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2008067952     |                                |                 | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Mental Disorder; Overdose                  | Chantix                     |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Lyrica                      |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Amitriptyline Hydrochloride |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Lisinopril                  |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Metformin                   |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Isosorbide                  |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Lexapro                     |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Vytorin                     |                    |                    | S               |                              | Text:10/20                     |                 | Not Reported |                |
|                                                              | Combivent                   |                    |                    | S               |                              | Text:2 Puffs Three Times A Day |                 | Not Reported |                |
|                                                              | Synthroid                   |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Cilostazol                  |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Coreg                       |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Plavix                      |                    |                    | S               |                              |                                |                 | Not Reported |                |
|                                                              | Actos                       |                    |                    | S               |                              |                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Oxycodone                                                                                                                                                                                                                                                                                                                                                            |                                   | S                  |                    | Not Reported    |                      |                                |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2008                                                                                                                                                                                                                                                                                                                                                          | 6325993                           | EXPEDITED (15-DAY) | Y                  | LT              | S07-USA-02000-02     |                                | 2 DAY           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature Fluctuation; Bradycardia Neonatal; Cyanosis Neonatal; Developmental Delay; Dysphagia; Infantile Apnoea; Ischaemic Stroke; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Movement Disorder; Muscle Tightness; Neonatal Disorder; Neonatal Hypotension; Neonatal Seizure; Poor Sucking Reflex; Umbilical Cord Around Neck | Lexapro                           |                    |                    | S               | Transplacental       | See Image                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Cymbalta                          |                    |                    | C               | Transplacental       | See Image                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Zoloft (Sertraline Hydrochloride) |                    |                    | C               | Transplacental       | See Image                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | (Sertraline Hydrochloride)        |                    |                    |                 |                      |                                |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2008                                                                                                                                                                                                                                                                                                                                                          | 6532285                           | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00038-01     |                                | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Interstitial Lung Disease                                                                                                                                                                                                                                                                                                          | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg, (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Metformin Hydrochloride           |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Glyburide                         |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Atenolol                          |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                      | Diovan                            |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2008                                                                                                                                                                                                                                                                                                                                                          | 6686446                           | EXPEDITED (15-DAY) | Y                  | HO              | S08-GER-02071-01     |                                | 32 YR           | Male         | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Affective Disorder;                                                                                                           | Escitalopram Oxalate                                                     |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)       |                 | Not Reported |                |
| Agitation; Drug Interaction                                                                                                   | Buprenorphine\Naloxone                                                   |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)       |                 | Not Reported |                |
|                                                                                                                               | Omeprazol (20 Milligram)                                                 |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2008                                                                                                                   | 6689097                                                                  | EXPEDITED (15-DAY) | Y                  | HO              | S08-JPN-02087-01     |                               | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Apathy;                                                                                   | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| Aspartate Aminotransferase Increased; Blood Albumin Increased; Blood Alkaline Phosphatase Increased;                          | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| Blood Bilirubin Increased;                                                                                                    | Norvasc (Amlodipine Besilate) (Tablets) (Amlodipine Besilate)            |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Chloride Increased;                                                                                                     | Gaster                                                                   |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Cholesterol Increased; Blood Creatine Phosphokinase Increased;                                                          | Digoxin (Digoxin) (Tablets) (Digoxin)                                    |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Creatinine Decreased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood                             | Persantin (Dipyridamole) (Tablets) (Dipyridamole)                        |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Potassium Increased;                                                                                                          | Magmitt (Magnesium) (Tablets)                                            |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Sodium Increased;                                                                                                       | Primperan (Metoclopramide) (Tablets) (Metoclopramide)                    |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Urea Increased;                                                                                                         | Rize (Clotiazepam) (Tablets) (Clotiazepam)                               |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Blood Uric Acid Increased; Constipation; Decreased Appetite; Drug Ineffective;                                                | Rohypnol (Flunitrazepam) (Tablets) (Flunitrazepam)                       |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Dysgeusia; Feeling Guilty; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Haematocrit Increased; Haemoglobin | Alosenn (Tablets)                                                        |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Myslee (Zolpidem Tartrate) (Tablets) (Zolpidem Tartrate)                 |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Constan (Alprazolam) (Tablets) (Alprazolam)                              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Tofranil (Imipramine Hydrochloride) (Tablets) (Imipramine Hydrochloride) |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Laxoberon (Sodium Picosulfate) (Tablets) (Sodium Picosulfate)            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Magnesium Oxide (Tablets)                                                |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Increased; Initial Insomnia;  
 Insomnia; Intestinal  
 Obstruction; Irritability;  
 Loss Of Personal  
 Independence In Daily  
 Activities; Malaise; Night  
 Sweats; Panic Reaction;  
 Paralysis; Platelet Count  
 Increased; Protein Total  
 Decreased; Psychomotor  
 Retardation; Red Blood  
 Cell Count Increased;  
 Suicidal Ideation; Weight  
 Decreased; White Blood  
 Cell Count Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6741940       | DIRECT           | N                  | OT              |                      |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Increased Appetite; Off<br>Label Use; Weight<br>Increased | Lexapro        |              |            | S           | Oral         | 30 Milligrams Once Daily<br>Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6744439       | DIRECT           | N                  | DE              |                      |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Anxiety; Completed<br>Suicide; Disturbance In<br>Attention; Flight Of Ideas;<br>Obsessive Thoughts;<br>Paranoia; Thinking<br>Abnormal | Effexor<br>Lexapro |              |            | S<br>S      | Oral         | 75 Mg Qd Po        |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6749751       | EXPEDITED (15-DAY) | N                  | HO              | GXBR2008US01673      |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Amnesia; Communication Disorder; Disorientation; Feeling Abnormal; Pancreatitis; Road Traffic Accident; Sedation | Trazodone Hydrochloride |              |            | S           |              |                                     |                 | Not Reported |
|                                                                                                                  | Neurontin               |              |            | S           |              |                                     |                 | Not Reported |
|                                                                                                                  | Zoloft                  |              |            | S           | Oral         | Oral                                |                 | Not Reported |
|                                                                                                                  | Alprazolam (Alprazolam) |              |            | S           | Oral         | 2 Mg, Bid, Oral                     |                 | Not Reported |
|                                                                                                                  |                         |              |            |             | Oral         | 2 Mg, Bid, Oral                     |                 |              |
|                                                                                                                  | Seroquel                |              |            | S           | Oral         | 200 Mg, Qhs; Oral; 25 Mg, Qhs, Oral |                 | Not Reported |
|                                                                                                                  | Restoril                |              |            | S           | Oral         | 22.5 Mg, Qd2sdo, Oral               |                 | Not Reported |
|                                                                                                                  | Wellbutrin XL           |              |            | S           | Oral         | 300 Mg, Qd; Oral; 150 Mg, Qd, Oral  |                 | Not Reported |
|                                                                                                                  | Lexapro                 |              |            | S           | Oral         | 15 Mg, Qd; Oral                     |                 | Not Reported |
|                                                                                                                  | Cymbalta                |              |            | S           |              |                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6749772       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000474           |                      | 43 YR      | Female     | USA            |

  

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Lyme Disease | Lexapro        |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                |                |              |            |             | Oral         | See Image          |                 |              |
|                                |                |              |            |             | Oral         | See Image          |                 |              |
|                                |                |              |            |             | Oral         | See Image          |                 |              |
|                                | Aciphex        |              |            | C           |              |                    |                 | Not Reported |
|                                | Celebrex       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6749774       | EXPEDITED (15-DAY) | Y                  | HO              | 1000000337           |                      | 60 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Confusional State; Disorientation; Fall; Inappropriate Antidiuretic Hormone Secretion; Subarachnoid | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D); Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haemorrhage

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6750050       | EXPEDITED (15-DAY) | Y                  | HO              | 080821-0000629       |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dermatitis Bullous;<br>Intentional Overdose;<br>Toxicity To Various Agents | Tranxene T-Tab       |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                                            | Zyprexa              |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                                            | Atarax               |              |            | S           | Oral         | ; Po               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2008              | 6751403       | EXPEDITED (15-DAY) | Y                  | DE              | 1000000491           |                      | 23 YR      | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Completed Suicide; Gun<br>Shot Wound | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2008              | 6744732       | DIRECT           | N                  | HO, OT          |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Nephrolithiasis       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2008              | 6750826       | EXPEDITED (15-DAY) | Y                  | HO              | 1000000600           |                      | 63 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Haemolytic Anaemia;<br>Jaundice; White Blood<br>Cell Count Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                      | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1<br>D),Oral  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                            |   |      |                                    |              |
|----------------------------|---|------|------------------------------------|--------------|
| Escitalopram Oxalate       | S | Oral | 4.8 Mg (4.8 Mg, 1 In 1 D),<br>Oral | Not Reported |
| Opipram (Tablets)          | C |      |                                    | Not Reported |
| Aspirin                    | C |      |                                    | Not Reported |
| Calcium (Chewable Tablets) | C |      |                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2008              | 6751387       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000611           |                      | 56 YR      | Male       | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Benign Prostatic Hyperplasia; Urinary Retention | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                 | Abilify              |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)          |                 | Not Reported |
|                                                 | Insulin Nos          |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 27-Aug-2008              | 6739506       | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-ABBOTT-08P-056-<br>0471571-00 |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression;<br>Craniocerebral Injury;<br>Death; Disturbance In Attention; Fall;<br>Psychomotor Retardation;<br>Restlessness; Subdural Haematoma | Depakene                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Depakene                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Memantine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Loxapine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Mianserin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Mianserin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Acetylsalicylic Acid    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                 | Clonazepam              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                 | Risperidone             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2008              | 6746905       | DIRECT           | N                  | OT              |                      |                      | 56 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Condition Aggravated;<br>Disturbance In Attention;<br>Feeling Abnormal;<br>Memory Impairment;<br>Restless Legs Syndrome;<br>Weight Increased | Lexapro                       |                    |                    | S               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Wellbutrin XL                 |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Synthroid                     |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Nasonex                       |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Gabapentin                    |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Cyclobenzaprine Hydrochloride |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Prednisone                    |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Naproxen                      |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2008                                                                                                                                  | 6753445                       | EXPEDITED (15-DAY) | Y                  | DS              | 1000000619                   |                                  | 53 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                                                                                                           | Escitalopram Oxalate          |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                              | Escitalopram Oxalate          |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                              | Diazepam                      |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2008                                                                                                                                  | 6440617                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | L07-UKI-05193-01             |                                  | 76 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Potentiating Drug<br>Interaction; Sinus<br>Bradycardia; Torsade De<br>Pointes; Ventricular<br>Tachycardia       | Escitalopram Oxalate          |                    |                    | S               | Oral                         | 10 Mg (10 Mg), Oral              |                 | Not Reported |                |
|                                                                                                                                              | Propranolol                   |                    |                    | S               |                              | 80 Mg (80 Mg, D)                 |                 | Not Reported |                |
|                                                                                                                                              | Donepezil Hydrochloride       |                    |                    | S               |                              | 10 Mg (10 Mg, D)                 |                 | Not Reported |                |
|                                                                                                                                              | Omeprazole                    |                    |                    | S               |                              | 20 Mg (20 Mg)                    |                 | Not Reported |                |
|                                                                                                                                              | Ferrous Sulfate               |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                              | Prochlorperazine              |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2008                                                                                                                                  | 6743879                       | EXPEDITED (15-DAY) | N                  | OT              | PE-PFIZER INC-<br>2008068349 |                                  | 59 YR           | Female       | PER            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Asthenia;<br>Back Pain; Hepatic Pain;<br>Jaundice; Renal Pain | Xanax Xr             |              |            | S           |              | Daily Dose:1mg     |                 | Not Reported |
|                                                                               | Xanax Xr             |              |            | S           |              |                    |                 | Not Reported |
|                                                                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2008              | 6753518       | EXPEDITED (15-DAY) |                    | HO              | 004036               |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Hypothyroidism; Mental<br>Status Changes;<br>Overdose | Pletal                      |              |            | S           |              | 100 Mg, Bid, Unk       |                 | Not Reported |
|                                                       | Lexapro                     |              |            | S           |              | 10 Mg, Qam, Unk        |                 | Not Reported |
|                                                       | Amitriptyline Hydrochloride |              |            | S           |              | 25 Mg, Qpm, Unk        |                 | Not Reported |
|                                                       | Vytorin                     |              |            | S           |              | 1 Df, Bid,Unk          |                 | Not Reported |
|                                                       | Combivent                   |              |            | S           |              | 2 Puff, Tid, Unk       |                 | Not Reported |
|                                                       | Synthroid                   |              |            | S           |              | 50 Unk, Qam, Unk       |                 | Not Reported |
|                                                       | Chantix                     |              |            | S           |              | Unk,Unk,Unk            |                 | Not Reported |
|                                                       | Lisinopril                  |              |            | S           |              | 40 Mg, Qam, Unk        |                 | Not Reported |
|                                                       | Lyrica                      |              |            | S           |              | 100 Mg, Tid, Unk       |                 | Not Reported |
|                                                       | Metformin Hydrochloride     |              |            | S           |              | 500 Mg,Qam,Unk         |                 | Not Reported |
|                                                       | Metformin Hydrochloride     |              |            | S           |              | 1000mg, Qpm,Unk        |                 | Not Reported |
|                                                       | Coreg                       |              |            | S           |              | 25 Mg, Bid, Unk        |                 | Not Reported |
|                                                       | Isosorbide                  |              |            | S           |              | 10 Mg, Daily Dose, Unk |                 | Not Reported |
|                                                       | Plavix                      |              |            | S           |              | 75 Mg, Daily Dose, Unk |                 | Not Reported |
|                                                       | Actos                       |              |            | S           |              | 30 Mg, Daily Dose, Unk |                 | Not Reported |
|                                                       | Oxycodone Hydrochloride     |              |            | S           |              | 5 Mg, Tid, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2008              | 6760005       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00138        |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                       |                      |   |      |                             |              |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|-----------------------------|--------------|
| Breech Presentation;<br>Caesarean Section;<br>Maternal Drugs Affecting<br>Foetus; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Escitalopram Oxalate | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|-----------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2008              | 6747112       | DIRECT           | N                  | HO              |                      |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure; Swelling Face | Lexapro        |              |            | S           | Oral         | Once A Day Po      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2008              | 6756816       | EXPEDITED (15-DAY) | Y                  | HO              | 1000000707           |                      | 79 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Chronic Kidney Disease;<br>Confusional State;<br>Dehydration; Diarrhoea;<br>Hyponatraemia; Loss Of<br>Consciousness;<br>Orthostatic Hypotension | Escitalopram Oxalate                  |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                 | Kardegic (Acetylsalicylate<br>Lysine) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                 | Ebixa                                 |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                 | Aricept                               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                 | Coolmetec                             |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2008              | 6747222       | EXPEDITED (15-DAY) |                    | OT              | GB-TEVA-176754ISR    |                      | 60 YR      | Female     | GBR            |

| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disturbance In Sexual<br>Arousal | Fluoxetine                |              |            | S           |              |                    |                 | Teva         |
|                                  | Paroxetine Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                                  | Sertraline                |              |            | S           |              |                    |                 | Not Reported |
|                                  | Escitalopram Oxalate      |              |            | S           |              |                    |                 | Not Reported |
|                                  | Venlafaxine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Sep-2008              | 6748060       | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-ABBOTT-08P-056-0472756-00 |                      | 77 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Disturbance In Attention; Fall; Gait Disturbance; Psychomotor Skills Impaired; Subdural Haematoma | Depakene                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Depakene                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Loxapine                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Mianserin Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Mianserin Hydrochloride |              |            | S           | Oral         | Dose Increased Nos |                 | Not Reported |
|                                                                                                               | Memantine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Clonazepam              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                               | Acetylsalicylic Acid    |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2008              | 6752735       | DIRECT           | N                  | DE              |                      |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2008              | 6760696       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000712           |                      | 38 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------|-----------------|--------------|
| Amnesia; Anxiety; Decreased Appetite; Depression; Insomnia; Nausea; Sexual Dysfunction; Suicidal Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D), Oral; 10 Mg (10 Mg,1 In 1 D), Oral |                 | Not Reported |
|                                                                                                           |                      |              |            |             | Oral         | 5 Mg (5 Mg,1 In 1 D), Oral; 10 Mg (10 Mg,1 In 1 D), Oral |                 |              |

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| Multivitamin Nos                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |                    | C                  |                 |                              | Not Reported         |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Sep-2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6761489        | DIRECT             | N                  | RI              |                              |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Disorder;<br>Blepharospasm; Blood<br>Pressure Increased;<br>Burning Sensation; Chest<br>Pain; Condition<br>Aggravated; Depression;<br>Disturbance In Attention;<br>Dizziness; Dry Skin; Ear<br>Discomfort; Eyelid<br>Disorder; Eyelid Oedema;<br>Feeling Abnormal;<br>Haemangioma; Headache;<br>Memory Impairment;<br>Musculoskeletal Stiffness;<br>Nervousness; Penis<br>Disorder; Skin Fissures;<br>Speech Disorder;<br>Swelling; Testicular<br>Disorder; Vasodilatation | Lexapro        |                    |                    | S               | Oral                         | 10 Mg Per Day Po     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Sep-2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6730096        | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | AU-PFIZER INC-<br>2008066955 |                      | 31 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;<br>Hypomania                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Champix        |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Lexapro        |                    |                    | S               | Oral                         | Daily Dose:20mg      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Maxolon        |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Mirena         |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Symbicort      |                    |                    | C               | Respiratory<br>(inhalation)  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Ventolin       |                    |                    | C               |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Marijuana                                                                                                                                                                                                                                                                                         |                                                                    | C                  |                    | Not Reported     |                              |                                               |                 |                                                              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|-----------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| Alcohol                                                                                                                                                                                                                                                                                           |                                                                    | C                  |                    | Not Reported     |                              |                                               |                 |                                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 05-Sep-2008                                                                                                                                                                                                                                                                                       | 6754825                                                            | DIRECT             | Y                  | OT               |                              |                                               | 28 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                             | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Decreased Appetite;<br>Dizziness; Hypoaesthesia;<br>Infection; Insomnia;<br>Metabolic Disorder;<br>Muscle Tightness; Muscle<br>Twitching; Myalgia;<br>Nervous System Disorder;<br>Neuropathy Peripheral;<br>Palpitations; Paraesthesia;<br>Restless Legs Syndrome;<br>Tremor; Weight<br>Decreased | Lexapro                                                            |                    |                    | S                | Oral                         | 20mg Daily Po                                 |                 | Forest                                                       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 05-Sep-2008                                                                                                                                                                                                                                                                                       | 6762570                                                            | EXPEDITED (15-DAY) | N                  | OT               | 1000000738                   |                                               |                 | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                             | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Blood Alcohol Increased                                                                                                                                                                                                                                                                           | Lexapro<br>Alcohol                                                 |                    |                    | S<br>S           |                              |                                               |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                          | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 05-Sep-2008                                                                                                                                                                                                                                                                                       | 6762830                                                            | EXPEDITED (15-DAY) | Y                  | HO, LT           | 080827-0000645               |                                               | 26 YR           | Female                                                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                             | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Blood Alcohol Increased;<br>Coma; Incorrect Dose<br>Administered;<br>Leukocytosis; Pneumonia<br>Aspiration; Pneumonia<br>Staphylococcal; Rhonchi;                                                                                                                                                 | Tranxene T-Tab<br>Anafranil<br>Cyamemazine<br>Escitalopram Oxalate |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | 10 Mg; ;Op<br>75 Mg; ;Op<br>25 Mg; ;Op<br>;Op |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Suicide Attempt; Toxicity  
To Various Agents

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2008              | 6501351       | EXPEDITED (15-DAY) | Y                  | CA, DE, HO      | A0687245A            |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Atrial Septal Defect;<br>Cardiac Disorder; Death;<br>Heart Disease Congenital;<br>Maternal Exposure During<br>Pregnancy; Patent Ductus<br>Arteriosus; Pneumothorax | Paxil          |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                                                    | Lexapro        |              |            | S           |              | 10mg Per Day       |                 | Not Reported    |
|                                                                                                                                                                    | Prozac         |              |            | S           |              | 10mg Per Day       |                 | Not Reported    |
|                                                                                                                                                                    |                |              |            |             |              |                    |                 |                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2008              | 6751076       | EXPEDITED (15-DAY) | Y                  | OT              | GB-ABBOTT-08P-167-0473942-00 |                      | 58 YR      | Female     | GBR            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Suicidal<br>Ideation | Depakote       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                | Cipralelex     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                | Cipralelex     |              |            | S           |              |                    |                 | Not Reported |
|                                | Mirtazapine    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                | Mirtazapine    |              |            | S           |              |                    |                 | Not Reported |
|                                | Lithium        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2008              | 6751134       | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2008072477 |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Bradycardia; Syncope  | Accupril         |              |            | S           |              |                         |                 | Not Reported |
|                       | Omacor           |              |            | S           |              |                         |                 | Not Reported |
|                       | Sunitinib Malate |              |            | S           | Oral         |                         |                 | Not Reported |
|                       | Coreg            |              |            | S           |              |                         |                 | Not Reported |
|                       | Humalog          |              |            | S           |              | Text:25 Mg In Am; 25 Mg |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                     |                |                           |                    |                 |                      | In Pm (50/50)                                    |                 |                 |                |
|-----------------------------------------------------------------------------------------------------|----------------|---------------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|-----------------|----------------|
|                                                                                                     |                | Hydralazine Hydrochloride |                    | S               |                      |                                                  |                 |                 | Not Reported   |
|                                                                                                     |                | Lexapro                   |                    | S               |                      |                                                  |                 |                 | Not Reported   |
|                                                                                                     |                | Novolog                   |                    | S               | Subcutaneous         | Text:100 Units/MI-Freq:Tid                       |                 |                 | Not Reported   |
|                                                                                                     |                | Pravachol                 |                    | S               |                      |                                                  |                 |                 | Not Reported   |
|                                                                                                     |                | Acetylsalicylic Acid      |                    | C               |                      |                                                  |                 |                 | Not Reported   |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2008                                                                                         | 6541029        | EXPEDITED (15-DAY)        | Y                  | DE              | S08-USA-00135-01     |                                                  | 28 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Aphasia; Dysarthria;<br>Dyspnoea; Pulmonary<br>Congestion                                           | Lexapro        |                           |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2008                                                                                         | 6759646        | DIRECT                    | N                  | RI              |                      |                                                  | 28 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Withdrawal<br>Syndrome                                                                         | Paxil          |                           |                    | S               | Oral                 | 75mg 1 Daily Po                                  |                 | Glaxosmithkline |                |
|                                                                                                     | Lexapro        |                           |                    | S               | Oral                 | 20mg 1 Dially Po                                 |                 | Astrazeneca     |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2008                                                                                         | 6764873        | EXPEDITED (15-DAY)        | N                  | HO, OT          | 1000000820           |                                                  | 49 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardiac Output<br>Decreased; Drug<br>Withdrawal Syndrome;<br>Dyspnoea; Hypotension;<br>Irritability | Lexapro        |                           |                    | S               | Oral                 | 10 Mg (1 In 1 D) Per Oral;<br>5 Mg, Occasionally |                 | Not Reported    |                |
|                                                                                                     | Yasmin         |                           |                    | S               | Oral                 | 10 Mg (1 In 1 D) Per Oral;<br>5 Mg, Occasionally |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2008              | 6764889       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000782           |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Rheumatoid Arthritis  | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                                     |                 | Not Reported |
|                       | Bromazepam           |              |            | C           |              |                                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2008              | 6765724       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000806           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Dry Mouth; Dyspepsia; Enzyme Abnormality; Weight Decreased | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2008              | 6765868       | EXPEDITED (15-DAY) | Y                  | DS              | 1000000831           |                      | 60 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Visual Field Defect   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Remeron              |              |            | C           |              |                                  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2008              | 6367471       | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2007CH12301      |                      | 85 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Agitation; Akinesia; Antidepressant Drug Level Increased; Anxiety; C-Reactive Protein Increased; Clonus; Confusional State; Delirium; Disorientation; Drug Interaction; Extrapyrimal Disorder; Fall; General Physical Health Deterioration; Heart Rate Increased; Hyperreflexia; Muscle Rigidity; Personality Change; Pyrexia; Serotonin Syndrome; Urinary Tract Infection | Cefuroxime Axetil        |              |            | S           | Unknown                               |                    | 11 DAY          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Azathioprine             |              |            | C           |                                       | 75 Mg/D            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Perfalgan                |              |            | C           | Intravenous (not otherwise specified) | 1 G/D              | 2 DAY           | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Vancomycin Hydrochloride |              |            | C           | Intravenous (not otherwise specified) | 1500 Mg/D          | 6 DAY           | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Rocephin                 |              |            | C           | Intravenous (not otherwise specified) | 2000 Mg/D          | 2 DAY           | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Ebixa                    |              |            | C           |                                       | 20 Mg/D            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Haldol                   |              |            | C           |                                       | Unk, Prn           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Lorazepam                |              |            | C           |                                       | 1.5 Mg/D           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Rocaltrol                |              |            | C           |                                       | 0.25 Ug/D          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Calcium Seroquel         |              |            | C           |                                       | 12.5 Mg/D          | 10 DAY          | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Sandimmune               |              |            | S           | Unknown                               | 125 Mg/D           |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                                                                                            | Cipralelex               |              |            | S           | Unknown                               | 10 Mg/D            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                            | Cipralelex               |              |            | S           | Unknown                               | 15 Mg              | 2 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 10-Sep-2008              | 6444401       | EXPEDITED (15-DAY) | Y                  | HO, LT          | US-AVENTIS-200714845EU |                      | 72 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chest Pain; Dyspnoea  | Lovenox                 |              |            | S           | Subcutaneous |                    |                 | Aventis      |
|                       | Methadone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lexapro                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Coumadin                |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |                                       |              |
|------------------------|---|---------------------------------------|--------------|
| Coumadin               | S | Oral                                  | Not Reported |
| Reglan                 | C | Oral                                  | Not Reported |
| Ntg                    | C | Oral                                  | Not Reported |
| Gabapentin             | C | Oral                                  | Not Reported |
| Unspecified Ingredient | C | Intravenous (not otherwise specified) | Not Reported |
| Unspecified Ingredient | C | Intravenous (not otherwise specified) | Not Reported |
| Unspecified Ingredient | C | Intravenous (not otherwise specified) | Not Reported |
| Paclitaxel             | C | Intravenous (not otherwise specified) | Not Reported |
| Paclitaxel             | C | Intravenous (not otherwise specified) | Not Reported |
| Paclitaxel             | C | Intravenous (not otherwise specified) | Not Reported |
| Carboplatin            | C | Intravenous (not otherwise specified) | Not Reported |
| Carboplatin            | C | Intravenous (not otherwise specified) | Not Reported |
| Carboplatin            | C | Intravenous (not otherwise specified) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2008              | 6700096       | EXPEDITED (15-DAY) | Y                  | HO              | S08-DEN-02225-01     |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Gynaecomastia         | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg, (10 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Sep-2008              | 6736403       | EXPEDITED (15-DAY) | N                  | DS, OT          | DK-PFIZER INC-<br>2008068205 |                      | 34 YR      | Female     | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------|------------------------|-----------------|--------------|----------------|
| Tooth Loss                                              | Lyrica                        |                    |                    | S               | Oral                    | Daily Dose:375mg       |                 | Not Reported |                |
|                                                         | Cipralext                     |                    |                    | S               | Oral                    |                        |                 | Not Reported |                |
|                                                         | Zyprexa                       |                    |                    | S               | Oral                    |                        |                 | Not Reported |                |
|                                                         | Chlorprothixene Hydrochloride |                    |                    | S               | Oral                    | Freq:Three Times Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2008                                             | 6741345                       | EXPEDITED (15-DAY) | Y                  | HO              | PHBS2008CH05513         |                        | 84 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Hyperthermia; Serotonin Syndrome              | Ciclosporin                   |                    |                    | S               |                         |                        |                 | Novartis     |                |
|                                                         | Escitalopram Oxalate          |                    |                    | S               |                         |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2008                                             | 6763069                       | DIRECT             | N                  | CA, DE          |                         |                        | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Migraine; Pregnancy | Lexapro                       |                    |                    | S               | Oral                    | 10mg Once Daily Po     |                 | Not Reported |                |
|                                                         | Zoloft                        |                    |                    | S               | Oral                    | 50mg Once Daily Po     |                 | Pfizer       |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2008                                             | 6753355                       | EXPEDITED (15-DAY) | Y                  | OT              | GB-RANBAXY-2008RR-17654 |                        |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Sexual Arousal                           | Fluoxetine                    |                    |                    | S               |                         |                        |                 | Ranbaxy      |                |
|                                                         | Escitalopram Oxalate          |                    |                    | S               |                         |                        |                 | Not Reported |                |
|                                                         | Paroxetine Hydrochloride      |                    |                    | S               |                         |                        |                 | Not Reported |                |
|                                                         | Sertraline                    |                    |                    | S               |                         |                        |                 | Not Reported |                |
|                                                         | Venlafaxine                   |                    |                    | S               |                         |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2008                                             | 6767896                       | DIRECT             | Y                  | HO              |                         |                        | 35 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Agitation; Confusional<br>State; Delirium;<br>Hallucinations, Mixed;<br>Incorrect Dose<br>Administered; Mental<br>Status Changes;<br>Phaeochromocytoma;<br>Serotonin Syndrome;<br>Somnambulism | Trazodone Hydrochloride  |                    |                    | S               | Oral                           | 100 Mg Tid Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Escitalopram Oxalate     |                    |                    | S               | Oral                           | 20 Mg Every Day Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2008                                                                                                                                                                                                           | 6763812                  | DIRECT             | Y                  | HO              |                                |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Antidiuretic<br>Hormone Secretion                                                                                                                                                                       | Lexapro                  |                    |                    | S               | Oral                           | 10mg Daily Po        |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Levothyroxine            |                    |                    | C               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2008                                                                                                                                                                                                           | 6774185                  | EXPEDITED (15-DAY) | Y                  | OT              | 2008AP002288                   |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Sexual<br>Arousal                                                                                                                                                                                      | Paroxetine Hydrochloride |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Sertraline Hydrochloride |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Escitalopram Oxalate     |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Fluoxetine Hcl           |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                       | Venlafaxine              |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2008                                                                                                                                                                                                           | 6759283                  | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ASTRAZENECA-<br>2008CG01329 |                      | 77 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma; Drug<br>Interaction; Intentional                                                                                                                                                                   | Tenormin                 |                    |                    | S               | Oral                           |                      | 1 DAY           | Not Reported |                |
|                                                                                                                                                                                                                       | Digoxin                  |                    |                    | C               |                                |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                                              |   |      |  |       |  |  |              |
|----------------------------------------------------|----------------------------------------------|---|------|--|-------|--|--|--------------|
| Overdose; International Normalised Ratio Increased | Propoxyphene Hydrochloride And Acetaminophen | C |      |  |       |  |  | Not Reported |
|                                                    | Havlane                                      | C |      |  |       |  |  | Not Reported |
|                                                    | Previscan (Fluindione)                       | S | Oral |  | 1 YR  |  |  | Not Reported |
|                                                    | Previscan                                    | S | Oral |  |       |  |  | Not Reported |
|                                                    | Prozac                                       | S | Oral |  | 1 DAY |  |  | Not Reported |
|                                                    | Escitalopram Oxalate                         | S | Oral |  |       |  |  | Not Reported |
|                                                    | Cortancyl                                    | S | Oral |  | 1 DAY |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2008              | 6766363       | DIRECT           | N                  |                 |                      |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Abnormal Behaviour; Diarrhoea; Mental Disorder; Product Counterfeit; Product Quality Issue; Rash Pruritic | Lexapro        |              |            | S           | Oral         | 10mg 1 Daily Po    |                 | Forest                 |
|                                                                                                           | Wellbutrin     |              |            | S           | Oral         | 200mg 2 Daily Po   |                 | Global Pharmaceuticals |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2008              | 6773107       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000920           |                      | 16 YR      | Unknown    | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Intentional Overdose; Mydriasis; Sopor; Suicide Attempt | Escitalopram Oxalate   |              |            | S           | Oral         | (80 Mg, Once), Oral |                 | Not Reported |
|                                                         | Unspecified Ingredient |              |            | S           | Oral         | (Once), Oral        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2008              | 6688771       | EXPEDITED (15-DAY) | Y                  | HO, OT          | S08-USA-02110-01     |                      | 73 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Bundle Branch Block Right; Cardiac Aneurysm; | Lexapro        |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                              |                     |        |      |                                                                                |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------|------|--------------------------------------------------------------------------------|------------------------------|
| Cholecystitis Acute;<br>Cholelithiasis; Clostridial<br>Infection; Condition<br>Aggravated; Drug<br>Ineffective; Fluid Overload;<br>Pancreatic Cyst;<br>Pneumonia; Pulmonary<br>Congestion; Tremor;<br>Ventricular Arrhythmia | Diazepam<br>Lipitor | C<br>C | Oral | D), Oral<br>20 Mg (10 Mg, 2 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral | Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------|------|--------------------------------------------------------------------------------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2008              | 6773993       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000928           |                      | 4 YR       | Unknown    | DNK            |

| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Intentional Overdose;<br>Poisoning; Somnolence;<br>Victim Of Crime | Escitalopram Oxalate |              |            | S           | Oral         | (100 Mg, Once) Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2008              | 6774272       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000929           |                      | 60 YR      | Female     | DNK            |

| <u>Preferred Term</u>             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Female Sexual Arousal<br>Disorder | Escitalopram Oxalate      |              |            | S           |              |                    |                 | Not Reported |
|                                   | Fluoxetine                |              |            | S           |              |                    |                 | Not Reported |
|                                   | Paroxetine Hydrochloride  |              |            | S           |              |                    |                 | Not Reported |
|                                   | Sertraline                |              |            | S           |              |                    |                 | Not Reported |
|                                   | Venlafaxine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2008              | 6774316       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000942           |                      | 3 YR       | Unknown    | DNK            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Accidental Exposure To<br>Product; Dysarthria;<br>Electrocardiogram Qt<br>Prolonged; Muscle<br>Spasms; Somnolence; | Escitalopram Oxalate |              |            | S           | Oral         | (50 Mg, Once), Oral  |                 | Not Reported |
|                                                                                                                    | Pipamperone          |              |            | S           | Oral         | (200 Mg, Once), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2008              | 6774405       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000912           |                      | 49 YR      | Unknown    | DNK            |

| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Depressed Level Of Consciousness; Intentional Overdose; Suicide Attempt; Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | (70 Mg, Once), Oral |                 | Not Reported |
|                                                                                      | Zyprexa              |              |            | S           | Oral         | (Once), Oral        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2008              | 6636855       | EXPEDITED (15-DAY) | N                  | LT              | B0516569A            |                      | 38 YR      | Female     | PRT            |

| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Adhesion; Dyskinesia; Erythema; Genital Ulceration; Lip Swelling; Pyrexia; Rash; Skin Exfoliation; Skin Hyperpigmentation; Skin Lesion; Stevens-Johnson Syndrome | Lamictal               |              |            | S           | Oral         | 50mg Per Day       | 23 DAY          | Glaxosmithkline |
|                                                                                                                                                                  | Escitalopram Oxalate   |              |            | S           | Oral         | 10mg Per Day       | 23 DAY          | Not Reported    |
|                                                                                                                                                                  | Unspecified Ingredient |              |            | C           | Oral         |                    |                 | Not Reported    |
|                                                                                                                                                                  | Zolpidem Tartrate      |              |            | C           | Oral         |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2008              | 6598301       | EXPEDITED (15-DAY) | Y                  | OT              | S08-USA-00100-01     |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Caesarean Section; Haemorrhage; Maternal Exposure During Pregnancy; Placenta Praevia; Pregnancy | Lexapro                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 2 D), Oral |                 | Not Reported |
|                                                                                                 | Miralax (Macrogol) (Macrogol) |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                 | Vitamins (Nos)                |              |            | C           |              |                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 18-Sep-2008                                                                                                                        | 6710932                   | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2008061506                          |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Crying; Ill-Defined<br>Disorder; Incorrect Dose<br>Administered; Road Traffic<br>Accident; Trichotillomania | Chantix                   |                    |                    | S               | Oral                                              |                      |                 | Not Reported |                |
|                                                                                                                                    | Ambien                    |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Lexapro                   |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Zolpidem Tartrate         |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Valsartan                 |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Lisinopril                |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Labetalol                 |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Sep-2008                                                                                                                        | 6775748                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000000736                                        |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased;<br>Drug Ineffective; Overdose                                                                             | Lexapro                   |                    |                    | S               | Oral                                              | See Image            |                 | Not Reported |                |
|                                                                                                                                    |                           |                    |                    |                 | Oral                                              | See Image            |                 |              |                |
|                                                                                                                                    |                           |                    |                    |                 | Oral                                              | See Image            |                 |              |                |
|                                                                                                                                    |                           |                    |                    |                 | Oral                                              | See Image            |                 |              |                |
|                                                                                                                                    | Clonidine                 |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2008                                                                                                                        | 6385149                   | EXPEDITED (15-DAY) | N                  | OT              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200700907 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug<br>Interaction; Dyspnoea                                                                                   | Lortab                    |                    |                    | S               | Oral                                              | 5 Mg, Qd             | 4 DAY           | Tyco         |                |
|                                                                                                                                    | Lexapro                   |                    |                    | S               | Oral                                              | 10 Mg, Qd            |                 | Not Reported |                |
|                                                                                                                                    | Gemcitabine Hydrochloride |                    |                    | S               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Spiriva                   |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Serevent Diskus           |                    |                    | C               |                                                   |                      |                 | Not Reported |                |
|                                                                                                                                    | Unspecified Ingredient    |                    |                    | C               |                                                   |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------|-----------------|--------------|----------------|
| 19-Sep-2008                                                                                  | 6717906                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000000065                   |                                 | 70 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide; Mental Disorder                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                              | Metformin Hydrochloride |                    |                    | C               |                              |                                 |                 | Not Reported |                |
|                                                                                              | Crestor                 |                    |                    | C               |                              |                                 |                 | Not Reported |                |
|                                                                                              | Lecinopril              |                    |                    | C               |                              |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2008                                                                                  | 6718242                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000000043                   |                                 | 53 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Dyskinesia; Escherichia Urinary Tract Infection; Tremor | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 20 Mg, (10 Mg, 2 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                              | Seroquel                |                    |                    | S               | Oral                         | See Image                       |                 | Not Reported |                |
|                                                                                              | Tiapride                |                    |                    | S               | Oral                         | See Image                       |                 | Not Reported |                |
|                                                                                              |                         |                    |                    | S               | Oral                         | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                              | Lorazepam               |                    |                    |                 | Oral                         | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                              |                         |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D),Oral      |                 | Not Reported |                |
|                                                                                              | Lithium Carbonate       |                    |                    | C               |                              |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2008                                                                                  | 6765900                 | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-08P-163-0476197-00 |                                 | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme Increased                                                                     | Lexapro                 |                    |                    | S               | Oral                         |                                 |                 | Not Reported |                |
|                                                                                              | Unspecified Ingredient  |                    |                    | S               |                              |                                 |                 | Not Reported |                |
|                                                                                              | Clonazepam              |                    |                    | C               |                              |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 22-Sep-2008                 | 6766182                  | NON-EXPEDITED      | Y                  | HO, OT          | FR-VALEANT-2008VX001823    |                      | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                   | Librium                  |                    |                    | S               | Oral                       | Dose Unit:Unknown    |                 | Not Reported |                |
|                             | Escitalopram Oxalate     |                    |                    | S               | Oral                       | Dose Unit:Unknown    |                 | Not Reported |                |
|                             | Pyridoxine Hydrochloride |                    |                    | S               | Oral                       | Dose Unit:Unknown    |                 | Not Reported |                |
|                             | Pyridoxine Hydrochloride |                    |                    | S               | Oral                       | Dose Unit:Unknown    |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2008                 | 6773486                  | DIRECT             | Y                  | OT              |                            |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphagia; Muscle Tightness | Lexapro                  |                    |                    | S               | Oral                       | 10mg One Qd Po       |                 | Forest       |                |
| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2008                 | 6778545                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000001011                 |                      | 25 YR           | Female       | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bulimia Nervosa             | Escitalopram Oxalate     |                    |                    | S               | Oral                       | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2008                 | 6767425                  | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2007UW23647 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen False Positive  | Seroquel                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                             | Lexapro                  |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 23-Sep-2008                                                                                                                   | 6778606                 | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | 1000000978                 |                               | 69 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Balance Disorder; Brain Injury; Cognitive Disorder; Dizziness; Fall; Hyponatraemia; Impaired Self-Care; Incontinence | Escitalopram Oxalate    |                    |                    | S               | Oral                       | (Once), Oral                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2008                                                                                                                   | 6779038                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000001016                 |                               | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                                              | Lexapro                 |                    |                    | S               | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2008                                                                                                                   | 6604468                 | EXPEDITED (15-DAY) | Y                  |                 | NO-PFIZER INC-2008026809   |                               |                 | Female       | NOR            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Drug Intolerance; Hallucination; No Adverse Event                                           | Zoloft                  |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                               | Citalopram Hydrobromide |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                               | Ciprallex               |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                               | Triphasil-21            |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                               | Zopiclone               |                    |                    | C               | Oral                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2008                                                                                                                   | 6768342                 | NON-EXPEDITED      | Y                  |                 | US-ASTRAZENECA-2008UW12500 |                               | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                         |   |      |              |
|------------------------|-------------------------|---|------|--------------|
| Blood Testosterone     | Seroquel                | S | Oral | Not Reported |
| Abnormal; Hepatitis C; | Lexapro                 | S |      | Not Reported |
| Libido Decreased       | Methadone Hydrochloride | S |      | Not Reported |
|                        | Strattera               | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 24-Sep-2008              | 6770139        | NON-EXPEDITED    | Y                  | HO, OT          | US-ASTRAZENECA-2008UW01599 |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                 | Seroquel       |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Seroquel       |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 24-Sep-2008                                                  | 6781567                | EXPEDITED (15-DAY) | Y                  | OT              | 1000001029           |                               | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; International Normalised Ratio Fluctuation | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                              | Unspecified Ingredient |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 24-Sep-2008                               | 6783323              | EXPEDITED (15-DAY) | Y                  | DS              | 1000001025           |                              | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Accommodation Disorder; Visual Impairment | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In1 D), Oral |                 | Not Reported |                |
|                                           | Etoricoxib           |                    |                    | C               |                      |                              |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2008              | 6914727       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001013           |                      | 51 YR      | Female     | ESP            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Affect Lability;<br>Inappropriate Affect | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                          | Difur                |              |            | C           |              |                               |                 | Not Reported |
|                                          | Enbrel               |              |            | C           |              |                               |                 | Not Reported |
|                                          | Lorazepam            |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2008              | 7385690       | DIRECT           | Y                  |                 |                      |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased;<br>Aspartate Aminotransferase Increased;<br>Blood Alkaline Phosphatase Increased;<br>Blood Bilirubin Increased;<br>Fatigue; Jaundice; Liver Injury; Pruritus; Weight Decreased | Klonopin       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                    | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                    | Protonix       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                    | Labetalol      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                    | Multi-Vitamin  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 25-Sep-2008              | 6643578       | EXPEDITED (15-DAY) | Y                  | DE              | CH-ASTRAZENECA-2008PK00997 |                      | 43 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                       | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Shock; Toxicity To Various Agents; Vomiting | Seroquel        |              |            | S           | Oral         |                    | 305 DAY         | Not Reported |
|                                                             | Ciprallex       |              |            | S           | Oral         |                    | 427 DAY         | Not Reported |
|                                                             | Chloral Hydrate |              |            | S           | Oral         |                    | 185 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2008              | 6770985       | NON-EXPEDITED    | N                  |                 | A0669226A            |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                        |   |         |                 |
|------------------------------------|------------------------|---|---------|-----------------|
| Drug Interaction; Muscle Twitching | Wellbutrin XI          | S | Oral    | Glaxosmithkline |
|                                    | Lexapro                | S | Unknown | Not Reported    |
|                                    | Unspecified Ingredient | C |         | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2008              | 6771119       | NON-EXPEDITED    | N                  |                 | A0688264A            |                      | 59 YR      | Male       | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Depression; Insomnia; Libido Decreased; Mood Altered; Tremor | Wellbutrin XI  |              |            | S           | Oral         | 300mcg Per Day     |                 | Glaxosmithkline |
|                                                              | Lexapro        |              |            | S           |              | 5mg Per Day        | 1 MTH           | Not Reported    |
|                                                              | Lotrel         |              |            | C           |              |                    |                 | Not Reported    |
|                                                              | Crestor        |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2008              | 6771510       | NON-EXPEDITED    | N                  |                 | A0733132A            |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anxiety; Depression; Nervousness; Product Quality Issue; Product Residue Present | Bupropion Hydrochloride |              |            | S           | Oral         | 300mg Per Day      | 53 WEEK         | Glaxosmithkline |
|                                                                                  | Bupropion Hydrochloride |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                                                  | Lexapro                 |              |            | S           |              | 20mg Per Day       |                 | Not Reported    |
|                                                                                  | Lexapro                 |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                  | Unspecified Ingredient  |              |            | C           |              |                    |                 | Not Reported    |
|                                                                                  | Lorazepam               |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 25-Sep-2008              | 6771582       | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-14343693 |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Arrhythmia; Bradycardia; Hypoglycaemia; Syncope | Pravachol      |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                                                 | Accupril       |              |            | S           |              |                    |                 | Not Reported         |
|                                                 | Omacor         |              |            | S           |              |                    |                 | Not Reported         |
|                                                 | Coreg          |              |            | S           |              |                    |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                      | Humalog                   |                    | S               |                      | 25mg In Am:25mg In Pm   |                 | Not Reported |                |
|---------------------------------------------------|----------------------|---------------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
|                                                   |                      | Hydralazine Hydrochloride |                    | S               |                      |                         |                 | Not Reported |                |
|                                                   |                      | Lexapro                   |                    | S               |                      |                         |                 | Not Reported |                |
|                                                   |                      | Novolog                   |                    | S               | Subcutaneous         | 1 Df = 100 Units/MI     |                 | Not Reported |                |
|                                                   |                      | Acetylsalicylic Acid      |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2008                                       | 6776964              | DIRECT                    | Y                  | OT              |                      |                         | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Palpitations; Product Quality Issue               | Lexapro              |                           |                    | S               | Oral                 | 20mg Daily Po           |                 | Forest       |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Sep-2008                                       | 6782457              | EXPEDITED (15-DAY)        | Y                  | HO, OT          | 2008S1016649         |                         | 78 YR           | Female       | GBR            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased; Confusional State; Fall   | Indapamide           |                           |                    | S               | Oral                 | 1.5 Mg;Twice A Day;Oral |                 | Not Reported |                |
|                                                   | Escitalopram Oxalate |                           |                    | S               | Oral                 | 1.5 Mg;Twice A Day;Oral |                 | Not Reported |                |
|                                                   | Atenolol             |                           |                    | C               |                      |                         |                 | Not Reported |                |
|                                                   | Omeprazole           |                           |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2008                                       | 6778125              | DIRECT                    | Y                  | HO              |                      |                         | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blister; Burning Sensation; Pruritus; Skin Lesion | Lexapro              |                           |                    | S               | Oral                 | 1 Tab Qd Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2008                                       | 6778380              | DIRECT                    | Y                  | HO              |                      |                         | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          |                                |             |      |    |       |                                        |
|--------------------------------------------------------------------------|--------------------------------|-------------|------|----|-------|----------------------------------------|
| Condition Aggravated;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Lexapro<br>Actonel<br>Claritin | S<br>C<br>C | Oral | Po | 2 DAY | Forest<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------|--------------------------------|-------------|------|----|-------|----------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2008              | 6781840       | EXPEDITED (15-DAY) | N                  | OT              | 1000001015           |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Aggression; Alcohol<br>Poisoning; Physical<br>Assault; Spousal Abuse;<br>Treatment Noncompliance | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                  | Alcohol        |              |            | S           | Oral         | Consumed 6 Beers                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2008              | 6783517       | EXPEDITED (15-DAY) | Y                  | HO              | PAR_02346_2008       |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Bradycardia;<br>Hypoglycaemia; Syncope;<br>Unresponsive To Stimuli | Hydralazine Hydrochloride |              |            | S           |              | (25 Mg Tid)                                                  |                 | Not Reported |
|                                                                                                | Sutent                    |              |            | S           | Oral         | (50 Mg Qd [Held For 2<br>Weeks After Every 4<br>Weeks] Oral) |                 | Not Reported |
|                                                                                                | Nexavar                   |              |            | S           | Oral         | (400 Mg Bid Oral)                                            |                 | Not Reported |
|                                                                                                | Humalog                   |              |            | S           |              | (25 Mg Bid[25 Mg In Am;<br>W5 Mg In Pm] 50/50)               |                 | Not Reported |
|                                                                                                | Accupril                  |              |            | S           |              | 40 Mg Qd                                                     |                 | Not Reported |
|                                                                                                | Coreg                     |              |            | S           |              | 12.5 Mg Qd                                                   |                 | Not Reported |
|                                                                                                | Lexapro                   |              |            | S           |              | 20 Mg Qd                                                     |                 | Not Reported |
|                                                                                                | Pravachol                 |              |            | S           |              | 40 Mg Qd                                                     |                 | Not Reported |
|                                                                                                | Omacor                    |              |            | S           |              | 1000 Mg Qid                                                  |                 | Not Reported |
|                                                                                                | Acetylsalicylic Acid      |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                                | Novolog (Not Specified)   |              |            | C           | Subcutaneous | 100 Df Tid Subcutaneous                                      |                 | Not Reported |
|                                                                                                | Acetylsalicylic Acid      |              |            | C           |              |                                                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 29-Sep-2008                                                                                                                                                                                                                                        | 6659592                                             | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01753-01     |                                  | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Dizziness; Fatigue;<br>Hypotension; Palpitations;<br>Paraesthesia; Tremor                                                                                                                                                                  | Lexapro                                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                    | Tamoxifen Citrate                                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                    | Monopril (Fosinopril Sodium)<br>(Fosinopril Sodium) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                    | Hydrochlorothiazide                                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2008                                                                                                                                                                                                                                        | 6697753                                             | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | S08-GER-02195-01     |                                  | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Respiratory Depression;<br>Somnolence; Suicide<br>Attempt                                                                                                                                                                 | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | 800 Mg, Once, Oral               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                    | Tramadol                                            |                    |                    | S               | Oral                 | 10000 Mg, Once, Oral             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2008                                                                                                                                                                                                                                        | 6725473                                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000000261           |                                  | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Blood Chloride<br>Decreased; Blood<br>Osmolarity Decreased;<br>Epigastric Discomfort;<br>General Physical Health<br>Deterioration;<br>Hypertension;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion; | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                    | Noroxin                                             |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Tremor; Urine Osmolarity  
Decreased; Urine Sodium  
Decreased; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 29-Sep-2008              | 6752507       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-08P-056-0473999-00 |                      | 82 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dementia; Drug Interaction; Haemoptysis; Hypotension; International Normalised Ratio Increased; Overdose | Lipanthyl                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Clopidogrel                  |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Metformin Hydrochloride      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Omeprazole                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Furosemide                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Chondroitin Sulfate (Bovine) |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Tamsulosin Hydrochloride     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Ultracet                     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Perindopril                  |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Lipanthyl                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                          | Escitalopram Oxalate         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Acenocoumarol                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                          | Acenocoumarol                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 29-Sep-2008              | 6774425       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-14100648 |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------|-----------------|----------------------|
| Tremor                | Buspar         |              |            | S           |              |                                                         | 5 DAY           | Bristol Myers Squibb |
|                       | Lexapro        |              |            | S           | Oral         | 10mg Taken From 01sep07 To Oct07 And From Oct07 To Cont |                 | Not Reported         |
|                       | Lyrica         |              |            | C           |              |                                                         |                 | Not Reported         |
|                       | Keppra         |              |            | C           |              |                                                         |                 | Not Reported         |



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|                                                                             | Wellbutrin               |                  |                    | C               |                                                 |                      |                 |                                      | Not Reported   |
|-----------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------------------------------|----------------|
|                                                                             | Imitrex                  |                  |                    | C               |                                                 |                      |                 |                                      | Not Reported   |
|                                                                             | Kerlone                  |                  |                    | C               |                                                 |                      |                 |                                      | Not Reported   |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                           | <u>Country</u> |
| 29-Sep-2008                                                                 | 6774446                  | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14186332 |                      | 47 YR           | Female                               | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                           |                |
| Depression                                                                  | Buspar<br>Lexapro        |                  |                    | S<br>S          |                                                 |                      |                 | Bristol Myers Squibb<br>Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                           | <u>Country</u> |
| 29-Sep-2008                                                                 | 6779011                  | DIRECT           | Y                  |                 |                                                 |                      | 95 YR           | Male                                 | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                           |                |
| Eye Pain; Lethargy                                                          | Lexapro                  |                  |                    | S               | Oral                                            | 10mg Qday Po         |                 | Not Reported                         |                |
|                                                                             | Coumadin                 |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Ferrous Sulfate          |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Benadryl                 |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Docusate                 |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Vitamin B12              |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Vicodin                  |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Combivent                |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Digoxin                  |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Diltiazem Hydrochloride  |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                           | <u>Country</u> |
| 29-Sep-2008                                                                 | 6779240                  | DIRECT           | N                  | RI              |                                                 |                      | 29 YR           | Female                               | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                           |                |
| Dizziness; Fatigue; Loss<br>Of Personal Independence<br>In Daily Activities | Lexapro                  |                  |                    | S               | Oral                                            | 20mg Once Daily Po   |                 | Forest                               |                |
|                                                                             | Fluoxetine               |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |
|                                                                             | Paroxetine Hydrochloride |                  |                    | C               |                                                 |                      |                 | Not Reported                         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 29-Sep-2008                                                                                                                                                                      | 6779246                 | DIRECT             | N                  | HO              |                      |                                  | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Anal Incontinence;<br>Asthenia; Blood Pressure<br>Decreased; Burning<br>Sensation; Fall; Malaise;<br>Muscle Spasms; Pyrexia;<br>Vein Disorder; Vomiting | Lexapro                 |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2008                                                                                                                                                                      | 6785126                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001086           |                                  | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Generalised Tonic-<br>Clonic Seizure                                                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                  | Zyprexa                 |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                                                                                                  | Pegasys (Injection)     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                  | Copegus                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                  | Norvir                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                  | Reyataz (200 Milligram) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2008                                                                                                                                                                      | 6914732                 | DIRECT             | N                  | DE              |                      |                                  | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hospitalisation                                                                                                                                                                  | Lexapro                 |                    |                    | S               | Oral                 | One Daily Po                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2008                                                                                                                                                                      | 6753350                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000000625           |                                  | 38 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                            | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>       |                |
|----------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|-------------------------------|-----------------|------------------|----------------|
| Hypoacusis; Inner Ear Disorder; Nystagmus; Stress                                | Escitalopram Oxalate                         |                    |                    | S               | Oral                                        | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported     |                |
|                                                                                  | Prazepam                                     |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Sep-2008                                                                      | 6774895                                      | EXPEDITED (15-DAY) | Y                  | HO              | AT-RANBAXY-2008RR-18117                     |                               | 34 YR           | Male             | AUT            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Interaction; Mania                                                          | Topiramate                                   |                    |                    | S               |                                             | 100 Mg, Bid                   |                 | Ranbaxy          |                |
|                                                                                  | Escitalopram Oxalate                         |                    |                    | S               |                                             | 10 Mg, Bid                    |                 | Not Reported     |                |
|                                                                                  | Risperidone                                  |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
|                                                                                  | Chlorprothixene                              |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Sep-2008                                                                      | 6775674                                      | EXPEDITED (15-DAY) | N                  | HO              | FR-ELI_LILLY_AND_COMP<br>ANY-FR200809003749 |                               | 77 YR           | Male             | FRA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>       |                |
| Drug Interaction; Intentional Overdose; International Normalised Ratio Increased | Prozac                                       |                    |                    | S               | Oral                                        |                               |                 | Eli Lilly And Co |                |
|                                                                                  | Previscan (Fluindione)                       |                    |                    | C               | Oral                                        | 20 Mg, Unk                    |                 | Not Reported     |                |
|                                                                                  | Hemigoxine                                   |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
|                                                                                  | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
|                                                                                  | Havlane                                      |                    |                    | C               |                                             |                               |                 | Not Reported     |                |
|                                                                                  | Prozac                                       |                    |                    | S               | Oral                                        | 14 D/F, Unk                   | 1 DAY           | Eli Lilly And Co |                |
|                                                                                  | Tenormin                                     |                    |                    | S               | Oral                                        | 14 D/F, Unk                   |                 | Not Reported     |                |
|                                                                                  | Escitalopram Oxalate                         |                    |                    | S               | Oral                                        |                               |                 | Not Reported     |                |
| Cortancyl                                                                        |                                              |                    | S                  | Oral            | 50 Mg, Daily (1/D)                          |                               | Not Reported    |                  |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 30-Sep-2008                                                                      | 6779695                                      | DIRECT             | Y                  | OT              |                                             |                               |                 | Male             | USA            |

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| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Dyspnoea                                                                                                  | Paxil                              |                    |                    | S               | Intravenous (not otherwise specified) | 20 Mg Am Iv                                            |                 | Not Reported |                |
|                                                                                                                    | Lexapro                            |                    |                    | S               | Intravenous (not otherwise specified) | Iv 20 Mg Qd                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2008                                                                                                        | 6782071                            | DIRECT             | N                  | OT              |                                       |                                                        | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Weight Increased                                                                                      | Lexapro                            |                    |                    | S               | Oral                                  | 5mg Daily Po                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2008                                                                                                        | 6784176                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000001090                            |                                                        | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Dementia; Pyrexia                                                                               | Escitalopram Oxalate               |                    |                    | S               | Oral                                  | 5 Mg (5 Mg, 1 In 1 D), Oral                            |                 | Not Reported |                |
|                                                                                                                    | Vastarel                           |                    |                    | C               |                                       |                                                        |                 | Not Reported |                |
|                                                                                                                    | Cacit D3 (Powder)                  |                    |                    | C               |                                       |                                                        |                 | Not Reported |                |
|                                                                                                                    | Tenormin                           |                    |                    | C               |                                       |                                                        |                 | Not Reported |                |
|                                                                                                                    | Minisintrom                        |                    |                    | C               |                                       |                                                        |                 | Not Reported |                |
|                                                                                                                    | Eupressyl (30 Milligram, Capsules) |                    |                    | C               |                                       |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2008                                                                                                        | 6784387                            | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001060                            |                                                        | 77 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Coma; Drug Interaction; Intentional Overdose; International Normalised Ratio Increased; Sinus Arrest; | Escitalopram Oxalate               |                    |                    | S               | Oral                                  | Oral; (Once), Oral                                     |                 | Not Reported |                |
|                                                                                                                    | Prozac                             |                    |                    | S               | Oral                                  | Oral; (Once), Oral<br>(14 Dosage Forms, Once)<br>,Oral |                 | Not Reported |                |

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|                 |                                                 |   |      |                                  |              |
|-----------------|-------------------------------------------------|---|------|----------------------------------|--------------|
| Suicide Attempt | Tenormin                                        | S | Oral | (14 Dosage Forms, Once)<br>,Oral | Not Reported |
|                 | Fluindione                                      | S | Oral | Oral                             | Not Reported |
|                 | Prednisone                                      | S | Oral | (50 Mg, Once) ,Oral              | Not Reported |
|                 | Previscan (Fluindione)                          | S |      |                                  | Not Reported |
|                 | Hemigoxine                                      | C |      |                                  | Not Reported |
|                 | Havlane                                         | C |      |                                  | Not Reported |
|                 | Propoxyphene Hydrochloride<br>And Acetaminophen | C |      |                                  | Not Reported |

| <u>FDA Received Date</u>      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 01-Oct-2008                   | 6692917              | EXPEDITED (15-DAY) | Y                  | OT              | S08-GER-02162-01     |                                 | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Osteoporosis; Rib<br>Fracture | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                               | Insidon              |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                               | Etilefrin            |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                               | Berotec              |                    |                    | C               |                      |                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------|-------------------------|-----------------|--------------|----------------|
| 01-Oct-2008                                      | 6776161        | EXPEDITED (15-DAY) |                    | HO              | US-NOVOPROD-<br>279604 |                         | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia;<br>Hypoglycaemic<br>Unconsciousness | Novolog        |                    |                    | S               | Subcutaneous           | 100 Unk, Unk            |                 | Novo Nordisk |                |
|                                                  | Accupril       |                    |                    | S               | Oral                   | Unk Mg, Qd              |                 | Not Reported |                |
|                                                  | Icosapent      |                    |                    | S               | Oral                   | 1000 Mg, Qid            |                 | Not Reported |                |
|                                                  | Coreg          |                    |                    | S               |                        | 12.5 Mg, Qd             |                 | Not Reported |                |
|                                                  | Humalog        |                    |                    | S               | Subcutaneous           | 25 Mg, In The Am And Pm |                 | Not Reported |                |
|                                                  | Hydralazine    |                    |                    | S               | Oral                   | 25 Mg, Tid              |                 | Not Reported |                |
|                                                  | Lexapro        |                    |                    | S               | Oral                   | 20 Mg, Qd               |                 | Not Reported |                |
|                                                  | Pravachol      |                    |                    | S               | Oral                   | 40 Mg, Qd               |                 | Not Reported |                |
|                                                  | Aspirin        |                    |                    | C               | Oral                   | 81 Mg, Qd               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| 01-Oct-2008                                                              | 6778631                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000000996                    |                                  | 21 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anger; Anxiety; Injury;<br>Skin Laceration; Tremor;<br>Visual Impairment | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In D) ,<br>Oral  |                          | Not Reported        |                         |
|                                                                          | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Oct-2008                                                              | 6789576                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 10000001092                   |                                  |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Torticollis                                                              | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Oct-2008                                                              | 6790807                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 10000001092                   |                                  |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Torticollis                                                              | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Oct-2008                                                              | 6752847                 | EXPEDITED (15-DAY)        | Y                           | DS                       | 10000000579                   |                                  | 34 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Tooth Fracture;<br>Tooth Loss                                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Oral                             |                          | Not Reported        |                         |
|                                                                          | Chlorprothixene         |                           |                             | S                        | Oral                          | Oral                             |                          | Not Reported        |                         |
|                                                                          | Lyrica                  |                           |                             | S                        | Oral                          | Oral                             |                          | Not Reported        |                         |

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|                                                                                   |                             |                    |                    |                 |                             |                       |                 |              |                |
|-----------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------------|-----------------------|-----------------|--------------|----------------|
| Zyprexa                                                                           |                             |                    | S                  | Oral            | 5 Mg (5 Mg, 1 In 1 D), Oral |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2008                                                                       | 6792618                     | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000004073                  |                       | 19 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Intentional Overdose; Respiratory Depression; Sopor; Suicide Attempt | Escitalopram Oxalate        |                    |                    | S               | Oral                        | (400 Mg, Once), Oral  |                 | Not Reported |                |
|                                                                                   | Alprazolam                  |                    |                    | S               | Oral                        | (15 Mg, Once), Oral   |                 | Not Reported |                |
|                                                                                   | Amitriptyline Hydrochloride |                    |                    | S               | Oral                        | 2500 Mg, Once), Oral  |                 | Not Reported |                |
|                                                                                   | Promethazine Hydrochloride  |                    |                    | S               | Oral                        | (250 Mg, Once), Oral  |                 | Not Reported |                |
|                                                                                   | Edronax                     |                    |                    | S               | Oral                        | 80 Mg, Once) , Oral   |                 | Not Reported |                |
|                                                                                   | Naltrexone Hydrochloride    |                    |                    | S               | Oral                        | (300 Mg, Once) , Oral |                 | Not Reported |                |
|                                                                                   | Unspecified Ingredient      |                    |                    | S               | Oral                        | 1 Bottle (Once), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Oct-2008                                                                       | 6792693                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000001135                  |                       | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                           | Lexapro                     |                    |                    | S               | Oral                        | Oral                  |                 | Not Reported |                |
|                                                                                   | Ultram                      |                    |                    | S               |                             |                       |                 | Not Reported |                |
|                                                                                   | Alcohol                     |                    |                    | S               |                             |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2008                                                                       | 6768556                     | EXPEDITED (15-DAY) | N                  | OT              | DK-PFIZER INC-2008076539    |                       | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Interaction                                                      | Champix                     |                    |                    | S               | Oral                        |                       |                 | Not Reported |                |
|                                                                                   | Ciprallex                   |                    |                    | S               | Oral                        |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Oct-2008                                                                       | 6778415                     | EXPEDITED (15-DAY) | N                  | HO              | A0750331A                   |                       | 63 YR           | Male         | USA            |

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| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|-----------------|
| Bradycardia; Syncope  | Carvedilol                |              |            | S           | Oral         | 12.5mg Per Day              |                 | Glaxosmithkline |
|                       | Lovaza                    |              |            | S           | Oral         | 1000mg Four Times Per Day   |                 | Glaxosmithkline |
|                       | Accupril                  |              |            | S           | Oral         | 40mg Per Day                |                 | Not Reported    |
|                       | Unspecified Ingredient    |              |            | S           | Oral         |                             |                 | Glaxosmithkline |
|                       | Humalog                   |              |            | S           | Subcutaneous |                             |                 | Not Reported    |
|                       | Hydralazine Hydrochloride |              |            | S           |              | 25mg Three Times Per Day    |                 | Not Reported    |
|                       | Lexapro                   |              |            | S           |              | 20mg Per Day                |                 | Not Reported    |
|                       | Novolog                   |              |            | S           |              | 100unit Three Times Per Day |                 | Not Reported    |
|                       | Pravachol                 |              |            | S           |              | 40mg Per Day                |                 | Not Reported    |
|                       | Aspirin                   |              |            | C           |              |                             |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2008              | 6778722       | NON-EXPEDITED    | N                  |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2008-<br>BP-14 |                      |            | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Anxiety; Eye Pruritus;<br>Rash | Ranitidine     |              |            | S           | Oral         | 150mg              |                 | Boehringer Ingelheim |
|                                | Lexapro        |              |            | S           |              | 10mg               |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2008              | 6778770       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2008080121 |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Drug Abuse | Xanax            |              |            | S           |              |                    |                 | Not Reported |
|                        | Morphine Sulfate |              |            | S           |              |                    |                 | Not Reported |
|                        | Oxycontin        |              |            | S           |              |                    |                 | Not Reported |
|                        | Vicodin          |              |            | S           |              |                    |                 | Not Reported |
|                        | Lexapro          |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                               |   |              |
|--|-------------------------------|---|--------------|
|  | Marijuana                     | S | Not Reported |
|  | Cocaine                       | S | Not Reported |
|  | 2,3-Methylenedioxyamphetamine | S | Not Reported |
|  | Heroin                        | S | Not Reported |

| <u>FDA Received Date</u>             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Oct-2008                          | 6787543                | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000001118           |                      | 29 YR           | Male         | DEU            |
| <u>Preferred Term</u>                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Gastric Haemorrhage; | Escitalopram Oxalate   |                    |                    | S               | Oral                 | (Once), Oral         |                 | Not Reported |                |
| Haemodialysis; Hypoxia;              | Metoprolol             |                    |                    | S               | Oral                 | (Once), Oral         |                 | Not Reported |                |
| Intentional Overdose;                | Albuterol Sulfate      |                    |                    | S               | Oral                 | (Once), Oral         |                 | Not Reported |                |
| Seizure; Suicide Attempt             | Tramadol Hydrochloride |                    |                    | S               | Oral                 | (Once), Oral         |                 | Not Reported |                |
|                                      | Trimipramine           |                    |                    | S               | Oral                 | (Once), Oral         |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 03-Oct-2008                                            | 6787555              | EXPEDITED (15-DAY) | Y                  | OT              | 1000001116           |                               | 54 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Head Injury; Transient Ischaemic Attack; Vertigo | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 04-Oct-2008              | 6786263        | DIRECT           |                    | HO              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2008              | 6788766       | EXPEDITED (15-DAY) | Y                  | CA              | 1000001124           |                      | < 1 DAY    | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------------------|-----------------|--------------|----------------|
| Congenital Hand Malformation; Maternal Drugs Affecting Foetus  | Escitalopram Oxalate             |                    |                    | S               | Transplacental             | 10 Mg (10 Mg, 1 In 1 D),Transplacental |                 | Not Reported |                |
|                                                                | Imovane (5 Milligram)            |                    |                    | C               |                            |                                        |                 | Not Reported |                |
|                                                                | Vallergan (10 Milligram)         |                    |                    | C               |                            |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2008                                                    | 6788987                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000001185                 |                                        | 74 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Urinary Incontinence                        | Escitalopram Oxalate             |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
|                                                                | Seroquel                         |                    |                    | S               | Oral                       | 200 Mg (100 Mg, 2 In 1 D), Oral        |                 | Not Reported |                |
|                                                                | Reminyl                          |                    |                    | S               | Oral                       | 16 Mg (16 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
|                                                                | Navixen (600 Milligram, Tablets) |                    |                    | C               |                            |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Oct-2008                                                    | 6780726                          | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2008UW02220 |                                        | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Arthralgia; Bone Pain; Insomnia; Joint Swelling       | Arimidex                         |                    |                    | S               | Oral                       |                                        |                 | Not Reported |                |
|                                                                | Lexapro                          |                    |                    | S               |                            |                                        |                 | Not Reported |                |
|                                                                | Lexapro                          |                    |                    | S               |                            |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2008                                                    | 6796528                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000001209                 |                                        | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Intellectual Disability; Intentional Overdose; Suicide Attempt | Escitalopram Oxalate             |                    |                    | S               | Oral                       | (30 Mg, Once), Oral                    |                 | Not Reported |                |
|                                                                | Diphenhydramine                  |                    |                    | S               | Oral                       | (300 Mg, Once), Oral                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                         |                    |                    |                 |                      |                                |                       |              |                |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------------|--------------|----------------|
| Alcohol                  |                         |                    | S                  |                 | Oral                 |                                | 3 Liters (Once), Oral |              | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>            | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2008              | 6790877                 | DIRECT             | Y                  | HO              |                      |                                | 73 YR                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u>       | <u>Mfr</u>   |                |
| Hyponatraemia; Pain      | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg Daily Po Couple Of Years |                       | Forest       |                |
|                          | Insulin Glargine        |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Prandin                 |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Glimepiride             |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Plavix                  |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Diovan                  |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Labetalol               |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Norvasc                 |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Fosamax                 |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Metformin Hydrochloride |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Zocor                   |                    |                    | C               |                      |                                |                       | Not Reported |                |
|                          | Lorazepam               |                    |                    | C               |                      |                                |                       | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>            | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2008              | 6791424                 | EXPEDITED (15-DAY) | Y                  | OT              | 2008S1017200         |                                | 62 YR                 | Female       | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u>       | <u>Mfr</u>   |                |
| Akathisia;               | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg;Daily                    |                       | Not Reported |                |
| Choreoathetosis;         | Paliperidone            |                    |                    | S               |                      | 6 Mg;Daily                     |                       | Not Reported |                |
| Myoclonus                | Quetiapine              |                    |                    | C               |                      |                                |                       | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>            | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2008              | 6792603                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000001214           |                                | 43 YR                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u>       | <u>Mfr</u>   |                |
| Rash Macular             | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral  |                       | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |              |
|-------------------------|---|--------------|
| Bupropion               | S | Not Reported |
| Levothyroxine           | C | Not Reported |
| Metformin Hydrochloride | C | Not Reported |
| Advair Diskus           | C | Not Reported |
| Singulair               | C | Not Reported |
| Lisinopril              | C | Not Reported |
| Tricor                  | C | Not Reported |
| Lipitor                 | C | Not Reported |
| Aspirin                 | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2008              | 6792644       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001239           |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2008              | 6793040       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000001207           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Long Qt Syndrome;<br>Ventricular Fibrillation | Citalopram Hydrobromide |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                               | Escitalopram Oxalate    |              |            | S           | Oral         | 20-40 Mg (1 In 1 D), Oral        |                 | Not Reported |
|                                               | Citalopram Hydrobromide |              |            | S           | Oral         | 20-40 Mg (1 In 1 D), Oral        |                 | Not Reported |
|                                               | Fluxet                  |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                               | Urbason (Tablets)       |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Calciumacetat           |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Rocaltrol               |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Dynepo                  |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Fluvastatin             |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Furosemid               |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Madopar                 |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Metoprolol Succinate    |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Cellcept                |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Nifedipine              |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Amlodipine              |              |            | C           |              |                                  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |              |
|--------------------------|---|--------------|
| Pantozol                 | C | Not Reported |
| Ramipril                 | C | Not Reported |
| Renagel                  | C | Not Reported |
| Ranitidine Hydrochloride | C | Not Reported |
| Mimpara                  | C | Not Reported |
| Paracetamol              | C | Not Reported |
| Famotidine               | C | Not Reported |
| Rocephin                 | C | Not Reported |
| Metoprolol Retard        | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2008              | 6793480       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001221           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Anxiety; Panic Attack;<br>Post-Traumatic Stress<br>Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 1 Tablet (Once), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2008              | 6796943       | EXPEDITED (15-DAY) | N                  | DE, OT          | 1000001240           |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Completed Suicide;<br>Condition Aggravated;<br>Depression; Gun Shot<br>Wound | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2008              | 6685081       | EXPEDITED (15-DAY) | Y                  | HO              | S08-FRA-02026-01     |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Facial Paralysis; Tetany | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2008              | 6735255       | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000000438           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Culture Urine Positive;<br>Diabetes Mellitus<br>Inadequate Control;<br>Dialysis; Drug Interaction;<br>Enterococcal Infection;<br>Generalised Tonic-Clonic<br>Seizure; Hyponatraemia;<br>Incorrect Dose<br>Administered;<br>Pyelonephritis; Serotonin<br>Syndrome; Urosepsis | Escitalopram Oxalate      |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                     | Linezolid                 |              |            | S           |              | 1200 Mg (600 Mg, 1 In 12) |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                     | Metoclopramide            |              |            | C           |              |                           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                     | Ondansetron (4 Milligram) |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2008              | 6777830       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000966           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Depression; Inhibitory<br>Drug Interaction | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |
|                                            | Varenicline Tartrate |              |            | S           | Oral         | 2 Dosage Forms (1<br>Dosage Forms, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                            | Varenicline Tartrate |              |            | S           | Oral         | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Oct-2008              | 6789969       | DIRECT           | N                  | RI, OT          |                      |                      | 42 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |         |   |      |                  |        |
|----------------------------------------------------|---------|---|------|------------------|--------|
| Maculopathy; Retinal Disorder; Visual Field Defect | Lexapro | S | Oral | 10-20mg Daily Po | Forest |
|----------------------------------------------------|---------|---|------|------------------|--------|

| <u>FDA Received Date</u>                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Oct-2008                                     | 6794183                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | DSA_32337_2008       |                      | 90 YR           | Female       | ARG            |
| <u>Preferred Term</u>                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Incorrect Dose Administered; Serotonin Syndrome | Enalapril Maleate       |                    |                    | S               |                      | (10 Mg Qd)           |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate    |                    |                    | S               |                      | (20 Mg Qd)           |                 | Not Reported |                |
|                                                 | Mianserin Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Oct-2008                                             | 6586364              | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-00740-01     |                                                            | 26 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Therapy Non-Responder | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                         |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 2.5 Mg (5 Mg, 1 In 2 D), Oral                              |                 | Not Reported |                |
|                                                         | Clonazepam           |                    |                    | S               | Oral                 | 2 Mg (2 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 14-Oct-2008                             | 6786312        | EXPEDITED (15-DAY) | Y                  | OT              | ES-JNJFOC-20081001771 |                      | 74 YR           | Female       | ESP            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Urinary Incontinence | Reminyl        |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                         | Cipralext      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                         | Seroquel       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                            |                        |                    |                    |                 |                      |                               |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Navixen                                                                                                                                                                                                                    |                        | C                  |                    | Not Reported    |                      |                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2008                                                                                                                                                                                                                | 6787539                | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000001129           |                               | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris; Drug Interaction; Therapeutic Product Ineffective                                                                                                                                                         | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                            | Unspecified Ingredient |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2008                                                                                                                                                                                                                | 6787589                | EXPEDITED (15-DAY) | Y                  | HO              | 1000001084           |                               | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Chloride Decreased; Blood Potassium Decreased; Carbon Dioxide Decreased; Dehydration; Headache; Hyponatraemia; Memory Impairment; Nausea; Photopsia; Seizure; Tonic Clonic Movements; Urinary Incontinence; Vomiting | Lexapro                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                            | Atenolol               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                            | Xanax                  |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2008                                                                                                                                                                                                                | 6792276                | DIRECT             | N                  | HO, LT, OT      |                      |                               | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Sleep Disorder; Suicidal Ideation                                                                                                                                                                                          | Lexapro                |                    |                    | S               | Oral                 | 10 Mg 1x Daily Po             | 6 WEEK          | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 14-Oct-2008                                                                                       | 6794719                    | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01937-01     |                                                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bursitis; Oedema<br>Peripheral; Pain In<br>Extremity; Vitamin D<br>Decreased; Weight<br>Increased | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                     |                 | Not Reported |                |
|                                                                                                   | Ambien (Zolpidem Tartrate) |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                                   | (Zolpidem Tartrate)        |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                                   | Metformin (Metformin)      |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                                   | (Metformin)                |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                                   | Multi-Vitamin              |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
|                                                                                                   | Vicoprofen                 |                    |                    | C               |                      |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2008                                                                                       | 6795249                    | EXPEDITED (15-DAY) | Y                  | HO              | 6046261              |                                                      | 68 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event; Wrong<br>Product Administered                                                   | Levothyroxine Sodium       |                    |                    | S               | Oral                 | 1 Dosage Forms, 1 In 1 D)<br>Oral                    |                 | Not Reported |                |
|                                                                                                   | Bisoprolol Fumarate        |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D) Oral                           |                 | Not Reported |                |
|                                                                                                   | Nicorandil                 |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D)<br>Oral |                 | Not Reported |                |
|                                                                                                   | Vastarel                   |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D)<br>Oral |                 | Not Reported |                |
|                                                                                                   | Furosemide                 |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D)<br>Oral |                 | Not Reported |                |
|                                                                                                   | Ramipril                   |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D)<br>Oral |                 | Not Reported |                |
|                                                                                                   | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D) Oral                           |                 | Not Reported |                |
|                                                                                                   | Potassium Chloride         |                    |                    | S               | Oral                 | 1 Dosage Forms (1                                    |                 | Not Reported |                |
|                                                                                                   |                            |                    |                    |                 |                      |                                                      |                 |              |                |

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Dosage Forms, 1 In 1 D)  
Oral

| <a href="#">FDA Received Date</a>                                                                                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Oct-2008                                                                                                                                                                                                         | 6795872                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000001274                    |                               |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Thyroiditis                                                                                                                                                                                                         | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2008                                                                                                                                                                                                         | 6709184                 | EXPEDITED (15-DAY)        | Y                           | OT                       | A0738185A                     |                               | 24 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anticonvulsant Drug Level Decreased; Aura; Constipation; Dizziness; Feeling Abnormal; Gastroenteritis Viral; Headache; Hyperhidrosis; Loss Of Consciousness; Nausea; Pallor; Paraesthesia; Postictal State; Seizure | Lamictal                |                           |                             | S                        | Oral                          | 100mg Twice Per Day           |                          | Glaxosmithkline     |                         |
|                                                                                                                                                                                                                     | Lexapro                 |                           |                             | S                        | Unknown                       |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Oct-2008                                                                                                                                                                                                         | 6788362                 | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-ABBOTT-08P-056-0481120-00  |                               | 53 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Priapism                                                                                                                                                                                                            | Depakote                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                                                                                     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                                                                                                                     | Risperidone             |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Oct-2008                                                                                                                                                                                                         | 6795092                 | DIRECT                    | Y                           |                          |                               |                               |                          | Unknown             | USA                     |

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| <u>Preferred Term</u>                             | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------|----------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Product Quality Issue           | Lexapro                                                  |                    |                    | S               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Oct-2008                                       | 6798102                                                  | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001205               |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Intentional Overdose; Suicide Attempt | Lexapro                                                  |                    |                    | S               | Oral                     | (Once), Oral                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                       | 6317900                                                  | EXPEDITED (15-DAY) | Y                  |                 | US-PFIZER INC-2007038671 |                               | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                  | Chantix                                                  |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                   | Lexapro                                                  |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                   | Lasix                                                    |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                   | Advair Diskus                                            |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                   | Duoneb                                                   |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                   | Albuterol                                                |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                       | 6656597                                                  | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01795-01         |                               | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Tunnel Vision                                     | Escitalopram Oxalate                                     |                    |                    | S               | Oral                     | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                   | Temesta (Lorazepam) (2.5 Milligram, Tablets) (Lorazepam) |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                       | 6737727                                                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000000386               |                               | 40 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Decreased Appetite; Gallbladder Polyp; Hepatic Cyst; Liver Injury; Weight Decreased | Lexapro                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; Oral |                 | Not Reported |                |
|                                                                                                                                                               |                        |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; Oral |                 |              |                |
|                                                                                                                                                               | Unspecified Ingredient |                    |                    | S               |                      | 45/15 Mg Daily, 60/30 Mg Daily      |                 | Not Reported |                |
|                                                                                                                                                               |                        |                    |                    |                 |                      | 45/15 Mg Daily, 60/30 Mg Daily      |                 |              |                |
|                                                                                                                                                               | Lisinopril             |                    |                    | C               |                      | 45/15 Mg Daily, 60/30 Mg Daily      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                                                                                                                                   | 6795840                | EXPEDITED (15-DAY) | Y                  | OT              | 1000001267           |                                     | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Flat Affect; Suicidal Ideation; Therapy Non-Responder                                                                                                         | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                                                                                                                                   | 6796340                | DIRECT             | N                  | HO, LT          |                      |                                     | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Suicidal Ideation; Suicide Attempt                                                                                                       | Lexapro                |                    |                    | S               | Oral                 | 1.5 Tablets Once A Day Po           | 2 MTH           | Not Reported |                |
|                                                                                                                                                               | Ic Clonazepam          |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                               | Ic Bupropion Hcl       |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2008                                                                                                                                                   | 6798638                | EXPEDITED (15-DAY) | N                  | OT              | 1000001348           |                                     |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                               |                                      |                    |                    |                 |                              |                                        |                 |                              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------|-----------------|------------------------------|----------------|
| Gambling Disorder                                                                                                                                             |                                      | Lexapro            |                    | S               |                              | Not Reported                           |                 |                              |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 17-Oct-2008                                                                                                                                                   | 6799685                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001342                   |                                        | 66 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Confusional State;<br>Delusion; Drug Interaction                                                                                                              | Escitalopram Oxalate                 |                    |                    | S               | Oral                         | Oral                                   |                 | Not Reported                 |                |
|                                                                                                                                                               | Azilect                              |                    |                    | S               | Oral                         | Oral                                   |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 17-Oct-2008                                                                                                                                                   | 6799703                              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001363                   |                                        | 39 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Headache; Intentional<br>Overdose; International<br>Normalised Ratio<br>Increased; Psychomotor<br>Retardation; Somnolence;<br>Suicide Attempt;<br>Tachycardia | Escitalopram Oxalate                 |                    |                    | S               | Oral                         | 10 Tablets (Once), Oral;<br>Oral       |                 | Not Reported                 |                |
|                                                                                                                                                               | Anafranil                            |                    |                    | S               | Oral                         | 1 Box (Once), Oral                     |                 | Not Reported                 |                |
|                                                                                                                                                               | Xanax                                |                    |                    | S               | Oral                         | (2 Dosage Forms, Once),<br>Oral; Oral  |                 | Not Reported                 |                |
|                                                                                                                                                               | Cyamemazine                          |                    |                    | S               | Oral                         | (10 Dosage Forms, Once),<br>Oral; Oral |                 | Not Reported                 |                |
|                                                                                                                                                               | Previscan (Fluindione)<br>Omeprazole |                    |                    | C<br>C          |                              |                                        |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 18-Oct-2008                                                                                                                                                   | 6280202                              | EXPEDITED (15-DAY) | N                  | HO, OT          | US-PFIZER INC-<br>2007024530 |                                        | 49 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Ear Discomfort; Eye<br>Swelling; Pruritus;<br>Urticaria                                                                                                       | Chantix                              |                    |                    | S               |                              |                                        |                 | Not Reported                 |                |
|                                                                                                                                                               | Lexapro                              |                    |                    | S               |                              |                                        |                 | Not Reported                 |                |
|                                                                                                                                                               | Albuterol                            |                    |                    | C               |                              |                                        |                 | Not Reported                 |                |
|                                                                                                                                                               | Lasix                                |                    |                    | C               |                              |                                        |                 | Not Reported                 |                |
|                                                                                                                                                               | Advair Diskus                        |                    |                    | C               |                              |                                        |                 | Not Reported                 |                |
|                                                                                                                                                               | Duoneb                               |                    |                    | C               |                              |                                        |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 20-Oct-2008                                                                                                             | 6799809                              | EXPEDITED (15-DAY) | Y                  | HO              | WAES 0810USA01959        |                                           | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Decreased Appetite; Disorientation; Drug Interaction; Hypokalaemia; Hyponatraemia; Malaise; Muscular Weakness | Amiloride Hcl W/ Hydrochlorothiazide |                    |                    | S               | Oral                     | 5/50 Mg/Daily, Po                         |                 | Not Reported |                |
|                                                                                                                         | Escitalopram Oxalate                 |                    |                    | S               | Oral                     | 10 Mg/Daily, Po                           |                 | Not Reported |                |
|                                                                                                                         | Adartrel                             |                    |                    | C               |                          |                                           |                 | Not Reported |                |
|                                                                                                                         | Metformin Hydrochloride              |                    |                    | C               |                          |                                           |                 | Not Reported |                |
|                                                                                                                         | Idaptan                              |                    |                    | C               |                          |                                           |                 | Not Reported |                |
|                                                                                                                         | Lorazepam                            |                    |                    | C               |                          |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2008                                                                                                             | 6800222                              | EXPEDITED (15-DAY) | Y                  | OT              | 1000000653               |                                           | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Immune Thrombocytopenic Purpura                                                                                         | Lexapro                              |                    |                    | S               | Oral                     | 5 Mg , 10 Mg ,(5 Mg, 10mg, 1 In 1d), Oral |                 | Not Reported |                |
|                                                                                                                         |                                      |                    |                    |                 | Oral                     | 5 Mg , 10 Mg ,(5 Mg, 10mg, 1 In 1d), Oral |                 |              |                |
|                                                                                                                         | Haldol                               |                    |                    | C               |                          |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2008                                                                                                             | 6778708                              | EXPEDITED (15-DAY) | Y                  | OT              | DK-PFIZER INC-2008075214 |                                           | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Accommodation Disorder; Drug Interaction; Dyskinesia                                                                    | Lyrica                               |                    |                    | S               | Oral                     |                                           |                 | Not Reported |                |
|                                                                                                                         | Lyrica                               |                    |                    | S               |                          | Text:Bid Daily Tdd:450mg                  |                 | Not Reported |                |
|                                                                                                                         | Sertindole                           |                    |                    | S               | Oral                     |                                           |                 | Not Reported |                |
|                                                                                                                         | Sertindole                           |                    |                    | S               |                          |                                           |                 | Not Reported |                |
|                                                                                                                         | Cipralelex                           |                    |                    | S               | Oral                     |                                           |                 | Not Reported |                |
|                                                                                                                         | Cipralelex                           |                    |                    | S               |                          |                                           |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|------------------------------------|-----------------|----------------------|----------------|
| 21-Oct-2008                                                                                                                                                         | 6810290                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000001497                                          |                                    | 24 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>           |                |
| Anticonvulsant Drug Level Decreased; Constipation; Convulsive Threshold Lowered; Disorientation; Loss Of Consciousness; Overdose; Paraesthesia; Seizure; Somnolence | Lexapro                         |                    |                    | S               | Oral                                                | Oral                               |                 | Not Reported         |                |
|                                                                                                                                                                     | Lexapro                         |                    |                    | S               | Oral                                                | 20 Mg (20 Mg), Oral                |                 | Not Reported         |                |
|                                                                                                                                                                     | Lamictal                        |                    |                    | S               | Oral                                                | 200 Mg ( 100 Mg, 2 In I Day), Oral |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Oct-2008                                                                                                                                                         | 6726650                         | EXPEDITED (15-DAY) | Y                  | LT              | 1000000266                                          |                                    | 59 YR           | Female               | DNK            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypoglycaemic Unconsciousness                                                                                                                                       | Escitalopram Oxalate            |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D), Oral      |                 | Not Reported         |                |
|                                                                                                                                                                     | Escitalopram Oxalate            |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D), Oral      |                 | Not Reported         |                |
|                                                                                                                                                                     | Insuman Basal Insulin Novorapid |                    |                    | C               |                                                     |                                    |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Oct-2008                                                                                                                                                         | 6776622                         | NON-EXPEDITED      | N                  |                 | US-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2008-BP-14 |                                    | 75 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>           |                |
| Joint Swelling; Middle Insomnia; Oedema Peripheral; Pollakiuria                                                                                                     | Flomax                          |                    |                    | S               | Oral                                                | .4mg                               |                 | Boehringer Ingelheim |                |
|                                                                                                                                                                     | Lexapro                         |                    |                    | S               |                                                     |                                    |                 | Not Reported         |                |
|                                                                                                                                                                     | Toprol XL                       |                    |                    | C               |                                                     |                                    |                 | Not Reported         |                |
|                                                                                                                                                                     | Zocor                           |                    |                    | C               |                                                     |                                    |                 | Not Reported         |                |
|                                                                                                                                                                     | Omeprazole                      |                    |                    | C               |                                                     |                                    |                 | Not Reported         |                |
|                                                                                                                                                                     | Maxalt                          |                    |                    | C               |                                                     |                                    |                 | Not Reported         |                |

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| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                    | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|------------------------------------------------------------------|--------------------------|------------------------------|-------------------------|
| 22-Oct-2008                                                                                                                                              | 6799528                 | DIRECT                    | Y                           | HO                       |                               |                                                                  | 88 YR                    | Unknown                      | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                      | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Hypersensitivity Vasculitis                                                                                                                              | Lexapro<br>Amantadine   |                           |                             | S<br>S                   |                               |                                                                  |                          | Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                    | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 23-Oct-2008                                                                                                                                              | 6686371                 | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-USA-02020-01              |                                                                  | 34 YR                    | Female                       | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                      | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Abdominal Discomfort;<br>Anal Incontinence;<br>Cardiac Flutter; Diarrhoea;<br>Fall; Fatigue; Headache;<br>Loss Of Consciousness;<br>Nausea; Palpitations | Lexapro<br>Xanax        |                           |                             | S<br>C                   | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                 |                          | Not Reported<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                    | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 23-Oct-2008                                                                                                                                              | 6802045                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000001412                    |                                                                  | 37 YR                    | Female                       | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                      | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Hypothyroidism                                                                                                                                           | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral; 10 Mg (10 Mg, 1 In 1 D)<br>,Oral |                          | Not Reported                 |                         |
|                                                                                                                                                          | Levothyroxine           |                           |                             | C                        | Oral                          | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral; 10 Mg (10 Mg, 1 In 1 D)<br>,Oral |                          | Not Reported                 |                         |
| <a href="#">FDA Received Date</a>                                                                                                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                    | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
| 23-Oct-2008                                                                                                                                              | 6802047                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000001409                    |                                                                  | 81 YR                    | Female                       | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                      | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |



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|                                                                                                               |                                                              |                      |                    |                 |                      |                                  |                 |                      |                |
|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|----------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------|----------------|
| Anxiety; Apraxia; Delirium;<br>Disorientation                                                                 |                                                              | Escitalopram Oxalate |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 23-Oct-2008                                                                                                   | 6802049                                                      | EXPEDITED (15-DAY)   | Y                  | OT              | 1000001408           |                                  | 41 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypotension; Mydriasis;<br>Sopor; Suicide Attempt;<br>Tachycardia                                             | Escitalopram Oxalate                                         |                      |                    | S               | Oral                 | (Once) ,Oral                     |                 | Not Reported         |                |
|                                                                                                               | Doxepin                                                      |                      |                    | S               | Oral                 | (Once) ,Oral                     |                 | Not Reported         |                |
|                                                                                                               | Alcohol                                                      |                      |                    | S               | Oral                 | (Once) ,Oral                     |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 24-Oct-2008                                                                                                   | 6521475                                                      | EXPEDITED (15-DAY)   | Y                  | HO              | US-WYE-H01814307     |                                  | 20 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Dysarthria; Lethargy;<br>Mydriasis; Overdose;<br>Serotonin Syndrome                                           | Chlorpheniramine<br>Maleate\Dextromethorphan<br>Hydrobromide |                      |                    | S               | Unknown              | Unknown                          |                 | Wyeth                |                |
|                                                                                                               | Benztrapine Mesylate                                         |                      |                    | S               | Unknown              | Unknown                          |                 | Unknown              |                |
|                                                                                                               | Escitalopram Oxalate                                         |                      |                    | S               | Unknown              | Unknown                          |                 | Unknown              |                |
|                                                                                                               | Aripiprazole                                                 |                      |                    | S               | Unknown              | Unknown                          |                 | Bristol Myers Squibb |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>                                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 24-Oct-2008                                                                                                   | 6587601                                                      | EXPEDITED (15-DAY)   | Y                  | OT              | S08-ITA-00825-01     |                                  |                 | Female               | DNK            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>                                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Induced;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Premature Separation Of<br>Placenta | Escitalopram Oxalate                                         |                      |                    | S               |                      |                                  |                 | Not Reported         |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 27-Oct-2008                                                                                                                                                                                                    | 6631553                 | EXPEDITED (15-DAY) | Y                  | HO              | ES-ASTRAZENECA-2008AC01089 |                               | 48 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Cholestatic                                                                                                                                                                                          | Seroquel                |                    |                    | S               | Oral                       |                               | 5 DAY           | Not Reported |                |
|                                                                                                                                                                                                                | Clomethiazole           |                    |                    | S               | Oral                       |                               | 11 DAY          | Not Reported |                |
|                                                                                                                                                                                                                | Cipralext               |                    |                    | S               | Oral                       |                               | 4 DAY           | Not Reported |                |
|                                                                                                                                                                                                                | Topamax                 |                    |                    | S               | Oral                       |                               | 4 DAY           | Not Reported |                |
|                                                                                                                                                                                                                | Clorazepate Dipotassium |                    |                    | S               | Oral                       |                               | 11 DAY          | Not Reported |                |
|                                                                                                                                                                                                                | Bromazepam              |                    |                    | S               | Oral                       |                               | 5 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2008                                                                                                                                                                                                    | 6746782                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000000513                 |                               | 84 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block Complete; Blood Urine Present; Dizziness; Haematocrit Decreased; Haemoglobin Decreased; Protein Urine Present; Red Blood Cell Count Decreased; Refusal Of Treatment By Patient; Syncope | Escitalopram Oxalate    |                    |                    | S               | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                | Proscar                 |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                | Folvite (Tablets)       |                    |                    | C               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Oct-2008                                                                                                                                                                                                    | 6805712                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000001444                 |                               | 88 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Drug Interaction; Hyponatraemia; Overdose                                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               | Oral                       | 30 Mg (15 Mg, 2 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |      |                                  |              |
|--------------------|---|------|----------------------------------|--------------|
| Atacand            | S | Oral | 16 Mg (16 Mg, 1 In 1 D),<br>Oral | Not Reported |
| Madopar (Tablets)  | C |      |                                  | Not Reported |
| Omeprazole         | C |      |                                  | Not Reported |
| Cardyl (Tablets)   | C |      |                                  | Not Reported |
| Osteopor (Tablets) | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2008              | 6813684       | DIRECT           | Y                  | LT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Condition<br>Aggravated; Insomnia;<br>Suicidal Ideation;<br>Therapeutic Response<br>Unexpected | Paroxetine Hydrochloride |              |            | S           | Oral         | 12.5mg Daily Oral  |                 | Not Reported |
|                                                                                                         | Paxil Cr                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2008              | 6793456       | EXPEDITED (15-DAY) | Y                  | DE              | 1000001204           |                      | 47 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Completed Suicide     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg 910 Mg, 1 In 1 D);<br>Oral |                 | Not Reported |
|                       | Lexomil              |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2008              | 6802821       | DIRECT           | Y                  | HO              |                      |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged;<br>Hypermetabolism;<br>Hyperthermia; Serotonin<br>Syndrome; Torsade De<br>Pointes; Ventricular<br>Tachycardia | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                  | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                  | Azilect                 |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| 28-Oct-2008                                                         | 6812251                  | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000001457                    |                                  | 82 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Euphoric Mood                                              | Escitalopram Oxalate     |                           |                             | S                        | Oral                          | 5 Mg (5 Mg, 1 In 1 D); Oral      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Oct-2008                                                         | 6803927                  | DIRECT                    | Y                           | OT                       |                               |                                  | 33 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Intolerance;<br>Hyperhidrosis; Nausea;<br>Urticaria            | Wellbutrin Sr            |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
|                                                                     | Lexapro                  |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
|                                                                     | Sertraline               |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
|                                                                     | Paroxetine Hydrochloride |                           |                             | S                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Oct-2008                                                         | 6804518                  | DIRECT                    | N                           | HO                       |                               |                                  | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Head Titubation; Muscle<br>Twitching; Serotonin<br>Syndrome; Tremor | Lexapro                  |                           |                             | S                        |                               | 10 Mg Once A Day                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2008                                                         | 6707975                  | EXPEDITED (15-DAY)        | Y                           | OT                       | S08-FRA-02314-01              |                                  | 40 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Disorder                                                    | Escitalopram Oxalate     |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2008                                                         | 6787523                  | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000001138                    |                                  | 82 YR                    | Male                | DNK                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------|-----------------|--------------|----------------|
| Blood Pressure Systolic Decreased; Dementia; Haemoglobin Decreased; Haemoptysis; International Normalised Ratio Increased | Escitalopram Oxalate         |                    |                    | S               | Oral                         | Oral                        |                 | Not Reported |                |
|                                                                                                                           | Lipanthyl                    |                    |                    | S               | Oral                         | Oral                        |                 | Not Reported |                |
|                                                                                                                           | Acenocoumarol                |                    |                    | S               | Oral                         | 4 Mg (4 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                           | Clopidogrel                  |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Metformin Hydrochloride      |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Omeprazole                   |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Furosemide                   |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Chondroitin Sulfate (Bovine) |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Tamsulosin Hydrochloride     |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Ultracet                     |                    |                    | C               |                              |                             |                 | Not Reported |                |
| Perindopril                                                                                                               |                              |                    | C                  |                 |                              |                             | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2008                                                                                                               | 6799165                      | EXPEDITED (15-DAY) | Y                  | HO              | AT-ASTRAZENECA-2008PK02305   |                             | 40 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperprolactinaemia                                                                                                       | Seroquel                     |                    |                    | S               | Oral                         |                             |                 | Not Reported |                |
|                                                                                                                           | Cipralex                     |                    |                    | S               | Oral                         |                             |                 | Not Reported |                |
|                                                                                                                           | Haldol                       |                    |                    | S               | Oral                         |                             |                 | Not Reported |                |
|                                                                                                                           | Zyprexa                      |                    |                    | S               | Oral                         |                             | 1 DAY           | Not Reported |                |
|                                                                                                                           | Zyprexa                      |                    |                    | S               | Oral                         |                             | 14 DAY          | Not Reported |                |
|                                                                                                                           | Risperdal                    |                    |                    | S               | Oral                         |                             |                 | Not Reported |                |
|                                                                                                                           | Risperdal                    |                    |                    | S               | Oral                         |                             | 14 DAY          | Not Reported |                |
|                                                                                                                           | Euthyrox                     |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Depakene                     |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                           | Ferrous Sulfate              |                    |                    | C               | Oral                         |                             |                 | Not Reported |                |
| Abilify                                                                                                                   |                              |                    | C                  | Oral            |                              |                             | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2008                                                                                                               | 6800092                      | EXPEDITED (15-DAY) | Y                  | OT              | ES-ABBOTT-08P-144-0484269-00 |                             | 12 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                       |                                          |                    |                    |                 |                          |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Hallucination, Visual                                                                                                 | Cipralext                                |                    | S                  | Oral            |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2008                                                                                                           | 6800402                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2008090022 |                      | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                                                                                                                  | Amlodipine                               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                       | Escitalopram Oxalate                     |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                       | Clotiazepam                              |                    |                    | S               | Oral                     | Text:Every Day       |                 | Not Reported |                |
|                                                                                                                       | Zopiclone                                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                       | Niflumic Acid                            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2008                                                                                                           | 6778537                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000001007               |                      | 82 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dementia; Drug Interaction; Haemoglobin Decreased; Haemoptysis; Hypotension; International Normalised Ratio Increased | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
|                                                                                                                       | Sintrom                                  |                    |                    | S               | Oral                     | (4 Mg), Oral         |                 | Not Reported |                |
|                                                                                                                       | Lipanthyl                                |                    |                    | S               | Oral                     | Oral                 |                 | Not Reported |                |
|                                                                                                                       | Plavix                                   |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Glucophage                               |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Omeprazole                               |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Coversyl                                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Lasix                                    |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Chondrosulf                              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Omix                                     |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                       | Tramadol Hydrochloride And Acetaminophen |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Oct-2008                                                                                                           | 6800973                                  | EXPEDITED (15-DAY) | Y                  | HO              | DE-WYE-G02444108         |                      | 83 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                            |                              |   |      |       |              |
|------------------------------------------------------------|------------------------------|---|------|-------|--------------|
| Antidepressant Drug Level Increased; Dehydration; Delirium | Venlafaxine Hydrochloride    | S | Oral | 7 DAY | Wyeth        |
|                                                            | Venlafaxine Hydrochloride    | S | Oral | 4 DAY | Wyeth        |
|                                                            | Venlafaxine Hydrochloride    | S | Oral | 8 DAY | Wyeth        |
|                                                            | Ziprasidone Hydrochloride    | S | Oral |       | Pfizer       |
|                                                            | Cipralex                     | S | Oral |       | Lundbeck     |
|                                                            | Remergil                     | S | Oral |       | Not Reported |
|                                                            | Novodigal (Digoxin)          | C | Oral |       | Not Reported |
|                                                            | Enalapril Maleate            | C | Oral |       | Hexal        |
|                                                            | Furosemide                   | C | Oral |       | Hexal        |
|                                                            | Kalinor (Potassium Chloride) | C | Oral |       | Not Reported |
|                                                            | Godamed                      | C | Oral |       | Not Reported |
|                                                            | Creon                        | C | Oral |       | Not Reported |
|                                                            | Lithium Carbonate            | C | Oral |       | Not Reported |
|                                                            | Piretanide                   | C | Oral |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 31-Oct-2008              | 6801521       | EXPEDITED (15-DAY) | Y                  | OT              | FR-SANOFI-SYNTHELABO-A02200803149 |                      |            | Male       | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Delirium; Intentional Overdose | Stilnox              |              |            | S           | Oral         |                      | 1 DAY           | Not Reported |
|                                | Acetaminophen        |              |            | S           | Oral         |                      | 1 DAY           | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           | Oral         | 2 Tablets Once       | 1 DAY           | Not Reported |
|                                | Valpromide           |              |            | S           | Oral         |                      | 1 DAY           | Not Reported |
|                                | Doliprane            |              |            | C           | Oral         | 2 To 4 Mg Daily Dose |                 | Not Reported |
|                                | Valpromide           |              |            | C           | Oral         | Unk                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2008              | 6809539       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001506           |                      | 54 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Dizziness; Hypertensive Crisis; Nausea; Rash; Vertigo               | Escitalopram Oxalate          | S                  | Oral               | 10 Mg (10 Mg, 1 In 1 D), Oral |                       | Not Reported                  |                 |              |                |
|---------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-------------------------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                     | Optruma (Tablets)             | C                  |                    |                               | Not Reported          |                               |                 |              |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2008                                                         | 6810244                       | DIRECT             | N                  | OT                            |                       |                               | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicidal Ideation; Thinking Abnormal                               | Lexapro                       |                    |                    | S                             | Oral                  | 10 Mg 1 X Daily Po            |                 | Not Reported |                |
|                                                                     | Paxil                         |                    |                    | S                             | Oral                  | 25 Mg 1 Daily Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2008                                                         | 6810563                       | EXPEDITED (15-DAY) | Y                  | DE                            | CHPA2008US18074       |                               | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                   | Dextromethorphan Hydrobromide |                    | Y                  | S                             | Oral                  | Oral                          |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate          |                    |                    | S                             | Oral                  | Oral                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2008                                                         | 6811593                       | EXPEDITED (15-DAY) | Y                  | OT                            | 1000001510            |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Ineffective; Self-Injurious Ideation; Weight Increased | Escitalopram Oxalate          |                    |                    | S                             | Oral                  | 20 Mg (20 Mg, 1 In 1 D); Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2008                                                         | 6799623                       | EXPEDITED (15-DAY) | Y                  | HO                            | AT-JNJFOC-20081005023 |                               | 40 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hospitalisation; Hyperprolactinaemia                                | Haldol                        |                    |                    | S                             | Oral                  |                               |                 | Not Reported |                |



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|                          |   |         |              |
|--------------------------|---|---------|--------------|
| Risperdal                | S | Unknown | Not Reported |
| Ciprallex                | S | Unknown | Not Reported |
| Zyprexa                  | S | Unknown | Not Reported |
| Zyprexa                  | S | Unknown | Not Reported |
| Seroquel                 | S | Unknown | Not Reported |
| Etilefrine Hydrochloride | C | Oral    | Not Reported |
| Euthyrox                 | C | Unknown | Not Reported |
| Depakene                 | C | Unknown | Not Reported |
| Ferro-Gradumet           | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2008              | 6812806       | EXPEDITED (15-DAY) | N                  | DE              | 1000001525           |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Asphyxia; Completed Suicide; Depression | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2008              | 6812953       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001529           |                      | 32 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2008              | 6812955       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001532           |                      | 32 YR      | Female     | DNK            |

| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Atrial Fibrillation; Supraventricular Extrasystoles | Escitalopram Oxalate |              |            | S           |              | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------|-----------------|--------------|----------------|
| 05-Nov-2008                                                                                                                                                  | 6804111                                       | EXPEDITED (15-DAY) | Y                  | HO              | DE-ASTRAZENECA-2008PK02327 |                           |                 | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hepatic Function Abnormal                                                                                                                  | Cymbalta                                      |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                                                                              | Seroquel                                      |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Lamotrigine                                   |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Ciprallex                                     |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Naloxone Hydrochloride\Tilidine Hydrochloride |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Ziprasidone Hydrochloride                     |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Sortis                                        |                    |                    | S               |                            |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2008                                                                                                                                                  | 6813822                                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000001544                 |                           | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                            | Lexapro                                       |                    |                    | S               | Oral                       | 10 Mg (10 Mg, Once), Oral |                 | Not Reported |                |
|                                                                                                                                                              | Talcid (Tablets)                              |                    |                    | C               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Omeprazole                                    |                    |                    | C               |                            |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2008                                                                                                                                                  | 6799008                                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-PFIZER INC-2008082179   |                           | 19 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Phosphokinase Increased; Cardiovascular Insufficiency; Generalised Tonic-Clonic Seizure; Neuroleptic Malignant Syndrome; Neutropenia; Pyrexia | Ziprasidone                                   |                    |                    | S               | Oral                       |                           |                 | Not Reported |                |
|                                                                                                                                                              | Clozapine                                     |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Haloperidol                                   |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Lexapro                                       |                    |                    | S               |                            |                           |                 | Not Reported |                |
|                                                                                                                                                              | Periactin                                     |                    |                    | S               |                            |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 06-Nov-2008                                                                                                                                                                                                                  | 6804872                | EXPEDITED (15-DAY) | N                  | DE, HO, LT      | BE-BAYER-200829139GPV |                                               | 57 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Cardiac Arrest; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Torsade De Pointes                                                                                                                       | Avelox                 |                    |                    | S               | Oral                  | Total Daily Dose: 400 Mg<br>Unit Dose: 400 Mg |                 | Bayer        |                |
|                                                                                                                                                                                                                              | Daonil                 |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Ramipril               |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Bisoprolol             |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Orap                   |                    |                    | S               | Unknown               |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Escitalopram Oxalate   |                    |                    | S               | Unknown               |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2008                                                                                                                                                                                                                  | 6812991                | DIRECT             | Y                  | HO, LT          |                       |                                               | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Agitation; Anaemia; Cerebral Disorder; Cognitive Disorder; Depression; Disturbance In Attention; Drug Hypersensitivity; Infectious Mononucleosis; Insomnia; Memory Impairment; Suicidal Ideation; Tremor | Lexapro                |                    |                    | S               | Oral                  | 5 Mg. Once A Day Po                           |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Cymbalta               |                    |                    | S               | Oral                  | 30 Mg. Once A Day Po                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Nov-2008                                                                                                                                                                                                                  | 6814914                | EXPEDITED (15-DAY) | Y                  | HO              | 1000001553            |                                               | 28 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Pain                                                                                                                                                                                                                  | Escitalopram Oxalate   |                    |                    | S               |                       | 10 Mg (10 Mg, 1 In 1 D)                       |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Zoloft (100 Milligram) |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Stangyl (25 Milligram) |                    |                    | C               |                       |                                               |                 | Not Reported |                |

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| Ximovan                                                                                                          |                      | C                  |                    | Not Reported    |                      |                                                                                                                                                                                                                                                                                                                                                                                                         |                 |              |                |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Remergil                                                                                                         |                      | C                  |                    | Not Reported    |                      |                                                                                                                                                                                                                                                                                                                                                                                                         |                 |              |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                                                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2008                                                                                                      | 6797423              | EXPEDITED (15-DAY) | N                  | HO              | US-GENENTECH-270237  |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                                                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage Intracranial; Maternal Exposure During Pregnancy; Seizure                                            | Xolair               |                    |                    | S               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Genentech    |                |
|                                                                                                                  | Lexapro              |                    |                    | S               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                  | Flonase              |                    |                    | S               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                  | Advair Diskus        |                    |                    | C               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                  | Medrol               |                    |                    | C               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                  | Ranitidine           |                    |                    | C               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                  | Zyrtec               |                    |                    | C               | Transplacental       |                                                                                                                                                                                                                                                                                                                                                                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                                                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Nov-2008                                                                                                      | 6814503              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001575           |                                                                                                                                                                                                                                                                                                                                                                                                         | 42 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                                                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Drug Interaction; Gamma-Glutamyltransferase Increased; Hepatic Function Abnormal; Overdose | Escitalopram Oxalate |                    |                    | S               |                      | 60 Mg (60 Mg, 1 In 1 D)                                                                                                                                                                                                                                                                                                                                                                                 |                 | Not Reported |                |
|                                                                                                                  | Cymbalta             |                    |                    | S               |                      | 30 Mg (30 Mg, 1 In 1 D);<br>60 Mg (60 Mg, 1 In 1 D);<br>90 Mg (90 Mg, 1 In 1 D);<br>150 Mg (150 Mg, 1 In 1 D)<br>30 Mg (30 Mg, 1 In 1 D);<br>60 Mg (60 Mg, 1 In 1 D);<br>90 Mg (90 Mg, 1 In 1 D);<br>150 Mg (150 Mg, 1 In 1 D)<br>30 Mg (30 Mg, 1 In 1 D);<br>60 Mg (60 Mg, 1 In 1 D);<br>90 Mg (90 Mg, 1 In 1 D);<br>150 Mg (150 Mg, 1 In 1 D)<br>30 Mg (30 Mg, 1 In 1 D);<br>60 Mg (60 Mg, 1 In 1 D); |                 | Not Reported |                |

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|                   |   |                                                                                                                                                                        |              |
|-------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                   |   | 90 Mg (90 Mg, 1 In 1 D);<br>150 Mg (150 Mg, 1 In 1 D)<br>30 Mg (30 Mg, 1 In 1 D);<br>60 Mg (60 Mg, 1 In 1 D);<br>90 Mg (90 Mg, 1 In 1 D);<br>150 Mg (150 Mg, 1 In 1 D) |              |
| Cymbalta          | S | 180 Mg (180 Mg, 1 In 1 D)                                                                                                                                              | Not Reported |
| Lamotrigine       | S | 200 Mg (200 Mg, 1 In 1 D)                                                                                                                                              | Not Reported |
| Seroquel          | S | 700 Mg (700 Mg, 1 In 1 D)                                                                                                                                              | Not Reported |
| Tilidine          | S | 400 Mg (400 Mg, 1 In 1 D)                                                                                                                                              | Not Reported |
| Ziprasidone       | S | 240 Mg (240 Mg, 1 In 1 D)                                                                                                                                              | Not Reported |
| Atorvastatin      | S | 10 Mg (10 Mg, 1 In 1 D)                                                                                                                                                | Not Reported |
| Lithium Carbonate | C |                                                                                                                                                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2008              | 6809521       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001514           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Depression; Partial<br>Seizures | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                              |                 | Not Reported |
|                                                          | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5mg,1 In 1 D), Oral :<br>10 Mg (10 Mg,1 In 1 D),<br>Oral : 5 Mg (5 Mg,1 In 1 D)<br>Oral |                 | Not Reported |
|                                                          |                      |              |            |             | Oral         | 5 Mg (5mg,1 In 1 D), Oral :<br>10 Mg (10 Mg,1 In 1 D),<br>Oral : 5 Mg (5 Mg,1 In 1 D)<br>Oral |                 |              |
|                                                          | Sertraline           |              |            | C           |              |                                                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2008              | 6816135       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000001585           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                        |   |      |      |  |  |  |  |              |
|----------------------------------------------------------|------------------------|---|------|------|--|--|--|--|--------------|
| Acute Psychosis; Drug Interaction; Hallucination, Visual | Escitalopram Oxalate   | S | Oral | Oral |  |  |  |  | Not Reported |
|                                                          | Champix                | S |      |      |  |  |  |  | Not Reported |
|                                                          | Elymus Repens Top      | S |      |      |  |  |  |  | Not Reported |
|                                                          | Unspecified Ingredient | C |      |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2008              | 6829382       | EXPEDITED (15-DAY) | Y                  | DE              | CHPA2008US17934      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Aspirin                           |              | Y          | S           | Oral         | Oral               |                 | Not Reported |
|                       | Caffeine                          |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Quetiapine Fumarate               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Acetaminophen\Butalbital\Caffeine |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Acetaminophen (Paracetamol)       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Ibuprofen (Ibuprofen)             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Escitalopram Oxalate              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Naproxen (Naproxen)               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Fexofenadine                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Unspecified Ingredient            |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Nov-2008              | 6808496       | EXPEDITED (15-DAY) | Y                  | DE              | CH-ASTRAZENECA-2008PK02424 |                      | 39 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Seroquel       |              |            | S           | Oral         |                    | 6 DAY           | Not Reported |
|                       | Seroquel       |              |            | S           | Oral         |                    | 6 DAY           | Not Reported |
|                       | Cipralex       |              |            | S           | Oral         |                    | 6 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2008              | 6815708       | DIRECT           | N                  | OT              |                      |                      | 39 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>          |                |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|---------------------|----------------|
| Bruxism; Dermatitis<br>Exfoliative; Hypertension;<br>Paraesthesia; Photopsia;<br>Thyroid Cyst; Vertigo;<br>Withdrawal Syndrome | Lexapro                              |                    |                    | S               | Oral                 | 5 Mg Every Other Day Po          |                 | Not Reported        |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>          | <u>Country</u> |
| 12-Nov-2008                                                                                                                    | 6809756                              | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-H06650808     |                                  | 66 YR           | Female              | FRA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>          |                |
| Aphasia; Hyponatraemia;<br>Seizure; Tremor                                                                                     | Inipomp                              |                    |                    | S               | Oral                 |                                  |                 | Wyeth               |                |
|                                                                                                                                | Escitalopram Oxalate                 |                    |                    | S               | Oral                 |                                  |                 | Lundbeck            |                |
|                                                                                                                                | Tegretal                             |                    |                    | S               | Oral                 |                                  |                 | Novartis            |                |
|                                                                                                                                | Valsartan And<br>Hydrochlorothiazide |                    |                    | S               | Oral                 |                                  |                 | Rhone Poulenc Rorer |                |
|                                                                                                                                | Actonel                              |                    |                    | C               |                      | Unknown                          |                 | Procter And Gamble  |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>          | <u>Country</u> |
| 12-Nov-2008                                                                                                                    | 6816261                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001587           |                                  | 86 YR           | Female              | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>          |                |
| Diverticulum Intestinal;<br>Intestinal Ischaemia;<br>Intestinal Ulcer; Rectal<br>Haemorrhage                                   | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported        |                |
|                                                                                                                                | Aspirin Lysine                       |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                 | Not Reported        |                |
|                                                                                                                                | Triatec (Ramipril)                   |                    |                    | C               |                      |                                  |                 | Not Reported        |                |
|                                                                                                                                | Lyrica                               |                    |                    | C               |                      |                                  |                 | Not Reported        |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>          | <u>Country</u> |
| 12-Nov-2008                                                                                                                    | 6816264                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001595           |                                  | 83 YR           | Female              | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>          |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                |                                  |   |                         |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---|-------------------------|--------------|
| Anal Incontinence; Body Temperature Decreased; Dehydration; Delirium; Disorientation; Drug Interaction; Drug Level Increased; Dysarthria; Enuresis; Somnolence | Escitalopram Oxalate             | S | 20 Mg (20 Mg, 1 In 1 D) | Not Reported |
|                                                                                                                                                                | Venlafaxine Hydrochloride        | S | See Image               | Not Reported |
|                                                                                                                                                                |                                  |   | See Image               |              |
|                                                                                                                                                                |                                  |   | See Image               |              |
|                                                                                                                                                                | Remergil                         | S | 15 Mg (15 Mg, 1 In 1 D) | Not Reported |
|                                                                                                                                                                | Ziprasidone                      | S | 20 Mg (20 Mg, 1 In 1 D) | Not Reported |
|                                                                                                                                                                | Quilonorm                        | C |                         | Not Reported |
|                                                                                                                                                                | Novodigal (.Beta.-Acetyldigoxin) | C |                         | Not Reported |
|                                                                                                                                                                | Enalapril Maleate                | C |                         | Not Reported |
|                                                                                                                                                                | Furorese                         | C |                         | Not Reported |
|                                                                                                                                                                | Arelix                           | C |                         | Not Reported |
|                                                                                                                                                                | Kalinor                          | C |                         | Not Reported |
|                                                                                                                                                                | Godamed                          | C |                         | Not Reported |
|                                                                                                                                                                | Creon                            | C |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2008              | 6776269       | EXPEDITED (15-DAY) | Y                  | CA              | 1000000956           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Apgar Score Low; Bradycardia Neonatal; Caesarean Section; Dismorphism; Ear Malformation; Hypotonia Neonatal; Infantile Apnoea; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Selective Eating Disorder | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |
|                                                                                                                                                                                                                              | Abilify              |              |            | S           | Transplacental | 30 Mg (30 Mg, 1 In 1 D), Tranplacental  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2008              | 6816590       | DIRECT           | N                  | LT              |                      |                      | 51 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aggression; Anger; Anxiety; Bipolar Disorder; Crying; Drug Withdrawal | Cipralext      |              |            | S           | Oral         | 20mg Daily Po      |                 | Lundbeck   |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Syndrome; Insomnia;  
Irritability; Mania;  
Paraesthesia; Physical  
Assault; Restlessness

| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 14-Nov-2008               | 6800676                | EXPEDITED (15-DAY) | Y                  | DE              | 1000001380           |                                  | 47 YR           | Female       | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Stress | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                           | Atenolol               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                           | Hydrochlorothiazide    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                           | Sleep Medication Nos   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2008               | 6805200                | EXPEDITED (15-DAY) | Y                  | HO              | 1000001433           |                                  | 70 YR           | Male         | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma;       | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
| Drug Interaction;         | Previscan (Fluindione) |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| International Normalised  | Kerlone                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| Ratio Increased           | Digoxine               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                           | Furosemide             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2008               | 6819212                | DIRECT             | N                  | OT              |                      |                                  | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Anger            | Risperdal              |                    |                    | S               |                      | 3 Mg Once A Day                  |                 | Not Reported |                |
|                           | Lexapro                |                    |                    | S               |                      | 10mg Once A Day                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 17-Nov-2008                                                 | 6820393              | EXPEDITED (15-DAY) | Y                  | DE              | 1000001658                            |                                   | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                           | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 10 Mg (10 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
|                                                             | Seroquel             |                    |                    | S               | Oral                                  | 12.5 Mg (12.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2008                                                 | 6820395              | EXPEDITED (15-DAY) | Y                  | OT              | 1000001682                            |                                   | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Metrorrhagia; Proctitis; Rectal Haemorrhage                 | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 10 Mg (10 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2008                                                 | 6815218              | EXPEDITED (15-DAY) | Y                  | HO              | US-GENENTECH-271632                   |                                   | 64 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Mucosal Inflammation; Neutrophil Count Decreased | Bevacizumab          |                    |                    | S               | Intravenous (not otherwise specified) | 15 Mg/Kg, Q3w                     |                 | Not Reported |                |
|                                                             | Taxotere             |                    |                    | S               | Intravenous (not otherwise specified) | 75 Mg/M2, Q3w                     |                 | Not Reported |                |
|                                                             | Cisplatin            |                    |                    | S               | Intravenous (not otherwise specified) | 75 Mg/M2, Q3w                     |                 | Not Reported |                |
|                                                             | Lexapro              |                    |                    | S               | Unknown                               |                                   |                 | Not Reported |                |
|                                                             | Elocon               |                    |                    | S               | Unknown                               |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2008                                                 | 6820951              | EXPEDITED (15-DAY) | Y                  | HO              | 2008S1019713                          |                                   | 20 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| Blood Glucose Decreased;<br>Intentional Overdose;<br>Serotonin Syndrome | Dextromethorphan                                              |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                         | Hydrobromide                                                  |                    |                    |                 |                      |                                 |                 |              |                |
|                                                                         | Escitalopram Oxalate                                          |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                         | Benzatropine                                                  |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                         | Aripiprazole                                                  |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2008                                                             | 6640541                                                       | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-01558-01     |                                 | 60 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left                                                | Escitalopram Oxalate                                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, Once A Day), Oral |                 | Not Reported |                |
|                                                                         | Atarax (Hydroxyzine Hydrochloride)(Hydroxyzine Hydrochloride) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2008                                                             | 6823392                                                       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000001310           |                                 | 87 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Loss Of Consciousness; Malaise                           | Escitalopram Oxalate                                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 N 1 D), Oral    |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate                                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                         | Nitriderm(5 Milligram)                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                         | Atenolol (200 Milligram)                                      |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                         | Corvasal (2 Milligram)                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                         | Previscan (Fluindione)                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2008                                                             | 6790327                                                       | EXPEDITED (15-DAY) | Y                  | DE              | US-WYE-H06378608     |                                 | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                                     |                    |                    |                 |                            |                                                |                   |                                                    |                |
|--------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------|-------------------|----------------------------------------------------|----------------|
| Death                                                                          | Pristiq Extended Release<br>Lexapro | S<br>S             | Unknown            |                 |                            |                                                | Wyeth<br>Lundbeck |                                                    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>        | <u>Sex</u>                                         | <u>Country</u> |
| 20-Nov-2008                                                                    | 6816450                             | NON-EXPEDITED      | N                  |                 | A0731228A                  |                                                | 64 YR             | Female                                             | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u>   | <u>Mfr</u>                                         |                |
| Depression; Drug Ineffective; Middle Insomnia; Product Residue Present; Tremor | Bupropion Hydrochloride<br>Lexapro  |                    |                    | S<br>S          | Oral<br>Oral               | 100mg See Dosage Text                          |                   | Glaxosmithkline<br>Not Reported                    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>        | <u>Sex</u>                                         | <u>Country</u> |
| 20-Nov-2008                                                                    | 6816664                             | NON-EXPEDITED      | N                  |                 | A0752013A                  |                                                |                   | Male                                               | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u>   | <u>Mfr</u>                                         |                |
| Psychomotor Hyperactivity; Sleep Disorder                                      | Veramyst<br>Lexapro<br>Valtrex      |                    |                    | S<br>S<br>C     | Nasal<br>Unknown           | 2spr At Night<br>10mg Per Day                  |                   | Glaxosmithkline<br>Not Reported<br>Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>        | <u>Sex</u>                                         | <u>Country</u> |
| 21-Nov-2008                                                                    | 6818578                             | EXPEDITED (15-DAY) | Y                  | HO              | BE-ASTRAZENECA-2008AC02515 |                                                | 46 YR             | Female                                             | BEL            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u>   | <u>Mfr</u>                                         |                |
| Depression; Suicide Attempt                                                    | Seroquel Xr<br>Escitalopram Oxalate |                    |                    | S<br>S          | Oral                       | Suicidal Attempt With 20 Capsules Of Sipralexa |                   | Not Reported<br>Not Reported                       |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                           | <u>Age</u>        | <u>Sex</u>                                         | <u>Country</u> |
| 21-Nov-2008                                                                    | 6826095                             | DIRECT             |                    | HO              |                            |                                                | 66 YR             | Female                                             | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                             | <u>Duration</u>   | <u>Mfr</u>                                         |                |

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|                                                                                                                                                 |                                                                                                        |                                      |              |                                            |                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Alcohol Use; Blood Pressure Systolic Increased; Confusional State; Electrocardiogram Qt Prolonged; Movement Disorder; Overdose; Suicide Attempt | Lexapro<br>Xanax<br>Darvocet<br>Doxepin<br>Norvasc<br>Prevacid<br>Trazodone Hydrochloride<br>Temazepam | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral | Lexapro Daily 20mg Po<br>Xanax 1 Mg Po Tid | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2008              | 6829970       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001730           |                      | 53 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                           | <u>Product</u>                                                                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |
|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| Adrenal Insufficiency; Blood Glucose Increased; Fatigue; Nausea | Escitalopram Oxalate<br>Levemir<br>Hydrokortison Nycomed<br>Tostrex Gel<br>Florinef Acetate<br>Tetralysal<br>Oxscand<br>Novorapid |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | Oral               |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2008              | 6832258       | DIRECT           | N                  | OT              |                      |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------|
| Abnormal Behaviour; Anger; Autophony; Disturbance In Attention; Feeling Abnormal; Feeling Cold; Feeling Hot; Flushing; Hyperhidrosis; Ill-Defined Disorder; Mydriasis; Night Sweats; Palpitations; Personality Change; Photophobia | Lexapro<br>Trazodone Hydrochloride<br>Femring |              |            | S<br>C<br>C | Oral         | 10mg Daily Po      |                 | Forest<br>Not Reported<br>Not Reported |

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| <u>FDA Received Date</u>                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------|-----------------|--------------|----------------|
| 21-Nov-2008                                                                                           | 6833522                 | EXPEDITED (15-DAY) | N                  | OT              | 1000001694           |                                                             | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Splenic Cyst; Vomiting                                                 | Lexapro                 |                    |                    | S               | Oral                 | 5 Mg, (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                       | Clorazepate Dipotassium |                    |                    | C               | Oral                 | 5 Mg, (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Nov-2008                                                                                           | 6843401                 | DIRECT             | N                  | OT              |                      |                                                             | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Healing; Increased Tendency To Bruise                                                        | Citalopram              |                    |                    | S               | Oral                 | 20mg Daily Po                                               |                 | Aurobindo    |                |
|                                                                                                       | Celexa                  |                    |                    | S               |                      |                                                             |                 | Not Reported |                |
|                                                                                                       | Lexapro                 |                    |                    | S               |                      |                                                             |                 | Not Reported |                |
|                                                                                                       | Bupropion               |                    |                    | C               |                      |                                                             |                 | Not Reported |                |
|                                                                                                       | Cozaar                  |                    |                    | C               |                      |                                                             |                 | Not Reported |                |
|                                                                                                       | Doxycycline             |                    |                    | C               |                      |                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2008                                                                                           | 6829009                 | DIRECT             | N                  | HO, OT          |                      |                                                             | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Irritation; Fungal Infection; Influenza Like Illness; Lethargy; Migraine; Urinary Tract Infection | Escitalopram Oxalate    |                    |                    | S               |                      | 28 Mgs. 1 Daily At Night Protocol No. Sct Md-50             |                 | Not Reported |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 25-Nov-2008               | 6820949                | EXPEDITED (15-DAY) |                    | OT              | US-AVENTIS-200817910US                   |                      | 38 YR           | Female               | USA            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Heart Rate Increased;     | Allegra-D              |                    |                    | S               | Oral                                     | Dose: Unk            |                 | Aventis              |                |
| Hypoaesthesia; Mydriasis; | Lexapro                |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
| Panic Attack;             | Lexapro                |                    |                    | S               | Oral                                     |                      |                 | Not Reported         |                |
| Paraesthesia              | Skelaxin               |                    |                    | S               |                                          | Dose: Unk            |                 | Not Reported         |                |
|                           | Unspecified Ingredient |                    |                    | S               |                                          | Dose: Unk            |                 | Not Reported         |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Nov-2008               | 6821552                | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-14418560 |                      | 83 YR           | Female               | USA            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Ulcer                     | Coumadin               |                    |                    | S               | Oral                                     |                      |                 | Bristol Myers Squibb |                |
|                           | Lexapro                |                    |                    | S               | Oral                                     | 10 Mg Tabs           |                 | Not Reported         |                |
|                           | Torseamide             |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Nadolol                |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Potassium              |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Clonidine              |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Meclizine              |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Monopril               |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Neurontin              |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
|                           | Vitamins Nos           |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Nov-2008               | 6832172                | EXPEDITED (15-DAY) | Y                  | OT              | 1000001756                               |                      | 55 YR           | Female               | USA            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cerebrovascular Accident  | Lexapro                |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                           | Cymbalta               |                    |                    | C               |                                          |                      |                 | Not Reported         |                |

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| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Nov-2008                       | 6833381                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000001765                    |                               | 30 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Sleep Sex                         | Lexapro                 |                           |                             | S                        | Oral                          | (10 Mg), Oral                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Nov-2008                       | 6833383                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000001753                    |                               | 50 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Dermatitis             | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),      |                          | Not Reported        |                         |
| Allergic; Eyelid Oedema;          |                         |                           |                             |                          |                               | Oral                          |                          |                     |                         |
| Face Oedema; Headache;            | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 5 Mg (5 Mg, 1 In 1 D), Oral   |                          | Not Reported        |                         |
| Hypoaesthesia                     |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Nov-2008                       | 6824387                 | EXPEDITED (15-DAY)        | N                           | HO                       | US-PFIZER INC-<br>2008097011  |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction;                 | Zyvox                   |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| Dyspnoea; Fatigue;                | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| Hypotension                       |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Nov-2008                       | 6659966                 | EXPEDITED (15-DAY)        | Y                           | CA                       | S08-USA-01791-02              |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Caesarean Section;                | Lexapro                 |                           |                             | S                        | Transplacental                | See Image                     |                          | Not Reported        |                         |
| Craniosynostosis;                 |                         |                           |                             |                          | Transplacental                | See Image                     |                          |                     |                         |
| Maternal Drugs Affecting          |                         |                           |                             |                          | Transplacental                | See Image                     |                          |                     |                         |
| Foetus                            |                         |                           |                             |                          | Transplacental                | See Image                     |                          |                     |                         |



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|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 28-Nov-2008              | 6799289        | EXPEDITED (15-DAY) | Y                  | OT              | 1000001269           |                               | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematemesis; Nausea     | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Symbicort      |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                          | Proventil Hfa  |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 28-Nov-2008                             | 6815051                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001574           |                                               | 66 YR           | Female       | DNK            |
| <u>Preferred Term</u>                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Hyponatraemia; Seizure; Tremor | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D), Oral                  |                 | Not Reported |                |
|                                         | Tegretol                      |                    |                    | S               | Oral                 | 1200 Mg (400 Mg, 3 In 1 D), Oral              |                 | Not Reported |                |
|                                         | Pantoprazole                  |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D), Oral                  |                 | Not Reported |                |
|                                         | Hydrochlorothiazide/Valsartan |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In D), Oral |                 | Not Reported |                |
|                                         | Carbamazepine                 |                    |                    | S               | Oral                 | 1200 Mg (400 Mg, 3 In 1 D), Oral              |                 | Not Reported |                |
|                                         | Actonel (Tablets)             |                    |                    | C               |                      |                                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 28-Nov-2008                                                   | 6832522        | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000001792           |                               | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Breast Cancer; Drug Interaction; Dyspnoea; Fatigue; | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                |   |      |                               |              |
|-------------------------------------------------------------|----------------|---|------|-------------------------------|--------------|
| Hypotension; Nosocomial Infection; Staphylococcal Infection | Lexapro        | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|                                                             | Avonex         | C |      |                               | Not Reported |
|                                                             | Lipitor        | C |      |                               | Not Reported |
|                                                             | Cozaar         | C |      |                               | Not Reported |
|                                                             | Synthroid      | C |      |                               | Not Reported |
|                                                             | Clonazepam     | C |      |                               | Not Reported |
|                                                             | Aspirin        | C |      |                               | Not Reported |
|                                                             | Vitamins (Nos) | C |      |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2008              | 6835343       | EXPEDITED (15-DAY) | Y                  | HO              | US025061             |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Clonus; Delirium; Diarrhoea; Dry Mouth; Hyperhidrosis; Hypervigilance; Mydriasis; Sleep Disorder; Suicide Attempt; Tachycardia | Provigil       |              |            | S           | Oral         | 200 Mg Oral        |                 | Not Reported |
|                                                                                                                                         | Lexapro        |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                                         | Depakote       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Amitriptyline  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Nov-2008              | 6836649       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001760           |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| General Physical Health Deterioration; Oedema Peripheral; Overdose | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                                                                    | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                                                                    | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                    | Clozapine            |              |            | C           |              |                                |                 | Not Reported |
|                                                                    | Valproate Sodium     |              |            | C           |              |                                |                 | Not Reported |
|                                                                    | Aspirin              |              |            | C           |              |                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Dec-2008               | 6838982                  | DIRECT             | N                  | DS, RI, OT      |                      |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;          | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg Daily Po       |                 | Forest       |                |
| Agitation; Anal           | Cetirizine Hydrochloride |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Haemorrhage;              | Fluticasone Propionate   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Chondropathy;             | Levothyronxin            |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Derealisation; Diarrhoea; | Clonazepam               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Dyskinesia; Fatigue; Flat |                          |                    |                    |                 |                      |                      |                 |              |                |
| Affect; Formication;      |                          |                    |                    |                 |                      |                      |                 |              |                |
| Headache; Impaired Work   |                          |                    |                    |                 |                      |                      |                 |              |                |
| Ability; Insomnia; Muscle |                          |                    |                    |                 |                      |                      |                 |              |                |
| Disorder; Muscle Spasms;  |                          |                    |                    |                 |                      |                      |                 |              |                |
| Myalgia; Nausea;          |                          |                    |                    |                 |                      |                      |                 |              |                |
| Nightmare; Palpitations;  |                          |                    |                    |                 |                      |                      |                 |              |                |
| Paraesthesia; Pruritus;   |                          |                    |                    |                 |                      |                      |                 |              |                |
| Pyrexia; Rash; Tremor;    |                          |                    |                    |                 |                      |                      |                 |              |                |
| Vertigo                   |                          |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2008               | 6841241                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000001815           |                      | 89 YR           | Female       | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Sciatica;  | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| Urinary Tract Infection   | Previscan (Fluindione)   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Enterococcal              | Lasix                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Olmotec                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Efferalgan Codeine       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                           | Myorelaxing Agents (Nos) |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2008               | 6841252                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000001816           |                      | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                      |   |      |                                  |              |
|---------------------------------------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Anaphylactic Reaction;<br>Drug Withdrawal<br>Syndrome; Pain Of Skin | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                     | Escitalopram Oxalate | S | Oral | 15 Mg (15 Mg, 1 In 1 D),<br>Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2008              | 6841919       | DIRECT           | N                  | OT              |                      |                      | 41 YR      | Female     | USA            |

  

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Alopecia              | Lexapro        |              |            | S           | Oral         | 20 Mg Once Daily Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 03-Dec-2008              | 6831257       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-<br>20081200324 |                      | 30 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Drug<br>Interaction; Eye Movement<br>Disorder; Nausea; Suicidal<br>Ideation; Tremor; Visual<br>Impairment; Vomiting | Flexeril                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Elavil                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Phenergan               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Darvocet                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Propranolol             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Hctz                    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Metformin Hydrochloride |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Xanax                   |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Synthroid               |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Tri-Sprintec            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Centrum                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                         | Wellbutrin              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Wellbutrin              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Tramadol Hydrochloride  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Lexapro                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                         | Lexapro                 |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 04-Dec-2008                                                                                                                                                                          | 6792695                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001137           |                               | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anaemia; Asthenia; Decreased Appetite; Haematochezia; Haemorrhage; Nausea                                                                                            | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                      | Lexapro                       |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D) Oral  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Dec-2008                                                                                                                                                                          | 6831764                       | EXPEDITED (15-DAY) | Y                  | HO              | US-RB-006932-08      |                               | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Dysarthria; Flushing; Hyperhidrosis; Hyperreflexia; Lethargy; Muscle Rigidity; Overdose; Pyrexia; Serotonin Syndrome; Sinus Tachycardia; Tremor | Dextromethorphan Hydrobromide |                    |                    | S               | Oral                 | Large Amount Ingested.        |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram Oxalate          |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Aripiprazole                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Benzatropine                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Chlorphenamine                |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Nicotine                      |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Marijuana                     |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Unspecified Ingredient        |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Phencyclidine                 |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2008                                                                                                                                                                          | 6746796                       | EXPEDITED (15-DAY) | Y                  | LT              | 1000000531           |                               | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Left Ventricular Failure                                                                                                                                                             | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral  |                 | Not Reported |                |
|                                                                                                                                                                                      | Furosemide                    |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Warfarin Sodium               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Spironolactone                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Digoxin                       |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                      | Aspirin                       |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------|-----------------|--------------|----------------|
| 08-Dec-2008                                                                                                                                                                      | 6835614              | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20081201102 |                                  | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Intentional Overdose;<br>Serotonin Syndrome                                                                                                                 | Flexeril             |                    |                    | S               |                       | 50-60 Mg Once                    |                 | Not Reported |                |
|                                                                                                                                                                                  | Lexapro              |                    |                    | S               |                       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2008                                                                                                                                                                      | 6856079              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000002998            |                                  | 65 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress<br>Syndrome; Alcoholism;<br>Blood Urea Increased;<br>Disturbance In Attention;<br>Encephalopathy; Gait<br>Disturbance; Hypokinesia;<br>Liver Disorder | Escitalopram Oxalate |                    |                    | S               | Oral                  | 6 Mg (6 Mg, 1 In 1 D) ,Oral      |                 | Not Reported |                |
|                                                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                  | 4 Mg (4 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2008                                                                                                                                                                      | 6833399              | EXPEDITED (15-DAY) | Y                  | DE              | 1000001749            |                                  | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Eosinophilic Myocarditis                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2008                                                                                                                                                                      | 6863762              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001476            |                                  | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Extrapyramidal Disorder;<br>Hyponatraemia;                                                                                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      |                   |        |                              |
|--------------------------------------------------------------------------------------|-------------------|--------|------------------------------|
| Macrocytosis; Pallor;<br>Parkinson'S Disease;<br>White Blood Cell Count<br>Increased | Equanil<br>Pritor | C<br>C | Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------|-------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2008              | 6841387              | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-08P-056-0491113-00 |                      | 45 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Leukopenia               | Escitalopram Oxalate |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                          | Prazepam             |                    |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 10-Dec-2008                                                                                | 6863580              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003033           |                                  | 40 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning;<br>Intentional Overdose;<br>Somnolence; Suicide<br>Attempt; Tachycardia | Escitalopram Oxalate |                    |                    | S               | Oral                 | 100 Mg (100 Mg, Once) ,<br>Oral  |                 | Not Reported |                |
|                                                                                            | Doxycycline          |                    |                    | S               | Oral                 | 2000 Mg (2000 Mg, Once),<br>Oral |                 | Not Reported |                |
|                                                                                            | Acetaminophen        |                    |                    | S               | Oral                 | 5000 Mg (5000 Mg, Once),<br>Oral |                 | Not Reported |                |
|                                                                                            | Tetrazepam           |                    |                    | S               | Oral                 | 2500 Mg (2500 Mg, Once),<br>Oral |                 | Not Reported |                |
|                                                                                            | Alcohol              |                    |                    | S               | Oral                 | Half A Bottle Of Hard<br>Liquor  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Dec-2008              | 6863600              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003021           |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Vitreous Detachment      | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2008              | 6864097       | EXPEDITED (15-DAY) | N                  | OT              | 2008S1021274         |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Decreased Appetite; Drug Interaction; Eye Movement Disorder; Food Craving; Headache; Nausea; Pruritus Generalised; Suicidal Ideation; Tremor; Visual Impairment; Vitreous Floaters; Vomiting; Weight Increased | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Mg; Daily; Oral, 10 Mg; Every Other Day; Oral |                 | Not Reported |
|                                                                                                                                                                                                                |                               |              |            |             | Oral         | 10 Mg; Daily; Oral, 10 Mg; Every Other Day; Oral |                 |              |
|                                                                                                                                                                                                                | Amitriptyline Hydrochloride   |              |            | S           | Oral         | 10 Mg; Daily; Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                | Tramadol Hydrochloride        |              |            | S           | Oral         | 50 Mg; Daily; Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                | Cyclobenzaprine Hydrochloride |              |            | S           | Oral         | 10 Mg; Daily; Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                | Phenergan                     |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Darvocet /00220901/           |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Propranolol                   |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Metformin Hydrochloride       |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Xanax                         |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Synthroid                     |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Tri-Sprintec                  |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Hydrochlorothiazide           |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Wellbutrin XL                 |              |            | C           |              |                                                  |                 | Not Reported |
|                                                                                                                                                                                                                | Centrum /00554501/            |              |            | C           |              |                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|------------|------------|----------------|
| 11-Dec-2008              | 6841781       | EXPEDITED (15-DAY) | N                  | HO              | FR-BRISTOL-MYERS SQUIBB COMPANY-14439194 |                      | 66 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|----------------------|
| Angioedema; Malaise   | Glucophage           |              |            | S           |              | Glucophage 500mg, Morning & Evening | 1 YR            | Bristol Myers Squibb |
|                       | Crestor              |              |            | S           |              |                                     | 1 YR            | Not Reported         |
|                       | Inexium              |              |            | S           |              |                                     | 1 YR            | Not Reported         |
|                       | Escitalopram Oxalate |              |            | S           |              |                                     | 1 YR            | Not Reported         |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Dec-2008                      | 6841907                 | NON-EXPEDITED      | N                  |                 | US-AMGEN-KDL274198   |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Erythematous; Rash Pruritic | Enbrel                  |                    |                    | S               | Subcutaneous         |                      |                 | Not Reported |                |
|                                  | Enbrel                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Unspecified Ingredient  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Tricor                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Verapamil Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Plavix                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Niacin                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Magnesium Oxide         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Unspecified Ingredient  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Crestor                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Flomax                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Singulair               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Zetia                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Protonix                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Symlin                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Synthroid               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                  | Topamax                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2008                      | 6864243                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000003036           |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Seizure    | Escitalopram Oxalate    |                    |                    | S               |                      | (1 Dose)             |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2008                      | 6865142                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000003027           |                      | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Petit Mal Epilepsy               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg), Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |              |
|-----------------------|---|--------------|
| Folic Acid            | C | Not Reported |
| Salbutamol (Ampoules) | C | Not Reported |
| Seretide              | C | Not Reported |
| Calcichew D3          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2008              | 6773930       | EXPEDITED (15-DAY) | Y                  | OT              | 1000000944           |                      | 53 YR      | Male       | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Anxiety; Fall; Generalised Tonic-Clonic Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg 1 In 1 D), Oral                               |                 | Not Reported |
|                                                 | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                 |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2008              | 6866136       | EXPEDITED (15-DAY) | Y                  | OT              | 1000003117           |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | Oral                            |                 | Not Reported |
|                       | Ultram         |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Flexeril       |              |            | S           | Oral         | Oral                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2008              | 6827753       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-SYNTHELABO-A02200803454 |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Bones Fracture; Fall | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported |
|                             | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |         |     |              |
|-----------------------------|---|---------|-----|--------------|
| Clotiazepam                 | S | Oral    |     | Not Reported |
| Indapamide\Perindopril      | S | Oral    |     | Not Reported |
| Erbumine                    |   |         |     |              |
| Lercanidipine Hydrochloride | S | Oral    |     | Not Reported |
| Doliprane                   | C | Unknown | Unk | Not Reported |
| Pravastatin Sodium          | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2008              | 6863469       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003038           |                      | 90 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                                                                                    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Drug Ineffective;                   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                                                                                                                                      |                 | Not Reported |
| Dyspnoea; Pulmonary<br>Oedema; Therapeutic<br>Response Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1in 1 D),<br>Oral                                                                                                                                                                       |                 | Not Reported |
|                                                                  | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral<br>10 Mg (10mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral<br>10 Mg (10mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2008              | 6866552       | EXPEDITED (15-DAY) | N                  | HO              | 1000003130           |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; Intentional<br>Self-Injury | Lexapro        |              |            | S           |              | Oral               |                 | Not Reported |
|                                       | Wellbutrin     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2008              | 6867076       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003101           |                      | 81 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                               | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------|-----------------|--------------|----------------|
| Asthenia; Confusional State; Drug Interaction; Fall; Fanconi Syndrome; Inappropriate Antidiuretic Hormone Secretion | Escitalopram Oxalate       |                    |                    | S               |                      | 10 Milligram (10 Mg),Oral; 3 WEEK<br>3 Weeks Prior To Hospitalization |                 | Not Reported |                |
|                                                                                                                     | Hydrochlorothiazide        |                    |                    | S               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Mirtazapine                |                    |                    | S               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Ramipril                   |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Donepezil Hydrochloride    |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Alendronic Acid            |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2008                                                                                                         | 6867086                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000003121           |                                                                       | 69 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Delirium; Disorientation; Drug Interaction; Hallucination                                        | Lexapro                    |                    |                    | S               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Tacrolimus                 |                    |                    | S               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Propoxyphene Hydrochloride |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Promethazine               |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
|                                                                                                                     | Lansoprazole               |                    |                    | C               |                      |                                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2008                                                                                                         | 6867695                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000003132           |                                                                       |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder                                                                                                    | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2008                                                                                                         | 6867703                    | EXPEDITED (15-DAY) | Y                  | DS              | 1000003106           |                                                                       | 41 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Speech Disorder; Tourette'S Disorder                                                                    | Escitalopram Oxalate       |                    |                    | S               | Oral                 | Oral                                                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 16-Dec-2008              | 6853975        | EXPEDITED (15-DAY) | N                  | OT              | A0760418A            |                      |                 | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Aggression; Somnolence   | Dexedrine      |                    |                    | S               | Unknown              |                      |                 | Glaxosmithkline |                |
|                          | Lexapro        |                    |                    | S               | Unknown              |                      |                 | Not Reported    |                |
|                          | Klonopin       |                    |                    | S               |                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Dec-2008                                                                                                                                                                                                                               | 6803782        | EXPEDITED (15-DAY) | N                  | DE              | 1000001403           |                      | 24 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Brain Contusion;<br>Completed Suicide; Gun<br>Shot Wound; Homicide;<br>Left Ventricular<br>Hypertrophy; Pulmonary<br>Haemorrhage;<br>Subarachnoid<br>Haemorrhage; Suicidal<br>Ideation; Treatment<br>Noncompliance | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                           | Risperdal      |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| 17-Dec-2008                                                               | 6855456              | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-G02769908     |                                          | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug Ineffective; Fall;<br>Hypertension; Malaise | Effexor              |                    |                    | S               | Oral                 | Unknown                                  |                 | Wyeth        |                |
|                                                                           | Stilnox              |                    |                    | S               | Oral                 | 10 Mg Strength;<br>Frequency Unspecified |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | Unknown                                  |                 | Lundbeck     |                |
|                                                                           | Atacand              |                    |                    | S               | Oral                 | 8 Mg Strength; Frequency                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                |                    |                    |                 |                                                 |                                                |                 |              |                |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------------------|-----------------|--------------|----------------|
| Vastarel                 |                | S                  |                    | Oral            |                                                 | Unspecified<br>Unknown                         |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2008              | 6820487        | EXPEDITED (15-DAY) | N                  | DE              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14414346 |                                                | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Abilify        |                    |                    | S               | Oral                                            | Start Date Of<br>Treatment:Over A Year<br>Ago. |                 | Not Reported |                |
|                          | Abilify        |                    |                    | S               | Oral                                            | Start Date Of<br>Treatment:Over A Year<br>Ago. |                 | Not Reported |                |
|                          | Abilify        |                    |                    | S               | Oral                                            | Start Date Of<br>Treatment:Over A Year<br>Ago. |                 | Not Reported |                |
|                          | Abilify        |                    |                    | S               | Oral                                            | Start Date Of<br>Treatment:Over A Year<br>Ago. |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                                                 |                                                |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                                                 |                                                |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                                                 |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2008              | 6860212        | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-<br>2008UW23143                  |                                                | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                 | Crestor        |                    |                    | S               | Oral                                            |                                                |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                                            |                                                | 12 MTH          | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                                            |                                                | 12 MTH          | Not Reported |                |
|                          | Synthroid      |                    |                    | S               | Oral                                            |                                                | 15 YR           | Not Reported |                |
|                          | Synthroid      |                    |                    | S               | Oral                                            | 100mcg Daily                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------------------------|--------------------------|-----------------|--------------|----------------|
| 18-Dec-2008                                          | 6870631                       | DIRECT             | Y                  |                 |                                         |                          | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Gastrointestinal<br>Haemorrhage | Lexapro                       |                    |                    | S               |                                         | One To Two Tablets Daily | 1 YR            | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2008                                          | 6861387                       | EXPEDITED (15-DAY) | Y                  | DE              | US-<br>KINGPHARMUSA00001<br>-K200801415 |                          | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                    | Levoxyl                       |                    |                    | S               | Oral                                    | Unk                      |                 | King         |                |
|                                                      | Acetaminophen And Codeine     |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Oxycodone                     |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Escitalopram Oxalate          |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Unspecified Ingredient        |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Diphenhydramine Hydrochloride |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Estradiol                     |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
|                                                      | Progesterone                  |                    |                    | S               | Oral                                    | Unk                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2008                                          | 6861611                       | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-<br>2008153578            |                          | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                    | Amlodipine Besylate           |                    |                    | S               |                                         |                          |                 | Pfizer       |                |
|                                                      | Atenolol                      |                    |                    | S               |                                         |                          |                 | Pfizer       |                |
|                                                      | Trazodone                     |                    |                    | S               |                                         |                          |                 | Not Reported |                |
|                                                      | Escitalopram Oxalate          |                    |                    | S               |                                         |                          |                 | Not Reported |                |
|                                                      | Duloxetine                    |                    |                    | S               |                                         |                          |                 | Not Reported |                |
|                                                      | Losartan                      |                    |                    | S               |                                         |                          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------------------------|------------------------------------------|-----------------|--------------|----------------|
| 19-Dec-2008                                     | 6871516                | DIRECT             | N                  | DE              |                                         |                                          | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                               | Lexapro                |                    |                    | S               | Other                                   | 10 Mg Tablet 1 Tablet<br>Every Mor Other |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2008                                     | 6871740                | DIRECT             | N                  | DS              |                                         |                                          | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation;<br>Nervous System Disorder   | Cymbalta               |                    |                    | S               |                                         | 5 1                                      |                 | Not Reported |                |
|                                                 | Ciprallex              |                    |                    | S               |                                         |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2008                                     | 8268283                | EXPEDITED (15-DAY) | N                  | OT              | US-<br>KINGPHARMUSA00001<br>-K200801406 |                                          | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Heart<br>Rate Increased;      | Skelaxin               |                    |                    | S               |                                         | Unk                                      |                 | King         |                |
| Hypoaesthesia; Mydriasis;                       | Allegra-D              |                    |                    | S               |                                         | Unk                                      |                 | Not Reported |                |
| Panic Attack;                                   | Lexapro                |                    |                    | S               | Oral                                    | 10 Mg, Qd                                | 1 DAY           | Not Reported |                |
| Paraesthesia                                    | Lexapro                |                    |                    | S               | Oral                                    | 5 Mg, Qd                                 | 2 DAY           | Not Reported |                |
|                                                 | Unspecified Ingredient |                    |                    | S               |                                         | Unk                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2008                                     | 6871837                | DIRECT             |                    | HO, OT          |                                         |                                          | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anger;<br>Condition Aggravated; | Lexapro                |                    |                    | S               | Oral                                    | 20 Mg 2 Pills Once A Day<br>Po           |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                     |            |   |      |           |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|------|-----------|--------------|
| Confusional State;<br>Contusion; Depression;<br>Diabetes Mellitus; Dry<br>Mouth; Eye Irritation;<br>Facial Pain; Headache;<br>Hostility; Hyperphagia;<br>Hypophagia; Mental<br>Disorder; Nasal<br>Discomfort; Sinus<br>Disorder; Tremor; Urine<br>Flow Decreased; Vision<br>Blurred | Wellbutrin | S | Oral | 300 Mg Po | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|------|-----------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2008              | 6786190       | NON-EXPEDITED    | Y                  | OT              | US-WYE-H05280808     |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Palpitations          | Pristiq Extended Release |              |            | S           | Oral         | 50 Mg 1x Per 1 Day, Oral |                 | Not Reported |
|                       | Lexapro                  |              |            | S           |              | 25 Mg 1x Per 1 Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2008              | 6808113       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001386           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                                                       | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------|--------------|
| Accommodation Disorder;<br>Anxiety; Buccoglossal<br>Syndrome; Drug<br>Interaction | Escitalopram Oxalate |              |            | S           | Oral                                                               | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                     |                 | Not Reported |
|                                                                                   | Sertindole           |              |            | S           | Oral                                                               | 24 Mg (24 Mg,1 In 1 D),<br>Oral                                                      |                 | Not Reported |
|                                                                                   | Lyrica               |              |            | S           | Occlusive dressing<br>technique<br>Occlusive dressing<br>technique | Oral, 450 Mg (450 Mg, 1 In<br>1 D), Oral<br>Oral, 450 Mg (450 Mg, 1 In<br>1 D), Oral |                 | Not Reported |
|                                                                                   | Escitalopram Oxalate |              |            | C           |                                                                    |                                                                                      |                 | Not Reported |
|                                                                                   | Sertindole (Tablets) |              |            | C           |                                                                    |                                                                                      |                 | Not Reported |
|                                                                                   | Lyrica               |              |            | C           |                                                                    |                                                                                      |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| 22-Dec-2008                                                                                                                                                            | 6809526              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001507           |                                                       | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Dehydration;<br>Fall; Head Injury;<br>Hyponatraemia; Loss Of<br>Consciousness;<br>Neurodegenerative<br>Disorder; Orthostatic<br>Hypotension; Renal<br>Failure | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |                |
|                                                                                                                                                                        | Clotiazepam          |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                        | Zopiclone            |                    |                    | S               | Oral                 | Oral                                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Amlodipine           |                    |                    | S               | Oral                 | (10 Mg), Oral                                         |                 | Not Reported |                |
|                                                                                                                                                                        | Niflumic Acid        |                    |                    | S               | Oral                 | Oral                                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 22-Dec-2008                                                                                                                                                            | 6823221                         | EXPEDITED (15-DAY) | Y                  | HO              | 1000001683           |                                  | 83 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Dizziness;<br>Gastric Ulcer; International<br>Normalised Ratio<br>Increased; Upper<br>Gastrointestinal<br>Haemorrhage; White<br>Blood Cell Count<br>Increased | Lexapro                         |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                        | Coumadin                        |                    |                    | S               | Oral                 | (2.5 Mg), Oral                   |                 | Not Reported |                |
|                                                                                                                                                                        | Torseamide (10 Milligram)       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Nadolol (20 Milligram)          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Potassium (10 Milliequivalents) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Clonidine (0.1 Milligram)       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Meclizine                       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Monopril                        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Neurontin                       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                        | Vitamins (Nos)                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|------------|----------------|
| 22-Dec-2008              | 6863161        | EXPEDITED (15-DAY) | Y                  | OT              | GB-ABBOTT-08P-167-<br>0492788-00 |                      |                 | Male       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |                      |   |      |              |
|--------------------|----------------------|---|------|--------------|
| Pancreatitis Acute | Escitalopram Oxalate | S | Oral | Not Reported |
|--------------------|----------------------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2008              | 6752466       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000000618           |                      | 26 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Atrioventricular Block Complete; Atrioventricular Block Second Degree; Drug Interaction; Ventricular Extrasystoles | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral                              |                 | Not Reported |
|                                                                                                                    | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                    |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                    | Abilify              |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                    |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2008              | 6816224       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000001647           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Intentional Overdose; Sopor; Suicide Attempt | Escitalopram Oxalate       |              |            | S           | Oral         | 260 Mg (260 Mg, Once), Oral   |                 | Not Reported |
|                                              | Clindamycin                |              |            | S           | Oral         | 2100 Mg (2100 Mg, Once), Oral |                 | Not Reported |
|                                              | Prothipendyl Hydrochloride |              |            | S           | Oral         | 40 (40 Once) , Oral           |                 | Not Reported |
|                                              | Stilnox                    |              |            | S           | Oral         | 90 Mg (90 Mg, Once), Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2008              | 6834656       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001801           |                      | 84 YR      | Female     | DEU            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Interstitial Lung Disease                                                                                  | Memantine Hydrochloride       |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
|                                                                                                            | Escitalopram Oxalate          |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |
|                                                                                                            | Aricept                       |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2008                                                                                                | 6865116                       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20081205286 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased; Cardiac Arrest; Completed Suicide; Respiratory Arrest; Toxicity To Various Agents | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Acetaminophen                 |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Acetaminophen                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Escitalopram Oxalate          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Bupropion                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Alcohol                       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Nifedipine                    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                            | Piroxicam                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2008                                                                                                | 6871818                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003238            |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                      | Lexapro                       |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                            | Ativan                        |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                            | Alcohol                       |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2008                                                                                                | 6871824                       | EXPEDITED (15-DAY) | N                  | DE              | 1000003193            |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                          | Lexapro                       |                    |                    | S               | Oral                  | Oral                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 23-Dec-2008                                                                                                                                                                                    | 6872214                           | DIRECT             | N                  | HO, OT          |                      |                                  | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Coordination<br>Abnormal; Diplopia;<br>Dyspnoea; Feeling Cold;<br>Headache; Hot Flush;<br>Muscular Weakness;<br>Nausea; Palpitations;<br>Tremor; Vertigo; Vision<br>Blurred; Vomiting | Lexapro                           |                    |                    | S               | Oral                 | 1 Dose/ 10mg 1 Time Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2008                                                                                                                                                                                    | 6873413                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000003227           |                                  | 76 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Bradyphrenia;<br>Dysstasia; General<br>Physical Health<br>Deterioration;<br>Hypochloraemia;<br>Hypokalaemia;<br>Hyponatraemia;<br>Somnolence                                         | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                | Indapamide\Perindopril            |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Aspegic [Acetylsalicylate Lysine] |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Prazepam                          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                | Fortimel                          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Dec-2008                                                                                                                                                                                    | 6779624                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000001022           |                                  | 32 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Urticaria                                                                                                                                                                                      | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 24-Dec-2008                                                | 6820334                        | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001678           |                               | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Large Intestine Perforation; Rectal Haemorrhage | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                            | Tercian (Drops (For Oral Use)) |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                            | Temesta (Tablets)              |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 24-Dec-2008                                           | 6865973              | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2008153710 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Piroxicam            |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                       | Cyclobenzaprine      |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                       | Acetaminophen        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                       | Bupropion            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                       | Alcohol              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                       | Nifedipine           |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 24-Dec-2008              | 6874024        | EXPEDITED (15-DAY) | Y                  | HO              | 1000003233           |                               | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Seizure      | Lexapro        |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2008              | 6878362       | EXPEDITED (15-DAY) | Y                  | CA              | 1000003244           |                      |            | Unknown    | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| Cleft Palate; Maternal<br>Drugs Affecting Foetus;<br>Maternal Exposure During<br>Pregnancy                | Lexapro                                |                    |                    | S               | Transplacental            | Tranplacental        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2008                                                                                               | 6873658                                | DIRECT             | N                  |                 |                           |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Dehydration;<br>Feeling Abnormal;<br>Hunger; Hyperhidrosis;<br>Loss Of Libido; Pain;<br>Thirst | Lexapro                                |                    |                    | S               | Oral                      | 10 Mg Day Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2008                                                                                               | 6867844                                | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-<br>20081205548 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                | Acetaminophen                          |                    | Y                  | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Acetaminophen                          |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Escitalopram Oxalate                   |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Alprazolam                             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Lorazepam                              |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                                                                                                           | Quetiapine                             |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2008                                                                                               | 6867860                                | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-<br>20081206435 |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                          | Acetaminophen And Codeine<br>Phosphate |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |         |              |
|-------------------------------|---|---------|--------------|
| Oxycodone                     | S | Unknown | Not Reported |
| Escitalopram Oxalate          | S | Unknown | Not Reported |
| Levothyroxine                 | S | Unknown | Not Reported |
| Unspecified Ingredient        | S | Unknown | Not Reported |
| Acetaminophen\Diphenhydramine | S | Unknown | Not Reported |
| Estradiol                     | S | Unknown | Not Reported |
| Progestine                    | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2008              | 6867968                | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2008153731 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Alprazolam             |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                          | Gabapentin             |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                          | Escitalopram Oxalate   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Lamotrigine            |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Alcohol                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Unspecified Ingredient |                    |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Dec-2008              | 6868129              | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2008154117 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Alprazolam           |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                          | Lorazepam            |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Acetaminophen        |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                          | Quetiapine           |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2008              | 6868276       | EXPEDITED (15-DAY) | N                  | HO, LT          | B0551250A            |                      | 47 YR      | Male       | FRA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|-----------------|
| Abdominal Pain; Anaemia;<br>Ascites; Pleural Effusion;<br>Splenic Haemorrhage | Arixtra              |              |            | S           | Unknown                                  |                    |                 | Glaxosmithkline |
|                                                                               | Escitalopram Oxalate |              |            | S           | Oral                                     |                    |                 | Unknown         |
|                                                                               | Rapamycin            |              |            | S           | Intravenous (not<br>otherwise specified) | 25mg Per Day       | 2 DAY           | Unknown         |
|                                                                               | Depakote             |              |            | C           | Unknown                                  |                    |                 | Unknown         |
|                                                                               | Forlax               |              |            | C           | Unknown                                  |                    |                 | Unknown         |
|                                                                               | Stilnox              |              |            | C           | Unknown                                  |                    |                 | Unknown         |
|                                                                               | Visceralgine         |              |            | C           | Unknown                                  |                    |                 | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2008              | 6868553       | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-<br>2008AC03380 |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Atenolol             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Amlodipine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trazodone            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Duloxetine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Losartan             |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2008              | 6868691       | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-<br>2008AC03257 |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Pulseless<br>Electrical Activity | Quetiapine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                        | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2008              | 6868710       | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-      |                      | 29 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2008AC03255

| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Completed Suicide                                              | Quetiapine             |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                | Acetaminophen          |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate   |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                | Lorazepam              |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                | Alprazolam             |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2008                                                    | 6706340                | EXPEDITED (15-DAY) | Y                  | OT              | S08-FRA-02344-01     |                                  | 24 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Rectal Haemorrhage;<br>Thrombocytopenia                        | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                | Alprazolam             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2008                                                    | 6874652                | DIRECT             | N                  | DE              |                      |                                  | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                              | Lexapro                |                    |                    | S               |                      | 10mg Daily                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2008                                                    | 6874865                | DIRECT             | Y                  | HO, LT          |                      |                                  | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Fatigue;<br>Nausea; Nodal<br>Arrhythmia; Presyncope; | Lexapro                |                    |                    | S               | Oral                 | Mg Qday Po                       |                 | Not Reported |                |
|                                                                | Tramadol Hydrochloride |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                |   |              |
|----------|----------------|---|--------------|
| Vomiting | Protonix       | C | Not Reported |
|          | Lyrica         | C | Not Reported |
|          | Carbo Levodopa | C | Not Reported |
|          | Lexapro        | C | Not Reported |
|          | Vitamin D Nos  | C | Not Reported |
|          | Oxcarbazepine  | C | Not Reported |
|          | Diazepam       | C | Not Reported |
|          | Asa            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2008              | 6875063       | DIRECT           | N                  | DE              |                      |                      | 46 YR      | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Cymbalta       |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Effexor Xr     |              |            | S           |              | 37.5 - 75 Mg.      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2008              | 6876621       | EXPEDITED (15-DAY) | N                  | OT              | 1000003317           |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Lethargy; Seizure     | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2008              | 6879835       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003265           |                      | 48 YR      | Male       | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 31-Dec-2008                       | 6772422                 | EXPEDITED (15-DAY)        | Y                           | OT                       | ZM-ABBOTT-08P-189-0477277-00  |                               | 32 YR                    | Male                | ZMB                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity Vasculitis       | Cipralext               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>         | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|---------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 31-Dec-2008                       | 6868116                 | EXPEDITED (15-DAY)        |                             | HO                       | FR-AVENTIS-200814464FR                |                               | 41 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                 | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicide Attempt                   | Lasix                   |                           |                             | S                        | Oral                                  |                               |                          | Aventis             |                         |
|                                   | Levomepromazine         |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Rivotril                |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Lyrica                  |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Anafranil               |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Tysabri                 |                           |                             | S                        | Intravenous (not otherwise specified) |                               |                          | Not Reported        |                         |
|                                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Effexor                 |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Tranxene T-Tab          |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |
|                                   | Tahor                   |                           |                             | S                        | Oral                                  |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>  | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------|--------------------------|---------------------|-------------------------|
| 31-Dec-2008                                 | 6877319                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000003312                    |                                | 56 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>    | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agranulocytosis; Toxicity To Various Agents | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (10 Mg, 1 In 1 D) , Oral |                          | Not Reported        |                         |
|                                             | Taxol                   |                           |                             | C                        |                               |                                |                          | Not Reported        |                         |
|                                             | Unspecified Ingredient  |                           |                             | C                        |                               |                                |                          | Not Reported        |                         |
|                                             | Prazepam                |                           |                             | C                        |                               |                                |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 31-Dec-2008                                                                 | 6878072                             | DIRECT             | N                  | RI              |                      |                                    | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Disturbance In Sexual Arousal; Paraesthesia; Sexual Dysfunction | Lexapro                             |                    |                    | S               | Oral<br>Oral         | 1 Once A Day Po<br>1 Once A Day Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2009                                                                 | 6765736                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000000810           |                                    | 57 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dyskinesia; Feeling Jittery; Tremor                               | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                             | Buscopan (20 Milligram)             |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Clonazepam (0.5 Milligram, Tablets) |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Lorazepam (0.05 Milligram)          |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Tylenol With Codeine No 3 (Tablets) |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Zopiclone (7.5 Milligram, Tablets)  |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2009                                                                 | 6805691                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000001447           |                                    | 31 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Bleeding Time Prolonged; Ecchymosis                                         | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2009                                                                 | 6877380                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000003340           |                                    | 50 YR           | Female       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Dysarthria; Ill-Defined Disorder; Intentional Overdose; Suicide Attempt                    | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 4 Tablets Once, Oral          |                 | Not Reported |                |
|                                                                                            | Carbamazepine             |                    |                    | S               | Oral                 | 3200 Mg, Once, Oral           |                 | Not Reported |                |
|                                                                                            | Doxepin Hydrochloride     |                    |                    | S               | Oral                 | 100 Mg, Once, Oral            |                 | Not Reported |                |
|                                                                                            | Alcohol                   |                    |                    | S               | Oral                 | 2 Glasses Of Wine, Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2009                                                                                | 6877466                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000003333           |                               | 49 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt; Systolic Hypertension | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 1000 Mg (1000 Mg, Once), Oral |                 | Not Reported |                |
|                                                                                            | Dihydrocodeine Bitartrate |                    |                    | S               | Oral                 | 120 Mg (120 Mg, Once), Oral   |                 | Not Reported |                |
|                                                                                            | Alcohol                   |                    |                    | S               | Oral                 | Once, Oral                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2009                                                                                | 6878022                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000003314           |                               | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypothyroidism                                                                             | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                            | Lexomil                   |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2009                                                                                | 6822976                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000001676           |                               | 52 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Chest Discomfort; Clonus; Cognitive Disorder; Demyelination; Drooling;          | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg), Oral           |                 | Not Reported |                |
|                                                                                            | Unspecified Ingredient    |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                            | Unspecified Ingredient    |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                            | Multivitamins And Mineral |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyskinesia; Dysphagia;  
Hypertension; Hypertonia;  
Hypomania;  
Hyponatraemia;  
Hypophagia; Major  
Depression; Muscle  
Rigidity; Musculoskeletal  
Stiffness; Mutism; Nasal  
Discomfort; Reduced  
Facial Expression;  
Regurgitation; Therapy  
Non-Responder; Urinary  
Incontinence; Vomiting  
Projectile

|                                                                                                                                                                                                 |                                                                                                          |                    |                    |                            |                                                     |                                                                                    |                 |                                                                                        |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|-----------------------------------------------------|------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------|----------------|
| Supplement                                                                                                                                                                                      |                                                                                                          |                    |                    |                            |                                                     |                                                                                    |                 |                                                                                        |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                                                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                                | <u>503B Facility</u>                                                               | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 05-Jan-2009                                                                                                                                                                                     | 6873157                                                                                                  | EXPEDITED (15-DAY) |                    | LT, OT                     | ES-ROXANE<br>LABORATORIES, INC.-<br>2008-RO-00468RO |                                                                                    | 81 YR           | Female                                                                                 | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                                                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                        | <u>Dosage Text</u>                                                                 | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Apathy; Asthenia; Dry<br>Skin; General Physical<br>Health Deterioration;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion; Motor<br>Dysfunction; Mucosal<br>Dryness; Pallor | Lorazepam<br>Metformin Hydrochloride<br>Amiodarone<br>Levothyroxine<br>Enalapril<br>Escitalopram Oxalate |                    |                    | S<br>S<br>S<br>S<br>S<br>S |                                                     | 1mg<br>1275mg<br>200mg<br>50mcg<br>10mg<br>10mg                                    |                 | Roxane<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                                                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                                | <u>503B Facility</u>                                                               | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 05-Jan-2009                                                                                                                                                                                     | 6914785                                                                                                  | DIRECT             | N                  | HO, LT, OT                 |                                                     |                                                                                    | 15 YR           | Female                                                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                                                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                        | <u>Dosage Text</u>                                                                 | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Condition Aggravated;<br>Depression; Suicidal<br>Behaviour                                                                                                                                      | Zoloft<br>Lexapro                                                                                        |                    |                    | S<br>S                     | Oral<br>Oral                                        | Low Dosage - Don'T<br>Remember Daily Po<br>Low Dosage - Don'T<br>Remember Daily Po |                 | Not Reported<br>Not Reported                                                           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 06-Jan-2009                                                                                                            | 6878648                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000003370           |                                                                 | 20 YR           | Male                                         | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Accidental Overdose;<br>Confusional State;<br>Diarrhoea; Headache;<br>Skin Burning Sensation;<br>Tearfulness; Vomiting | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 40 Mg (40 Mg, Once), Oral<br>: 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 06-Jan-2009                                                                                                            | 6879183                           | DIRECT             |                    | DE, DS, LT      |                      |                                                                 | 46 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| No Adverse Event                                                                                                       | Lexapro<br>Cymbalta<br>Effexor Xr |                    |                    | S<br>S<br>S     |                      | 75mg. Internal                                                  |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 06-Jan-2009                                                                                                            | 6879191                           | DIRECT             | N                  | DS, RI, OT      |                      |                                                                 | 29 YR           | Male                                         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Amnesia; Imprisonment;<br>Sexual Abuse                                                                                 | Ambien                            |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Trazodone Hydrochloride           |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Temazepam                         |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Paxil                             |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Celexa                            |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Restoril                          |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |
|                                                                                                                        | Lexapro                           |                    |                    | S               |                      | Various Daily                                                   |                 | Not Reported                                 |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 07-Jan-2009                                                                                                      | 6879993              | EXPEDITED (15-DAY) | Y                  | CA              | 1000003363           |                             |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Fetus; Neonatal Disorder; Pyelocaliectasis; Ureteric Obstruction; Vesicoureteric Reflux | Lexapro              |                    |                    | S               | Transplacental       | (20 Mg), Transplacental     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2009                                                                                                      | 6887386              | DIRECT             | Y                  | OT              |                      |                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Feeling Abnormal; Gastric Disorder; Headache; Nausea; Vomiting                                        | Bupropion            |                    |                    | S               | Oral                 | 150 Mg Once Qd Po           |                 | Not Reported |                |
|                                                                                                                  | Lexapro              |                    |                    | S               | Oral                 | 150 Mg Once Qd Po           |                 | Not Reported |                |
|                                                                                                                  |                      |                    |                    |                 |                      | 10 Mg Once Po Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2009                                                                                                      | 4028290              | EXPEDITED (15-DAY) | Y                  | DE              | 000103               |                             | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Completed Suicide; Intentional Product Misuse                                                        | Alprazolam           |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                  | Lamotrigine          |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2009                                                                                                      | 6862740              | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000003070           |                             | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Artificial Menopause; Generalised Tonic-Clonic Seizure;                                                 | Lexapro              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),    |                 | Not Reported |                |

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|                                                             |          |   |      |              |
|-------------------------------------------------------------|----------|---|------|--------------|
| Hand Fracture; Premature Menopause; Spinal Fracture; Tremor | Flexeril | C | Oral | Not Reported |
|-------------------------------------------------------------|----------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6876127       | EXPEDITED (15-DAY) | N                  | HO, OT          | FR-PFIZER INC-2009150668 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Intentional Overdose; Suicide Attempt | Tahor                |              |            | S           | Oral                                  | Every Day Tablets  |                 | Pfizer       |
|                                       | Lyrica               |              |            | S           | Oral                                  | 600 Mg, Unk        |                 | Pfizer       |
|                                       | Levomepromazine      |              |            | S           | Oral                                  | 25 Mg, 1x/Day      |                 | Not Reported |
|                                       | Furosemide           |              |            | S           | Oral                                  | 20 Mg, 1x/Day      |                 | Not Reported |
|                                       | Rivotril             |              |            | S           | Oral                                  | 2 Mg, Unk          |                 | Not Reported |
|                                       | Anafranil            |              |            | S           | Oral                                  | 50 Mg, Unk         |                 | Not Reported |
|                                       | Tysabri              |              |            | S           | Intravenous (not otherwise specified) | 300 Mg, Unk        |                 | Not Reported |
|                                       | Escitalopram Oxalate |              |            | S           | Oral                                  | 20 Mg, Unk         |                 | Not Reported |
|                                       | Effexor              |              |            | S           | Oral                                  | 75 Mg, Unk         |                 | Not Reported |
|                                       | Tranxene T-Tab       |              |            | S           | Oral                                  | 10 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6876282       | EXPEDITED (15-DAY) | Y                  | OT              | ES-JNJFOC-20090100169 |                      | 89 YR      | Female     | ESP            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Psychotic Disorder | Reminyl        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                      | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                      | Lormetazepam   |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6881075       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_32973_2009       |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|       |         |   |    |              |
|-------|---------|---|----|--------------|
| Death | Ativan  | S | Df | Not Reported |
|       | Lexapro | S | Df | Not Reported |
|       | Alcohol | S | Df | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6881191       | EXPEDITED (15-DAY) | N                  | HO, OT          | 1000003414           |                      | 39 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Alcohol Poisoning; Herpes Zoster; Imprisonment; Scar; Trigeminal Nerve Disorder | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                 | Alcohol        |              |            | S           | Oral         | Oral                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6881258       | EXPEDITED (15-DAY) | Y                  | DE              | 000099               |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Product Misuse | Alprazolam           |              |            | S           |              |                    |                 | Not Reported |
|                                               | Lorazepam            |              |            | S           |              |                    |                 | Not Reported |
|                                               | Acetaminophen        |              |            | S           |              |                    |                 | Not Reported |
|                                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                               | Quetiapine           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6887171       | EXPEDITED (15-DAY) | Y                  | DE              | 8040739              |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Product Misuse | Hydrocodone Bitartrate And Acetaminophen |              |            | S           |              |                    |                 | Not Reported |
|                                               | Trazodone Hydrochloride                  |              |            | S           |              |                    |                 | Not Reported |
|                                               | Escitalopram Oxalate                     |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jan-2009              | 6901646       | EXPEDITED (15-DAY) | N                  | OT              | B0552853A            |                      | 64 YR      | Male       | ESP            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|-----------------|----------------|
| Type 2 Diabetes Mellitus                                 | Fluticasone Propionate\Salmeterol Xinafoate |                    |                    | S               | Respiratory (inhalation) |                               |                 | Glaxosmithkline |                |
|                                                          | Escitalopram Oxalate                        |                    |                    | S               | Oral                     | 30mg Per Day                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jan-2009                                              | 7320184                                     | EXPEDITED (15-DAY) | Y                  | DE              | 8040746                  |                               | 40 YR           | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide; Intentional Product Misuse            | Hydrocodone Bitartrate & Acetaminophen      |                    |                    | S               |                          |                               |                 | Not Reported    |                |
|                                                          | Bupropion                                   |                    |                    | S               |                          |                               |                 | Not Reported    |                |
|                                                          | Escitalopram Oxalate                        |                    |                    | S               |                          |                               |                 | Not Reported    |                |
|                                                          |                                             |                    |                    |                 |                          |                               |                 |                 |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Jan-2009                                              | 6782703                                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | PT-PFIZER INC-2008083150 |                               |                 | Unknown         | PRT            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Psychosis; Drug Interaction; Hallucination, Visual | Champix                                     |                    |                    | S               | Oral                     |                               |                 | Pfizer          |                |
|                                                          | Unspecified Ingredient                      |                    |                    | C               |                          |                               |                 | Not Reported    |                |
|                                                          | Trazodone Hydrochloride                     |                    |                    | S               | Oral                     |                               |                 | Not Reported    |                |
|                                                          | Ciprallex                                   |                    |                    | S               |                          |                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 12-Jan-2009                                              | 6722037                                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000000179               |                               | 17 YR           | Male            | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Priapism; Therapy Non-Responder                          | Lexapro                                     |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |
|                                                          | Lexapro                                     |                    |                    | S               | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |
|                                                          | Risperdal                                   |                    |                    | C               |                          |                               |                 | Not Reported    |                |

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2009              | 6878445       | EXPEDITED (15-DAY) | N                  | OT              | A0762895A            |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|---------------|------------------------------|-----------------|-----------------|
| Amnesia; Asthenia;<br>Confusional State;<br>Dizziness; Drug<br>Interaction; Feeling<br>Abnormal; Limb Injury;<br>Localised Infection; Loss<br>Of Consciousness; Pain In<br>Extremity; Tremor;<br>Withdrawal Syndrome | Bupropion                     |              |            | S           | Oral          | 150mg Per Day                |                 | Glaxosmithkline |
|                                                                                                                                                                                                                      | Humira                        |              |            | S           | Subcutaneous  |                              |                 | Not Reported    |
|                                                                                                                                                                                                                      | Vicodin                       |              |            | S           | Oral          | 3tab Per Day                 |                 | Not Reported    |
|                                                                                                                                                                                                                      | Lexapro                       |              |            | S           | Oral          | 20mg Per Day                 |                 | Not Reported    |
|                                                                                                                                                                                                                      | Chlormezanone                 |              |            | S           |               |                              |                 | Not Reported    |
|                                                                                                                                                                                                                      | Amitriptyline                 |              |            | S           | Oral          | 75mg At Night                |                 | Not Reported    |
|                                                                                                                                                                                                                      | Rizatriptan Benzoate          |              |            | S           | Oral          | 10mg Per Day                 |                 | Not Reported    |
|                                                                                                                                                                                                                      | Pregabalin                    |              |            | S           | Oral          | 50mg Twice Per Day           |                 | Not Reported    |
|                                                                                                                                                                                                                      | Celecoxib                     |              |            | S           | Oral          | 200mg Per Day                |                 | Not Reported    |
|                                                                                                                                                                                                                      | Cyclobenzaprine Hydrochloride |              |            | S           | Oral          | 10mg Three Times Per<br>Day  |                 | Not Reported    |
|                                                                                                                                                                                                                      | Unspecified Ingredient        |              |            | S           | Oral          | 100mg Twice Per Day          |                 | Glaxosmithkline |
|                                                                                                                                                                                                                      | Clindamycin                   |              |            | S           | Oral          | 100mg Three Times Per<br>Day | 7 DAY           | Not Reported    |
|                                                                                                                                                                                                                      | Tetanus Toxoid Nos            |              |            | S           | Intramuscular |                              |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 13-Jan-2009              | 6879194       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-<br>20090101314 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Asthenia; Drug Interaction;<br>Loss Of Consciousness;<br>Pain In Extremity; Tremor | Cyclobenzaprine Hydrochloride |              |            | S           | Oral         | As Needed                          |                 | Not Reported |
|                                                                                    | Humira                        |              |            | S           |              | 40mg/0.8ml                         |                 | Not Reported |
|                                                                                    | Vicodin                       |              |            | S           |              | 5/500, 3 Times Daily, As<br>Needed |                 | Not Reported |
|                                                                                    | Lexapro                       |              |            | S           | Oral         |                                    |                 | Not Reported |
|                                                                                    | Chlormezanone                 |              |            | S           | Oral         |                                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |               |              |
|---------------------------------------|---|---------------|--------------|
| Amitriptyline                         | S | Oral          | Not Reported |
| Rizatriptan Benzoate                  | S | Oral          | Not Reported |
| Pregabalin                            | S | Oral          | Not Reported |
| Celecoxib                             | S | Oral          | Not Reported |
| Bupropion                             | S | Oral          | Not Reported |
| Minocycline\Minocycline Hydrochloride | S | Oral          | Not Reported |
| Clindamycin                           | S | Oral          | Not Reported |
| Tetanus Toxoid Nos                    | S | Intramuscular | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Jan-2009              | 6879507       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2009152367 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Orthostatic Hypotension | Amlodipine Besylate                      |              |            | S           | Oral         |                    |                 | Pfizer       |
|                         | Escitalopram Oxalate                     |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Amisulpride                              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Rilmenidine                              |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Aceprometazine\Meprobamate               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                         | Acetaminophen\Propoxyphene Hydrochloride |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2009              | 6889849       | DIRECT           | N                  |                 |                      |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     | 5 YR            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2009              | 6881169       | EXPEDITED (15-DAY) | Y                  | DE              | US-MERCK-0901USA00949 |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |                          |   |      |              |
|--------------------------------|--------------------------|---|------|--------------|
| Completed Suicide;<br>Overdose | Cozaar                   | S | Oral | Merck        |
|                                | Atenolol                 | S | Oral | Not Reported |
|                                | Trazodone Hydrochloride  | S | Oral | Not Reported |
|                                | Amlodipine               | S | Oral | Not Reported |
|                                | Escitalopram Oxalate     | S | Oral | Not Reported |
|                                | Duloxetine Hydrochloride | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2009              | 6887232       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003439           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Bladder Dilatation;<br>Cerebrovascular Accident;<br>Cognitive Disorder;<br>Disorientation;<br>Hyponatraemia; Oedema<br>Peripheral | Escitalopram Oxalate                            |              |            | S           | Oral         | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                   | Celebrex                                        |              |            | S           | Oral         | 200 Mg (200 Mg, 1 In 1 D),<br>Oral                    |                 | Not Reported |
|                                                                                                                                   | Hydrochlorothiazide/Valsartan                   |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Mopral                                          |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Esidrex                                         |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Urbanyl                                         |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Dafalgan                                        |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Propoxyphene Hydrochloride<br>And Acetaminophen |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                   | Motilium                                        |              |            | C           |              |                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2009              | 6891256       | DIRECT           | N                  | OT              |                      |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Burning<br>Sensation; Feeling<br>Abnormal; Feeling Hot;<br>Mental Disorder; Pain;<br>Paraesthesia; Pruritus;<br>Sensory Disturbance; | Lexapro        |              |            | S           |              | Daily              |                 | Not Reported |
|                                                                                                                                                 | Effexor Xr     |              |            | S           |              | Daily              |                 | Not Reported |
|                                                                                                                                                 | Lamictal       |              |            | S           |              | Daily              |                 | Not Reported |
|                                                                                                                                                 | Celexa         |              |            | S           |              | Daily              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                            |                               |                    |                    |                 |             |                           |                                             |                 |              |                |
|--------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------|---------------------------|---------------------------------------------|-----------------|--------------|----------------|
| Shock                                                                                      | Remeron                       |                    |                    | S               |             |                           | Daily                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2009                                                                                | 6796593                       | EXPEDITED (15-DAY) | Y                  | HO, OT          |             | 1000001307                |                                             | 62 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Akathisia;<br>Choreoathetosis; Drug<br>Interaction; Hypomania;<br>Nervousness   | Escitalopram Oxalate          |                    |                    |                 | S           |                           | 10 Mg (10 Mg, 1 In 1 D)                     |                 |              | Not Reported   |
|                                                                                            | Paliperidone                  |                    |                    |                 | S           |                           | 6 Mg (6 Mg, 1 In 1 D)                       |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2009                                                                                | 6881983                       | NON-EXPEDITED      | N                  |                 |             | US-BAYER-<br>200814635BCC |                                             | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Mental Disorder                                                     | Aleve                         |                    |                    |                 | S           | Oral                      |                                             |                 |              | Bayer          |
|                                                                                            | Lexapro                       |                    |                    |                 | S           | Oral                      | Total Daily Dose: 20 Mg<br>Unit Dose: 20 Mg |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |             | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2009                                                                                | 6887697                       | EXPEDITED (15-DAY) | Y                  | DE              |             | DSA_33014_2009            |                                             | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>                |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u> | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Intentional<br>Product Misuse;<br>Respiratory Arrest | Nifedipine                    |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Escitalopram Oxalate          |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Cyclobenzaprine Hydrochloride |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Acetaminophen                 |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Bupropion                     |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Alcohol                       |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |
|                                                                                            | Piroxicam                     |                    |                    |                 | S           | Oral                      | (Df Oral)                                   |                 |              | Not Reported   |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 15-Jan-2009                                                                                                            | 6888094                                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000003493           |                                                                                                                                                                                                                                                                                                                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Retinal Detachment                                                                                                     | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | Oral                                                                                                                                                                                                                                                                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2009                                                                                                            | 6888270                                      | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01768-01     |                                                                                                                                                                                                                                                                                                                             | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Maternal Exposure During Pregnancy; Mood Swings; Paraesthesia; Paranoia; Postpartum Haemorrhage; Pregnancy | Lexapro                                      |                    |                    | S               | Oral                 | 1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral 1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral 1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral 1 In 1 D, Oral; 20 Mg (20 Mg, 1 In 1 D), Oral ; 10 Mg, (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                        | Xanax                                        |                    |                    | C               |                      |                                                                                                                                                                                                                                                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2009                                                                                                            | 6888310                                      | EXPEDITED (15-DAY) | Y                  | DE, HO          | PAR_02529_2009       |                                                                                                                                                                                                                                                                                                                             | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Intentional Product Misuse; Poisoning                                                               | Meloxicam                                    |                    |                    | S               | Oral                 | Df, Oral                                                                                                                                                                                                                                                                                                                    |                 | Not Reported |                |
|                                                                                                                        | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | S               | Oral                 | Df, Oral                                                                                                                                                                                                                                                                                                                    |                 | Not Reported |                |
|                                                                                                                        | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | Df, Oral                                                                                                                                                                                                                                                                                                                    |                 | Not Reported |                |
|                                                                                                                        | Unspecified Ingredient                       |                    |                    | S               | Oral                 | Df, Oral                                                                                                                                                                                                                                                                                                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                  |                    |                    |                 |                      |                                                 |                 |                                              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|----------------------------------------------|----------------|
| Celecoxib                                                                                                                                                                                                                                                                                                                                                                                            |                                                                  |                    | S                  | Oral            | Oral                 | Not Reported                                    |                 |                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Jan-2009                                                                                                                                                                                                                                                                                                                                                                                          | 6888330                                                          | EXPEDITED (15-DAY) | Y                  | HO, LT          | GXKR2009AU00536      |                                                 | 82 YR           | Male                                         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Balance Disorder; Coma;<br>Delirium; Disorientation;<br>Endotracheal Intubation;<br>Fall; Gait Disturbance;<br>Illusion; Intentional<br>Overdose; Loss Of<br>Consciousness; Lung<br>Abscess; Mechanical<br>Ventilation; Movement<br>Disorder; Pleural Effusion;<br>Pneumonia Aspiration;<br>Productive Cough;<br>Rhabdomyolysis; Serratia<br>Infection; Staphylococcal<br>Infection; Suicide Attempt | Escitalopram Oxalate<br>Oxazepam<br>SulfamethoxazoleTrimethoprim |                    |                    | S<br>S<br>S     | Oral                 | 1 Df, Q12h; 2 Df, Q12h,<br>Hospital 35-48, Oral | 22 DAY          | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 15-Jan-2009                                                                                                                                                                                                                                                                                                                                                                                          | 6889127                                                          | EXPEDITED (15-DAY) | Y                  | LT              | 1000003453           |                                                 | 34 YR           | Male                                         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Generalised Tonic-Clonic<br>Seizure                                                                                                                                                                                                                                                                                                                                                                  | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Zopiclone        |                    |                    | S<br>S<br>C     | Oral                 | (20 Mg), Oral                                   |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 16-Jan-2009                                                                                                                                                                                                                                                                                                                                                                                          | 6809536                                                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000001505           |                                                 | 60 YR           | Male                                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Bradycardia; Heart Rate<br>Irregular; Malaise;                                                                                                                                                                                                                                                                                                                                                       | Escitalopram Oxalate                                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)                         |                 | Not Reported                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                             |        |  |  |  |  |  |  |  |       |                              |
|----------------------------------------------------|-----------------------------|--------|--|--|--|--|--|--|--|-------|------------------------------|
| Musculoskeletal Pain;<br>Ventricular Extrasystoles | Zurcal (Tablets)<br>Xalatan | C<br>C |  |  |  |  |  |  |  | ,Oral | Not Reported<br>Not Reported |
|----------------------------------------------------|-----------------------------|--------|--|--|--|--|--|--|--|-------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6816262       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000001596           |                      | 62 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                                                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------|------------|------------------|--------------|----------------------------------|-----------------|--------------------------------------------------------------|
| Gastrointestinal<br>Haemorrhage;<br>Haemodialysis;<br>Nephropathy Toxic; Renal<br>Failure; Tubulointerstitial<br>Nephritis | Escitalopram Oxalate<br>Alopam (10 Milligram, Tablets)<br>Crestor<br>Zolpidem |              |            | S<br>C<br>C<br>C | Oral         | 20 Mg (20 Mg, 1 In 1 D)<br>,Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6883136       | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-09P-163-<br>0497810-00 |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                                                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                               | <u>Route</u> | <u>Dosage Text</u>                                                                                                | <u>Duration</u> | <u>Mfr</u>                                                                                                                                   |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Completed Suicide     | Levothyroxine<br>Acetaminophen<br>Escitalopram Oxalate<br>Codeine<br>Oxycodone<br>Unspecified Ingredient<br>Diphenhydramine<br>Estradiol<br>Progesterone |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S<br>S |              | Ingestion<br>Ingestion<br>Ingestion<br>Ingestion<br>Ingestion<br>Ingestion<br>Ingestion<br>Ingestion<br>Ingestion |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6883336       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14013106 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Drug Screen Positive; Urine Odour Abnormal | Abilify        |                  |                    | S               | Oral                                     |                                                      |                 | Not Reported |                |
|                                                              | Provigil       |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
|                                                              | Keppra         |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
|                                                              | Lamictal       |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
|                                                              | Levothyroxine  |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2009                                                  | 6884386        | NON-EXPEDITED    | Y                  |                 | PR-BRISTOL-MYERS SQUIBB COMPANY-14327126 |                                                      |                 | Female       | PRI            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                                                        | Abilify        |                  |                    | S               |                                          | 1/2 Tablet,As Adjunctive Therapy                     |                 | Not Reported |                |
|                                                              | Abilify        |                  |                    | S               |                                          | 1/2 Tablet,As Adjunctive Therapy                     |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2009                                                  | 6884426        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-14336150 |                                                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                             | Abilify        |                  |                    | S               |                                          | Began 1 1/2 Years Ago, Stopped And Restarted 2 Times |                 | Not Reported |                |
|                                                              | Lexapro        |                  |                    | S               |                                          |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jan-2009                                                  | 6884530        | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-14351779 |                                                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |            |   |                                                                 |              |
|---------------------------------------|------------|---|-----------------------------------------------------------------|--------------|
| Galactorrhoea;<br>Hyperprolactinaemia | Abilify    | S | Dose Reduced To 2.5 Mg 20 MTH<br>And Was Possibly<br>Withdrawn. | Not Reported |
|                                       | Fluoxetine | S |                                                                 | Not Reported |
|                                       | Lexapro    | S |                                                                 | Not Reported |
|                                       | Cymbalta   | S |                                                                 | Not Reported |
|                                       | Strattera  | C |                                                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6884598       | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14362313 |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Restlessness | Abilify        |              |            | S           |              |                    |                 | Not Reported |
|                         | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6884662       | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14369326 |                      | 17 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Crying; Feeling Jittery | Abilify        |              |            | S           |              | Interrupted & Restarted<br>On 7oct08. 1/2 Tab On<br>Day 1 And 1/2 Tab On<br>Day 2. Then Discontinued. |                 | Not Reported |
|                                                   | Abilify        |              |            | S           |              | Interrupted & Restarted<br>On 7oct08. 1/2 Tab On<br>Day 1 And 1/2 Tab On<br>Day 2. Then Discontinued. |                 | Not Reported |
|                                                   | Abilify        |              |            | S           |              | Interrupted & Restarted<br>On 7oct08. 1/2 Tab On<br>Day 1 And 1/2 Tab On<br>Day 2. Then Discontinued. |                 | Not Reported |
|                                                   | Topamax        |              |            | S           |              |                                                                                                       |                 | Not Reported |
|                                                   | Lexapro        |              |            | S           |              |                                                                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| 16-Jan-2009                                                       | 6884786                                 | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14382543 |                      |                 | Unknown                      | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Ineffective                                                  | Abilify<br>Lexapro                      |                    |                    | S<br>S          |                                                 |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Jan-2009                                                       | 6885019                                 | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-09P-163-<br>0497579-00                |                      | 82 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide                                                 | Acetaminophen\Hydrocodone               |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
|                                                                   | Escitalopram Oxalate                    |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
|                                                                   | Trazodone Hydrochloride                 |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Jan-2009                                                       | 6885336                                 | EXPEDITED (15-DAY) |                    | DE              | US-ABBOTT-09P-163-<br>0497839-00                |                      | 40 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide                                                 | Acetaminophen\Hydrocodone<br>Bitartrate |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
|                                                                   | Escitalopram Oxalate                    |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
|                                                                   | Bupropion                               |                    |                    | S               |                                                 | Route: Ingestion     |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Jan-2009                                                       | 6890193                                 | EXPEDITED (15-DAY) | Y                  | LT              | 1000003508                                      |                      | 84 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bone Marrow Failure;<br>General Physical Health<br>Deterioration; | Escitalopram Oxalate                    |                    |                    | S               | Oral                                            | Oral                 |                 | Not Reported                 |                |
|                                                                   | Omeprazole                              |                    |                    | S               | Oral                                            | Oral                 |                 | Not Reported                 |                |

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|              |               |   |      |      |              |
|--------------|---------------|---|------|------|--------------|
| Pancytopenia | Nicorandil    | S | Oral | Oral | Not Reported |
|              | Nicorandil    | S | Oral | Oral | Not Reported |
|              | Zolpidem      | S | Oral | Oral | Not Reported |
|              | Acetaminophen | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6892632       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_32989_2009       |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Lorazepam            |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram Oxalate |              |            | S           |              | (Df)               |                 | Not Reported |
|                                 | Alprazolam           |              |            | S           |              | (Df)               |                 | Not Reported |
|                                 | Acetaminophen        |              |            | S           |              | (Df)               |                 | Not Reported |
|                                 | Quetiapine           |              |            | S           |              | (Df)               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jan-2009              | 6892706       | EXPEDITED (15-DAY) | N                  | OT              | S08-USA-01838-01     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Contusion; Diarrhoea;<br>Dizziness; Maternal<br>Exposure During<br>Pregnancy; Nausea;<br>Pregnancy; Vaginal<br>Haemorrhage | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral; 20 Mg (20 Mg, 1 In 1 D) ,Oral |                 | Not Reported |
|                                                                                                                            |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral; 20 Mg (20 Mg, 1 In 1 D) ,Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2009              | 6886521       | EXPEDITED (15-DAY) | Y                  | DE              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14470447 |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Trazodone Hydrochloride |              |            | S           | Oral         |                    |                 | Apothecon  |

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|                          |   |      |              |
|--------------------------|---|------|--------------|
| Atenolol                 | S | Oral | Sandoz       |
| Amlodipine               | S | Oral | Not Reported |
| Escitalopram Oxalate     | S | Oral | Not Reported |
| Duloxetine Hydrochloride | S | Oral | Not Reported |
| Losartan Potassium       | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2009              | 6886543       | EXPEDITED (15-DAY) | Y                  | DE              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14469928 |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Trazodone Hydrochloride                 |              |            | S           | Oral         |                    |                 | Apothecon    |
|                       | Acetaminophen\Hydrocodone<br>Bitartrate |              |            | S           | Oral         |                    |                 | Endo         |
|                       | Escitalopram Oxalate                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jan-2009              | 6886654       | EXPEDITED (15-DAY) | Y                  | DE              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14472617 |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Trazodone Hydrochloride |              |            | S           | Oral         |                    |                 | Apothecon    |
|                            | Acetaminophen           |              |            | S           | Oral         |                    |                 | Cadence      |
|                            | Oxcarbazepine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Zyprexa                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Benzodiazepine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2009              | 6821501       | EXPEDITED (15-DAY) | Y                  | OT              | 1000001582           |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                           |   |      |      |              |
|-----------------------------|---------------------------|---|------|------|--------------|
| Abnormal Behaviour;         | Lexapro                   | S | Oral | Oral | Not Reported |
| Amnesia; Anger; Anxiety;    | Xanax                     | S |      |      | Not Reported |
| Aphasia; Asbestosis;        | Zoloft                    | S |      |      | Not Reported |
| Attention                   | Neurontin                 | S |      |      | Not Reported |
| Deficit/Hyperactivity       | Trazodone Hydrochloride   | S |      |      | Not Reported |
| Disorder; Back Pain;        | Seroquel                  | S |      |      | Not Reported |
| Blood Cholesterol           | Wellbutrin                | S |      |      | Not Reported |
| Increased; Blood            | Restoril                  | S |      |      | Not Reported |
| Triglycerides Abnormal;     | Cymbalta                  | S |      |      | Not Reported |
| Bruxism; Condition          | Effexor                   | S |      |      | Not Reported |
| Aggravated; Constipation;   | Fenofibrate               | C |      |      | Not Reported |
| Decreased Appetite;         | Levothyroxine             | C |      |      | Not Reported |
| Depression; Dialysis;       | Ambien                    | C |      |      | Not Reported |
| Emotional Distress;         | Hydrochlorothiazide       | C |      |      | Not Reported |
| Feeling Abnormal;           | Acetaminophen\Hydrocodone | C |      |      | Not Reported |
| Hallucination; Headache;    | Bitartrate                |   |      |      |              |
| Hyperhidrosis;              | Carisoprodol              | C |      |      | Not Reported |
| Hypertension;               | Lisinopril                | C |      |      | Not Reported |
| Hypophagia;                 |                           |   |      |      |              |
| Hypothyroidism; Incorrect   |                           |   |      |      |              |
| Dose Administered;          |                           |   |      |      |              |
| Insomnia; Lethargy; Loss    |                           |   |      |      |              |
| Of Personal Independence    |                           |   |      |      |              |
| In Daily Activities; Mental |                           |   |      |      |              |
| Disorder; Muscle Spasms;    |                           |   |      |      |              |
| Muscle Twitching; Night     |                           |   |      |      |              |
| Sweats; Nightmare; Pain;    |                           |   |      |      |              |
| Pallor; Pancreatitis; Panic |                           |   |      |      |              |
| Attack; Paranoia; Renal     |                           |   |      |      |              |
| Failure; Restless Legs      |                           |   |      |      |              |
| Syndrome; Road Traffic      |                           |   |      |      |              |
| Accident; Screaming;        |                           |   |      |      |              |
| Sedation; Seizure; Sleep    |                           |   |      |      |              |
| Apnoea Syndrome; Social     |                           |   |      |      |              |
| Avoidant Behaviour;         |                           |   |      |      |              |
| Suicidal Ideation; Suicide  |                           |   |      |      |              |
| Attempt; Tachycardia;       |                           |   |      |      |              |
| Tardive Dyskinesia;         |                           |   |      |      |              |
| Terminal Insomnia;          |                           |   |      |      |              |
| Thyroid Disorder;           |                           |   |      |      |              |
| Treatment                   |                           |   |      |      |              |
| Noncompliance; Tremor;      |                           |   |      |      |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Urinary Incontinence;  
Vomiting; Weight  
Decreased; Withdrawal  
Syndrome

| <u>FDA Received Date</u>                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Jan-2009                                | 6892571                | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04058_2009       |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning            | Alprazolam             |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                            | Escitalopram Oxalate   |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                            | Lamotrigine            |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                            | Gabapentin             |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                            | Alcohol                |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
|                                            | Unspecified Ingredient |                    |                    | S               |                      | Df                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2009                                | 6892575                | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04055_2009       |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning            | Alprazolam             |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
|                                            | Escitalopram Oxalate   |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
|                                            | Lorazepam              |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
|                                            | Acetaminophen          |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
|                                            | Quetiapine             |                    |                    | S               | Oral                 | Df Oral              |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2009                                | 6894441                | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04193_2009       |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning Deliberate | Oxycodone              |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |   |      |                       |              |
|-------------------------------------|---|------|-----------------------|--------------|
| Acetaminophen And Codeine Phosphate | S |      | (Df Oral)             | Not Reported |
| Escitalopram Oxalate                | S | Oral | (Df Oral)             | Not Reported |
| Levothyroxine                       | S | Oral | (Df Oral)             | Not Reported |
| Unspecified Ingredient              | S | Oral | (Df Oral)             | Not Reported |
| Acetaminophen\Diphenhydramine       | S | Oral | (Df Oral)             | Not Reported |
| Estradiol                           | S | Oral | (Df Oral)             | Not Reported |
| Progesterone                        | S | Oral | (Df Oral) , (Df Oral) | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 21-Jan-2009                      | 6895646                 | DIRECT           | N                  | DE              |                      |                                       | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression | Lexapro                 |                  |                    | S               | Oral                 | 10mg Then Upped To 20mg Once A Day Po |                 | Not Reported |                |
|                                  | Trazodone Hydrochloride |                  |                    | S               | Oral                 | 100mg- 1 D Po                         |                 | Not Reported |                |
|                                  | Ambien Cr               |                  |                    | S               | Oral                 | L N Po                                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------------------------------------------------------------|-----------------|--------------|----------------|
| 21-Jan-2009                                                                  | 6896335              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000003529                            |                                                                            | 47 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Leukocytosis; Pleural Effusion; Splenic Haemorrhage; Thrombocytosis | Escitalopram Oxalate |                    |                    | S               | Oral                                  | Oral                                                                       |                 | Not Reported |                |
|                                                                              | Temsirolimus         |                    |                    | S               | Intravenous (not otherwise specified) | 25 Mg (25 Mg, 1 In 1 D), Intravenous; 25 Mg (25 Mg, 1 In 1 D), Intravenous |                 | Not Reported |                |
|                                                                              |                      |                    |                    |                 | Intravenous (not otherwise specified) | 25 Mg (25 Mg, 1 In 1 D), Intravenous; 25 Mg (25 Mg, 1 In 1 D), Intravenous |                 |              |                |
|                                                                              | Arixtra              |                    |                    | S               |                                       |                                                                            |                 | Not Reported |                |
|                                                                              | Visceralgine         |                    |                    | C               |                                       |                                                                            |                 | Not Reported |                |
|                                                                              | Depakote             |                    |                    | C               |                                       |                                                                            |                 | Not Reported |                |
|                                                                              | Forlax               |                    |                    | C               |                                       |                                                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |                         |                    |                    |                 |                      |                                                                                  |                 |              |                |
|--------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Stilnox                                                      |                         | C                  |                    | Not Reported    |                      |                                                                                  |                 |              |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2009                                                  | 6896501                 | EXPEDITED (15-DAY) | N                  | OT              | 1000003471           |                                                                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Heart Rate Decreased; Maternal Drugs Affecting Foetus | Lexapro                 |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                              |                         |                    |                    |                 | Transplacental       | 10 Mg (10 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 |              |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2009                                                  | 6897316                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000003556           |                                                                                  | 34 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                                                    |                 | Not Reported |                |
|                                                              | Alprazolam Tahor        |                    |                    |                 |                      |                                                                                  |                 |              |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2009                                                  | 7437756                 | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02513_2009       |                                                                                  | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning Deliberate                      | Amlodipine              |                    |                    | S               | Oral                 | (Df Oral)                                                                        |                 | Not Reported |                |
|                                                              | Atenolol                |                    |                    | S               | Oral                 | (Df Oral)                                                                        |                 |              |                |
|                                                              | Trazodone Hydrochloride |                    |                    | S               | Oral                 | (Df Oral)                                                                        |                 |              |                |
|                                                              | Escitalopram Oxalate    |                    |                    | S               | Oral                 | (Df Oral)                                                                        |                 |              |                |
|                                                              | Duloxetine              |                    |                    | S               | Oral                 | (Df Oral)                                                                        |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                   |                      |                    |                    |                 |                      |                                                                    |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| Losartan Potassium                                                                                                |                      |                    | S                  | Oral            | (Df Oral)            | Not Reported                                                       |                 |              |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2009                                                                                                       | 6737811              | EXPEDITED (15-DAY) | Y                  | HO              | 1000000375           |                                                                    | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Diarrhoea;<br>Fatigue; Flatulence;<br>Haematemesis; Scan<br>Adrenal Gland Abnormal;<br>Uterine Leiomyoma | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral; Oral                               |                 | Not Reported |                |
|                                                                                                                   |                      |                    |                    |                 | Oral                 | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral; Oral                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2009                                                                                                       | 6882870              | EXPEDITED (15-DAY) | Y                  | HO              | 1000003431           |                                                                    | 44 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Choloria;<br>Hepatitis Cholestatic                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral; 15 Mg (15 Mg, 1 In 1 D)<br>,Oral |                 | Not Reported |                |
|                                                                                                                   |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral; 15 Mg (15 Mg, 1 In 1 D)<br>,Oral |                 |              |                |
| Zolpidem Tartrate                                                                                                 |                      |                    | C                  | Not Reported    |                      |                                                                    |                 |              |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2009                                                                                                       | 6900052              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003557           |                                                                    | 30 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutrophil Count<br>Decreased; Platelet Count<br>Decreased; White Blood<br>Cell Count Decreased                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>,Oral                                   |                 | Not Reported |                |
|                                                                                                                   | Depakote             |                    |                    | S               | Oral                 | 1000 Mg (500 Mg, 2 In 1 D)<br>,Oral                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 22-Jan-2009                                                                  | 6900287                            | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04138_2009               |                                             | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning Deliberate                                   | Bupropion                          |                    |                    | S               | Oral                         | (Df Oral)                                   |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate               |                    |                    | S               | Oral                         | (Df Oral)                                   |                 | Not Reported |                |
|                                                                              | Acetaminophen\Hydrocodone          |                    |                    | S               | Oral                         | (Df Oral)                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jan-2009                                                                  | 6901182                            | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04118_2009               |                                             | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased;<br>Cardiac Arrest; Poisoning;<br>Respiratory Arrest | Bupropion Hydrochloride            |                    |                    | S               | Oral                         | Df Oral                                     |                 | Not Reported |                |
|                                                                              | Alcohol                            |                    |                    | S               | Oral                         | Df Oral                                     |                 | Not Reported |                |
|                                                                              | Tramadol Hydrochloride             |                    |                    | S               | Oral                         | Df Oral                                     |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate               |                    |                    | S               | Oral                         | Df Oral                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2009                                                                  | 6839882                            | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2008101316 |                                             |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall                                                                         | Xanax                              |                    |                    | S               | Oral                         | 0.5 Mg, 1x/Day                              |                 | Pfizer       |                |
|                                                                              | Zolpidem                           |                    |                    | S               | Oral                         | 1 Df Daily Every Day<br>Tdd:1 Df            |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate               |                    |                    | S               | Oral                         | 1 Df Daily Every Day<br>Tdd:1 Df            |                 | Not Reported |                |
|                                                                              | Indapamide\Perindopril<br>Erbumine |                    |                    | S               | Oral                         | *4mg/1.25mg Daily Every<br>Day Tdd:4mg/1.25 |                 | Not Reported |                |
|                                                                              | Lercanidipine Hydrochloride        |                    |                    | S               | Oral                         | 1 Df, 1x/Day                                |                 | Not Reported |                |
|                                                                              | Pravastatin                        |                    |                    | C               |                              |                                             |                 | Not Reported |                |
|                                                                              | Paracetamol                        |                    |                    | C               |                              |                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Macrogol                 |                                              |                    | C                  |                 |                         | Not Reported         |                 |              |                |
|--------------------------|----------------------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2009              | 6862637                                      | EXPEDITED (15-DAY) | N                  | HO, LT          | BR-GENENTECH-273165     |                      | 49 YR           | Female       | BRA            |
| <u>Preferred Term</u>    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthma                   | Xolair                                       |                    |                    | S               | Subcutaneous            | 300 Mg, 2/Week       |                 | Genentech    |                |
|                          | Xolair                                       |                    |                    | S               | Subcutaneous            | Unk                  |                 | Genentech    |                |
|                          | Lexapro                                      |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                          | Foraseq (Brazil)                             |                    |                    | C               |                         |                      |                 | Not Reported |                |
|                          | Spiriva                                      |                    |                    | C               |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2009              | 6889769                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-20865 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Meloxicam                                    |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                          | Escitalopram Oxalate                         |                    |                    | S               | Oral                    | Unk, Unk             |                 | Not Reported |                |
|                          | Celecoxib                                    |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                          | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                          |                                              |                    |                    |                 |                         |                      |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jan-2009              | 6889865                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-20959 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Acetaminophen                                |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                          | Escitalopram Oxalate                         |                    |                    | S               | Oral                    | Unk, Unk             |                 | Not Reported |                |
|                          | Alprazolam                                   |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                          | Lorazepam                                    |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                          | Quetiapine                                   |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------|-----------------|--------------|----------------|
| 23-Jan-2009                                                                                                                                                                                                   | 6899342                       | EXPEDITED (15-DAY) | Y                  | OT              | 2009S1000630          |                             | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure                                                                                                                                                                              | Escitalopram Oxalate          |                    |                    | S               |                       |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Linezolid                     |                    |                    | S               |                       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2009                                                                                                                                                                                                   | 6856102                       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000002979            |                             | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety; Asphyxia; Condition Aggravated; Disturbance In Attention; Drug Withdrawal Syndrome; Dyspnoea; Irritability; Malaise; Pharyngeal Oedema; Self-Medication; Speech Disorder; Swollen Tongue | Escitalopram Oxalate          |                    |                    | S               | Oral                  | 5 Mg (5 Mg, 1 In 1 D) ,Oral |                 | Not Reported |                |
|                                                                                                                                                                                                               | Stresam                       |                    |                    | C               |                       |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Triella (Tablets)             |                    |                    | C               |                       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                      | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2009                                                                                                                                                                                                   | 6876997                       | EXPEDITED (15-DAY) | Y                  | DE              | US-BAYER-200910098GPV |                             | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                                                                                                                    | Acetaminophen                 |                    | Y                  | S               | Oral                  |                             |                 | Bayer        |                |
|                                                                                                                                                                                                               | Nifedipine                    |                    |                    | S               | Oral                  |                             |                 | Bayer        |                |
|                                                                                                                                                                                                               | Piroxicam                     |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Escitalopram Oxalate          |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Bupropion                     |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                                                                                                                                                                               | Alcohol                       |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|--------------|----------------|
| 26-Jan-2009                                                                            | 6891486                | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-09P-056-0498576-00 |                         | 30 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutrophil Count Decreased; Platelet Count Decreased; White Blood Cell Count Decreased | Depakote               |                    |                    | S               | Oral                         |                         |                 | Not Reported |                |
|                                                                                        | Escitalopram Oxalate   |                    |                    | S               | Oral                         |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2009                                                                            | 6901541                | EXPEDITED (15-DAY) | Y                  | DE              | 1000003591                   |                         | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                      | Lexapro                |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                                                                        | Xanax                  |                    |                    | C               |                              | ,Oral                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2009                                                                            | 6903330                | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02783_2009               |                         | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning Deliberate                                                | Alprazolam             |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
|                                                                                        | Escitalopram Oxalate   |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
|                                                                                        | Lamotrigine            |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
|                                                                                        | Gabapentin             |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
|                                                                                        | Alcohol                |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
|                                                                                        | Unspecified Ingredient |                    |                    | S               |                              | (Df)                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2009                                                                            | 6903340                | EXPEDITED (15-DAY) | Y                  | DE              | PAR_02778_2009               |                         | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                            |                      |   |      |           |              |
|--------------------------------------------|----------------------|---|------|-----------|--------------|
| Completed Suicide;<br>Poisoning Deliberate | Alprazolam           | S | Oral | (Df Oral) | Not Reported |
|                                            | Quetiapine           | S | Oral | (Df Oral) | Not Reported |
|                                            | Escitalopram Oxalate | S | Oral | (Df Oral) | Not Reported |
|                                            | Lorazepam            | S | Oral | (Df Oral) | Not Reported |
|                                            | Acetaminophen        | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2009              | 6858753       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003005           |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Anxiety; Cervical Vertebral<br>Fracture; Condition<br>Aggravated; Fall;<br>Sedation; Somnolence;<br>Thrombocytopenia; Type 2<br>Diabetes Mellitus;<br>Violence-Related<br>Symptom | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                                                                                                                                                                             |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |
|                                                                                                                                                                                                             | Lexapro        |              |            | S           | Oral         | See Image                                                          |                 | Not Reported |
|                                                                                                                                                                                                             |                |              |            |             | Oral         | See Image                                                          |                 |              |
|                                                                                                                                                                                                             |                |              |            |             | Oral         | See Image                                                          |                 |              |
|                                                                                                                                                                                                             |                |              |            |             | Oral         | See Image                                                          |                 |              |
|                                                                                                                                                                                                             | Xanax          |              |            | S           | Oral         | 0.5 Mg (0.5 Mg, As<br>Required), Oral                              |                 | Not Reported |
|                                                                                                                                                                                                             | Lisinopril     |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                             | Protonix       |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                             | Norvasc        |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                             | Cinnamon       |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                             | Carafate       |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                             | Miralax        |              |            | C           |              |                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2009              | 6888084       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003457           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Alcohol Use; Blood<br>Pressure Diastolic | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                          |                                              |                    |                    |                 |                                                     |                                              |                 |              |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------------------------------|-----------------|--------------|-----------------------------------|
| Decreased; Drug Interaction; Malaise; Syncope                                                                                                            |                                              | Levaxin (Tablets)  |                    | C               |                                                     | ,Oral                                        |                 | Not Reported |                                   |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                    |
| 27-Jan-2009                                                                                                                                              | 6893918                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2009-DE-00 |                                              | 49 YR           | Female       | USA                               |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                                   |
| Completed Suicide; Drug Abuse                                                                                                                            | Meloxicam                                    |                    |                    | S               | Oral                                                |                                              |                 |              | Boehringer Ingelheim Not Reported |
|                                                                                                                                                          | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | S               |                                                     |                                              |                 |              |                                   |
|                                                                                                                                                          | Escitalopram Oxalate                         |                    |                    | S               |                                                     |                                              |                 |              |                                   |
|                                                                                                                                                          | Unspecified Ingredient                       |                    |                    | S               |                                                     |                                              |                 |              |                                   |
|                                                                                                                                                          | Celecoxib                                    |                    |                    | S               |                                                     |                                              |                 |              |                                   |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                    |
| 27-Jan-2009                                                                                                                                              | 6902819                                      | DIRECT             | N                  | RI              |                                                     |                                              | 26 YR           | Male         | USA                               |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                                   |
| Anaesthesia; Anhedonia; Anorgasmia; Condition Aggravated; Depression; Ejaculation Delayed; Ejaculation Disorder; Genital Disorder Male; Libido Decreased | Lexapro                                      |                    |                    | S               | Oral                                                | 10mg 1 Daily Po                              | 3 DAY           |              | Forest                            |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                    |
| 28-Jan-2009                                                                                                                                              | 6575575                                      | EXPEDITED (15-DAY) | Y                  | CA, DE          | S08-USA-00471-02                                    |                                              |                 | Female       | USA                               |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                                   |
| Cleft Palate; Limb Reduction Defect; Maternal Drugs Affecting Foetus; Skull                                                                              | Lexapro                                      |                    |                    | S               | Transplacental                                      | Transplacental                               |                 |              | Not Reported                      |
|                                                                                                                                                          | Rebif                                        |                    |                    | S               | Transplacental                                      | 44 Mcg, Three Times Per Week, Transplacental |                 |              | Not Reported                      |

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|                          |           |   |                |                |              |
|--------------------------|-----------|---|----------------|----------------|--------------|
| Malformation; Stillbirth | Neurontin | S | Transplacental | Transplacental | Not Reported |
|                          | Meclizine | S | Transplacental | Transplacental | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2009                             | 6894090                | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-21001  |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Suicidal Ideation | Gabapentin             |                    |                    | S               | Oral                     |                      |                 | Ranbaxy      |                |
|                                         | Lamotrigine            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                         | Alprazolam             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                         | Escitalopram Oxalate   |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                         | Alcohol                |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                         | Unspecified Ingredient |                    |                    | S               | Respiratory (inhalation) |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|-----------------|----------------|
| 28-Jan-2009              | 6894102                       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-21018 |                      | 53 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide        | Acetaminophen                 |                    |                    | S               | Oral                    |                      |                 | Ranbaxy         |                |
|                          | Escitalopram Oxalate          |                    |                    | S               | Oral                    |                      |                 | Not Reported    |                |
|                          | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                    |                      |                 | Ranbaxy         |                |
|                          | Bupropion                     |                    |                    | S               | Oral                    |                      |                 | Not Reported    |                |
|                          | Alcohol                       |                    |                    | S               | Oral                    |                      |                 | Not Reported    |                |
|                          | Nifedipine                    |                    |                    | S               | Oral                    |                      |                 | Not Reported    |                |
|                          | Piroxicam                     |                    |                    | S               | Oral                    |                      |                 | Agvar Chemicals |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|------------|----------------|
| 28-Jan-2009              | 6894523        | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20090106401 |                      | 78 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                                          |   |         |              |
|----------------------------------------------------------------------------------------------|------------------------------------------|---|---------|--------------|
| Confusional State; Drug Interaction; Hypertonia; Orthostatic Hypotension; Status Epilepticus | Tramadol Hydrochloride And Acetaminophen | S | Oral    | Not Reported |
|                                                                                              | Aricept                                  | S | Unknown | Not Reported |
|                                                                                              | Hydrochlorothiazide\Valsartan            | C | Unknown | Not Reported |
|                                                                                              | Calcium                                  | C | Unknown | Not Reported |
|                                                                                              | Fosamax                                  | C |         | Not Reported |
|                                                                                              | Escitalopram Oxalate                     | S | Oral    | Not Reported |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2009                                                                         | 6894705        | EXPEDITED (15-DAY) | N                  | OT              | AU-SANOFI-SYNTHELABO-A01200900474 |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Cerebrovascular Accident; Inappropriate Schedule Of Product Administration | Lexapro        |                    |                    | S               | Oral                              |                      |                 | Not Reported |                |
|                                                                                     | Stilnox        |                    |                    | S               | Oral                              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Jan-2009                                        | 6894771                       | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20090104313 |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| International Normalised Ratio Increased; Overdose | Acetaminophen\Diphenhydramine | Y                  |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                    | Escitalopram Oxalate          |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                    | Zolpidem                      |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 28-Jan-2009                    | 6904617              | EXPEDITED (15-DAY) | Y                  | DS              | 1000003655           |                              | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Urinary Incontinence | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg (30 Mg, 1 In 1 D),Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       |                         |                    |                    |                 |                         |                          |                 |                 |                |
|-------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------|--------------------------|-----------------|-----------------|----------------|
| Escitalopram Oxalate                                  |                         |                    | S                  | Oral            | Oral                    | Not Reported             |                 |                 |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2009                                           | 6895070                 | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-21217 |                          |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Completed Suicide                                     | Atenolol                |                    |                    | S               | Oral                    | Unk, Unk                 |                 | Ohm Lab         |                |
|                                                       | Amlodipine              |                    |                    | S               | Oral                    |                          |                 | Ranbaxy         |                |
|                                                       | Trazodone Hydrochloride |                    |                    | S               | Oral                    |                          |                 | Not Reported    |                |
|                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                    |                          |                 | Not Reported    |                |
|                                                       | Duloxetine              |                    |                    | S               | Oral                    |                          |                 | Not Reported    |                |
|                                                       | Losartan                |                    |                    | S               | Oral                    |                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2009                                           | 6895684                 | NON-EXPEDITED      | N                  |                 | A0702781A               |                          | 33 YR           | Female          | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Drug Interaction;<br>Psychomotor Hyperactivity | Wellbutrin              |                    |                    | S               |                         |                          |                 | Glaxosmithkline |                |
|                                                       | Lexapro                 |                    |                    | S               | Unknown                 |                          |                 | Not Reported    |                |
|                                                       | Ambien                  |                    |                    | S               | Unknown                 |                          |                 | Not Reported    |                |
|                                                       | Unspecified Ingredient  |                    |                    | S               | Unknown                 |                          |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 29-Jan-2009                                           | 6895756                 | NON-EXPEDITED      | N                  |                 | A0729964A               |                          | 38 YR           | Male            | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Aphthous Ulcer; Glossitis;<br>Headache                | Wellbutrin              |                    |                    | S               | Oral                    | 75mg Three Times Per Day |                 | Glaxosmithkline |                |
|                                                       | Lexapro                 |                    |                    | S               |                         | 10mg Per Day             |                 | Not Reported    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 29-Jan-2009                                      | 6898249              | EXPEDITED (15-DAY) | Y                  | DE              | 1000003543           |                                                                                               | 15 YR           | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Ineffective              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, |                 | Not Reported |                |
|                                                  |                      |                    |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, |                 |              |                |
|                                                  |                      |                    |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg, (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, |                 |              |                |
|                                                  | Lerginan             |                    |                    | C               |                      |                                                                                               |                 | Not Reported |                |
|                                                  | Triobe (Tablets)     |                    |                    | C               |                      |                                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2009                                      | 6905766              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003657           |                                                                                               |                 | Male         | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Electrocardiogram Qt Prolonged | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                                                                                          |                 | Not Reported |                |
|                                                  | Ambien               |                    |                    | C               |                      |                                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2009                                      | 6905821              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003652           |                                                                                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperacusis                                      | Lexapro              |                    |                    | S               | Oral                 | Oral                                                                                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|----------------------|----------------|
| 30-Jan-2009                                                                                                                                                                         | 6725505                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000000234                               |                               | 64 YR           | Female               | DNK            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>           |                |
| Alcohol Withdrawal Syndrome; Gastritis; Gastroesophageal Reflux Disease; Hepatic Fibrosis; Hepatic Steatosis; Hepatitis Cholestatic; Oesophageal Ulcer; Toxicity To Various Agents  | Escitalopram Oxalate           |                    |                    | S               | Oral                                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported         |                |
|                                                                                                                                                                                     | Hydrochlorothiazide/Irbesartan |                    |                    | S               | Oral                                     | (2 In 1 M), Oral              |                 | Not Reported         |                |
|                                                                                                                                                                                     | Unspecified Ingredient         |                    |                    | C               |                                          |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Benerva                        |                    |                    | C               |                                          |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Importal                       |                    |                    | C               |                                          |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Supradyn                       |                    |                    | C               |                                          |                               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Jan-2009                                                                                                                                                                         | 6889281                        | EXPEDITED (15-DAY) | N                  | OT              | ES-BRISTOL-MYERS SQUIBB COMPANY-14477640 |                               |                 | Male                 | ESP            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>           |                |
| Amylase Increased; Lipase Increased                                                                                                                                                 | Baraclude                      |                    |                    | S               |                                          |                               |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                     | Escitalopram Oxalate           |                    |                    | S               |                                          |                               |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                                                                            | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 30-Jan-2009                                                                                                                                                                         | 6897054                        | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-0901USA01520                    |                               | 23 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>           |                |
| Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome | Maxalt                         |                    |                    | S               | Oral                                     |                               |                 | Merck                |                |
|                                                                                                                                                                                     | Flexeril                       |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Humira                         |                    |                    | S               | Unknown                                  |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Vicodin                        |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Lexapro                        |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Chlormezanone                  |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Elavil                         |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |
|                                                                                                                                                                                     | Pregabalin                     |                    |                    | S               | Oral                                     |                               |                 | Not Reported         |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |               |              |
|---------------------------------------|---|---------------|--------------|
| Celecoxib                             | S | Oral          | Not Reported |
| Bupropion Hydrochloride               | S | Oral          | Not Reported |
| Minocycline\Minocycline Hydrochloride | S | Oral          | Not Reported |
| Clindamycin                           | S | Oral          | Not Reported |
| Tetanus Toxoid Nos                    | S | Intramuscular | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2009              | 6899552       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003609           |                      | 35 YR      | Male       | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cholestasis; Hepatitis | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2009              | 6907532       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003665           |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Hallucination; Overdose; Unresponsive To Stimuli | Escitalopram Oxalate |              |            | S           | Oral         | 90 Mg (90 Mg, Once), Oral |                 | Not Reported |
|                                                  | Alcohol              |              |            | S           | Oral         | Oral                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2009              | 6907558       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003683           |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2009              | 6907581       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003689           |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |                        |   |      |                                 |              |
|---------|------------------------|---|------|---------------------------------|--------------|
| Seizure | Escitalopram Oxalate   | S | Oral | 10 Mg (10 Mg, 1 In 1 D)<br>Oral | Not Reported |
|         | Aspirin Lysine         | C |      |                                 | Not Reported |
|         | Unspecified Ingredient | C |      |                                 | Not Reported |
|         | Unspecified Ingredient | C |      |                                 | Not Reported |
|         | Prazepam               | C |      |                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2009              | 6909529       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003695           |                      | 77 YR      | Male       | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Fall; Loss Of Consciousness; Malaise | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                      | Avodart              |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Aspirin Lysine       |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Plavix               |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Omexel               |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Celiprolol           |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Coversyl             |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Crestor              |              |            | C           |              |                                  |                 | Not Reported |
|                                      | Timoptic             |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 02-Feb-2009              | 6710135       | EXPEDITED (15-DAY) | Y                  | DE              | ZA-ASTRAZENECA-<br>2008SE03481 |                      | 30 YR      | Male       | ZAF            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Completed Suicide     | Seroquel       |              |            | S           | Oral         | 200 Mg Morning + 400 Mg<br>Night |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         | 20 Mg                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2009              | 6910182       | EXPEDITED (15-DAY) | Y                  | DE              | 2009S1000118         |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                                     |   |      |    |              |
|-------------------|-------------------------------------|---|------|----|--------------|
| Completed Suicide | Roxicodone                          | S | Oral | Po | Not Reported |
|                   | Acetaminophen And Codeine Phosphate | S | Oral | Po | Not Reported |
|                   | Escitalopram Oxalate                | S | Oral | Po | Not Reported |
|                   | Levothyroxine                       | S | Oral | Po | Not Reported |
|                   | Unspecified Ingredient              | S | Oral | Po | Not Reported |
|                   | Acetaminophen\Diphenhydramine       | S | Oral | Po | Not Reported |
|                   | Estradiol                           | S | Oral | Po | Not Reported |
|                   | Progestine                          | S | Oral | Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2009              | 6899800       | EXPEDITED (15-DAY) | N                  | OT              | US-WYE-H07876809     |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>       |
|---------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------|
| Abnormal Behaviour;       | Effexor                 |              |            | S           | Oral         | Unknown            |                 | Wyeth            |
| Amnesia; Anger; Anxiety;  | Lexapro                 |              |            | S           | Oral         | Unknown            |                 | Lundbeck         |
| Aphasia; Asbestosis;      | Lexapro                 |              |            | S           |              |                    |                 | Lundbeck         |
| Attention                 | Xanax                   |              |            | S           |              | Unknown            |                 | Not Reported     |
| Deficit/Hyperactivity     | Xanax                   |              |            | S           |              |                    |                 | Not Reported     |
| Disorder; Blood           | Xanax                   |              |            | S           |              |                    |                 | Not Reported     |
| Cholesterol Increased;    | Xanax                   |              |            | S           |              |                    |                 | Not Reported     |
| Blood Triglycerides       | Zoloft                  |              |            | S           |              | Unknown            |                 | Pfizer           |
| Increased; Bruxism;       | Neurontin               |              |            | S           |              | Unknown            |                 | Not Reported     |
| Condition Aggravated;     | Neurontin               |              |            | S           |              |                    |                 | Not Reported     |
| Constipation; Decreased   | Trazodone Hydrochloride |              |            | S           |              | Unknown            |                 | Unknown          |
| Appetite; Depression;     | Seroquel                |              |            | S           |              | Unknown            |                 | Unknown          |
| Disorientation; Drug      | Seroquel                |              |            | S           |              |                    |                 | Unknown          |
| Withdrawal Syndrome;      | Wellbutrin              |              |            | S           |              | Unknown            |                 | Glaxosmithkline  |
| Emotional Distress;       | Wellbutrin              |              |            | S           |              |                    |                 | Glaxosmithkline  |
| Feeling Abnormal;         | Restoril                |              |            | S           |              | Unknown            |                 | Not Reported     |
| Hallucination; Headache;  | Cymbalta                |              |            | S           |              | Unknown            |                 | Eli Lilly And Co |
| Hyperhidrosis;            | Levothyroxine           |              |            | C           |              |                    |                 | Unknown          |
| Hypertension;             | Ambien                  |              |            | C           |              |                    |                 | Not Reported     |
| Hypothyroidism; Insomnia; |                         |              |            |             |              |                    |                 |                  |
| Intentional Overdose;     |                         |              |            |             |              |                    |                 |                  |
| Lethargy; Loss Of         |                         |              |            |             |              |                    |                 |                  |
| Personal Independence In  |                         |              |            |             |              |                    |                 |                  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                         |                            |                                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------|
| Daily Activities; Mental Disorder; Muscle Spasms; Muscle Twitching; Night Sweats; Nightmare; Pancreatitis; Panic Reaction; Paranoia; Pyrexia; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Sedation; Seizure; Sleep Apnoea Syndrome; Social Avoidant Behaviour; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Terminal Insomnia; Tremor; Urinary Incontinence; Vomiting; Weight Decreased | Hydrochlorothiazide<br>Acetaminophen\Hydrocodone Bitartrate<br>Carisoprodol<br>Lisinopril<br>Fenofibrate<br>Fenofibrate | C<br>C<br>C<br>C<br>C<br>C | Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2009              | 6908759       | EXPEDITED (15-DAY) | Y                  | DE              | 2009S1000100         |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Darvocet-N 100       |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                       | Escitalopram Oxalate |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                       | Benzodiazepine       |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                       | Meloxicam            |              |            | S           | Oral         | ; Po               |                 | Not Reported |
|                                                       | Celecoxib            |              |            | S           | Oral         | ; Po               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2009              | 6866441       | EXPEDITED (15-DAY) | Y                  | HO              | ES-PFIZER INC-2008154990 |                      |            | Unknown    | ESP            |

| <u>Preferred Term</u> | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Agitation; Amnesia;   | Phenytoin Sodium |              |            | S           | Oral         | 100 Mg, Unk        |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |                                            |   |      |             |              |
|-------------------------------------------------------------------------|--------------------------------------------|---|------|-------------|--------------|
| Anticonvulsant Drug Level Above Therapeutic;                            | Lormetazepam                               | C | Oral | Unk         | Not Reported |
| Asthenia; Disorientation;                                               | Pantoprazole                               | C | Oral | Unk         | Not Reported |
| Disturbance In Social Behaviour; Drug Interaction; Dysarthria;          | Aldactone                                  | C | Oral | 100 Mg, Unk | Not Reported |
| Somnolence; Toxicity To Various Agents; Treatment Noncompliance; Tremor | Duphalac                                   | C | Oral | Unk         | Not Reported |
|                                                                         | Lactitol                                   | C | Oral | Unk         | Not Reported |
|                                                                         | Losartan Potassium And Hydrochlorothiazide | C | Oral | Unk         | Not Reported |
|                                                                         | Sucralfate                                 | C | Oral | Unk         | Not Reported |
|                                                                         | Escitalopram Oxalate                       | S | Oral | Unk         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2009              | 6900118       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20090106590 |                      |            | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Fentanyl               |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                            | Amitriptyline          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Amitriptyline          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Bupropion              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Tramadol Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Topiramate             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Morphine               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Citalopram             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Clonazepam             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Lexapro                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Hydrocodone            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Unspecified Ingredient |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Atropine               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                            | Nicotine               |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| 04-Feb-2009                                                                              | 6901095                | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-00679 |                                                                  | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                    | Gabapentin             |                    |                    | S               |                      | Unknown                                                          |                 | Watson       |                |
|                                                                                          | Alprazolam             |                    |                    | S               |                      | Unk                                                              |                 | Watson       |                |
|                                                                                          | Escitalopram Oxalate   |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Lamotrigine            |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Alcohol                |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Unspecified Ingredient |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2009                                                                              | 6909095                | DIRECT             | Y                  | OT              |                      |                                                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea; Drug Intolerance; Hyperhidrosis; Nausea; Nervousness; Rash; Vomiting | Effexor                |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Lexapro                |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Celexa                 |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Wellbutrin Sr          |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2009                                                                              | 6864238                | EXPEDITED (15-DAY) | Y                  | HO              | 1000003029           |                                                                  | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Arachnoid Cyst; Cerebral Cyst; Condition Aggravated; Meningeal Disorder; Seizure         | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 0.7143 Mg (5 Mg, 1 In 1 Wk), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                          |                        |                    |                    |                 | Oral                 | 0.7143 Mg (5 Mg, 1 In 1 Wk), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                          | Imovane                |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                          | Lexomil                |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Feb-2009               | 6901954                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-00636 |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                     | Estradiol                                    |                    |                    | S               |                      | Unknown              |                 | Watson       |                |
|                           | Acetaminophen\Codeine Phosphate              |                    |                    | S               |                      | Unk                  |                 | Watson       |                |
|                           | Oxycodone Hydrochloride                      |                    |                    | S               |                      | Unk                  |                 | Watson       |                |
|                           | Escitalopram Oxalate                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Levothyroxine                                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Unspecified Ingredient                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Acetaminophen\Diphenhydramine Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Progesterone                                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2009               | 6902106                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-00686 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest | Nifedipine                                   |                    |                    | S               |                      | Unknown              |                 | Watson       |                |
|                           | Piroxicam                                    |                    |                    | S               |                      | Unk                  |                 | Watson       |                |
|                           | Cyclobenzaprine Hydrochloride                |                    |                    | S               |                      | Unk                  |                 | Watson       |                |
|                           | Bupropion Hydrochloride                      |                    |                    | S               |                      | Unk                  |                 | Watson       |                |
|                           | Escitalopram Oxalate                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Acetaminophen                                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Alcohol                                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Feb-2009               | 6902507                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-00601 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest | Propoxyphene Hydrochloride And Acetaminophen |                    |                    | S               |                      | Unknown              |                 | Watson       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |     |              |
|--|----------------------|---|-----|--------------|
|  | Meloxicam            | S | Unk | Watson       |
|  | Escitalopram Oxalate | S |     | Not Reported |
|  | Benzodiazepine       | S |     | Not Reported |
|  | Celecoxib            | S |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2009              | 6913016       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2009S1001183         |                      | 52 YR      | Male       | CAN            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Activated Partial Thromboplastin Time Prolonged; Blood Creatine Increased; Blood Creatine Phosphokinase Increased; Blood Ph Decreased; Blood Pressure Decreased; Bundle Branch Block Right; Drug Screen Positive; Heart Rate Decreased; Hyperkalaemia; International Normalised Ratio Increased; Loss Of Consciousness; Nodal Rhythm; Oxygen Saturation Decreased; Sinus Tachycardia | Cipralex                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Diazepam                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Zopiclone               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Lorazepam               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Ms Contin               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Ms Contin               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Ms Contin               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Oxycocet                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Celexa                  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Oxycodone Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Oxycontin               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                      | Ramipril                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Feb-2009              | 7437762       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-00712 |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Amlodipine Besylate     |              |            | S           |              | Unknown            |                 | Watson       |
|                       | Atenolol                |              |            | S           |              | Unk                |                 | Watson       |
|                       | Trazodone Hydrochloride |              |            | S           |              | Unk                |                 | Watson       |
|                       | Escitalopram Oxalate    |              |            | S           |              | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |   |     |              |
|--------------------|---|-----|--------------|
| Duloxetine         | S | Unk | Not Reported |
| Losartan Potassium | S |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Feb-2009              | 6687881       | EXPEDITED (15-DAY) | N                  | OT              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200801054 |                      |            | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;         | Restoril                |              |            | S           |              | Unk, Qd            |                 | Tyco         |
| Amnesia; Anger; Anxiety;    | Restoril                |              |            | S           |              |                    |                 | Tyco         |
| Aphasia; Asbestosis;        | Seroquel                |              |            | S           |              | Unk, Qd            |                 | Not Reported |
| Attention                   | Seroquel                |              |            | S           |              |                    |                 | Not Reported |
| Deficit/Hyperactivity       | Wellbutrin              |              |            | S           |              | Unk, Qd            |                 | Not Reported |
| Disorder; Blood             | Wellbutrin              |              |            | S           |              |                    |                 | Not Reported |
| Cholesterol Abnormal;       | Lexapro                 |              |            | S           |              | Unk, Qd            |                 | Not Reported |
| Blood Pressure Increased;   | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
| Blood Triglycerides         | Cymbalta                |              |            | S           |              | Unk, Qd            |                 | Not Reported |
| Abnormal; Bruxism;          | Cymbalta                |              |            | S           |              |                    |                 | Not Reported |
| Confusional State;          | Zoloft                  |              |            | S           |              | Unk                |                 | Not Reported |
| Constipation; Depression;   | Zoloft                  |              |            | S           |              |                    |                 | Not Reported |
| Drug Withdrawal             | Xanax                   |              |            | S           |              | Unk, Qd            |                 | Not Reported |
| Headache; Dyskinesia;       | Xanax                   |              |            | S           |              |                    |                 | Not Reported |
| Emotional Distress;         | Xanax                   |              |            | S           |              |                    |                 | Not Reported |
| Feeling Abnormal; Gait      | Neurontin               |              |            | S           |              | Unk                |                 | Not Reported |
| Disturbance; Hallucination; | Neurontin               |              |            | S           |              |                    |                 | Not Reported |
| Hostility; Hyperhidrosis;   | Trazodone Hydrochloride |              |            | S           |              | Unk                |                 | Not Reported |
| Hypothyroidism; Lethargy;   | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
| Mental Disorder; Mental     | Lisinopril              |              |            | C           |              |                    |                 | Not Reported |
| Impairment; Muscle          | Fenofibrate             |              |            | C           |              |                    |                 | Not Reported |
| Spasms; Muscle              | Fenofibrate             |              |            | C           |              |                    |                 | Not Reported |
| Twitching; Night Sweats;    | Levothyroxine           |              |            | C           |              |                    |                 | Not Reported |
| Nightmare; Pain; Pallor;    | Ambien                  |              |            | C           |              |                    |                 | Not Reported |
| Pancreatitis; Panic Attack; | Hydrochlorothiazide     |              |            | C           |              |                    |                 | Not Reported |
| Paranoia; Pyrexia; Renal    | Hydrocodone Bitartrate  |              |            | C           |              |                    |                 | Not Reported |
| Failure; Restless Legs      | Carisoprodol            |              |            | C           |              |                    |                 | Not Reported |
| Syndrome; Road Traffic      |                         |              |            |             |              |                    |                 |              |
| Accident; Screaming;        |                         |              |            |             |              |                    |                 |              |
| Seizure; Sleep Apnoea       |                         |              |            |             |              |                    |                 |              |
| Syndrome; Stress;           |                         |              |            |             |              |                    |                 |              |
| Suicidal Ideation; Suicide  |                         |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Attempt; Tachycardia;  
Tardive Dyskinesia;  
Terminal Insomnia;  
Thyroid Disorder; Tremor;  
Urinary Incontinence;  
Vomiting; Weight  
Decreased; Withdrawal  
Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2009              | 6889066       | EXPEDITED (15-DAY) | Y                  | OT              | 1000003430           |                      | 49 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis Toxic       | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg)      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Feb-2009              | 6916347       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003751           |                      | 35 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;<br>Irritability; Mania;<br>Restlessness; Sleep<br>Disorder | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                   | Isoptin              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Ibuprofen            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                   | Omeprazole           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2009              | 6863575       | EXPEDITED (15-DAY) | Y                  | OT              | 1000003022           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Alcohol Use; Feeling Hot;<br>Nausea; Seizure;<br>Syncope; Tunnel Vision | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2009              | 6877968       | EXPEDITED (15-DAY) | Y                  | HO              | US-RANBAXY-2009RR-20314 |                      | 17 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>             | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------|-------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| Nephritis Allergic; Renal Failure | Ibuprofen                           |                    |                    | S               |                                             |                                |                 | Ranbaxy      |                |
|                                   | Lexapro                             |                    |                    | S               |                                             | 10 Mg, Unk                     | 183 DAY         | Not Reported |                |
|                                   | Lexapro                             |                    |                    | S               |                                             | 20 Mg, Unk                     |                 | Not Reported |                |
|                                   | Alprazolam                          |                    |                    | C               |                                             | 0.5 Mg, Prn                    |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2009                       | 6885066                             | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-14466262    |                                | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident          | Abilify                             |                    |                    | S               |                                             | Started With Aripiprazole 10mg |                 | Not Reported |                |
|                                   | Lexapro                             |                    |                    | S               |                                             |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2009                       | 6905029                             | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO HEALTHCARE/MALLIN CKRODT-T200900199 |                                | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                 | Oxycodone                           |                    |                    | S               |                                             |                                |                 | Tyco         |                |
|                                   | Acetaminophen And Codeine Phosphate |                    |                    | S               |                                             |                                |                 | Tyco         |                |
|                                   | Escitalopram Oxalate                |                    |                    | S               |                                             |                                |                 | Not Reported |                |
|                                   | Levothyroxine                       |                    |                    | S               |                                             |                                |                 | Not Reported |                |
|                                   | Unspecified Ingredient              |                    |                    | S               |                                             |                                |                 | Not Reported |                |
|                                   | Diphenhydramine Hydrochloride       |                    |                    | S               |                                             |                                |                 | Not Reported |                |
|                                   | Estradiol                           |                    |                    | S               |                                             |                                |                 | Not Reported |                |
|                                   | Progesterone                        |                    |                    | S               |                                             |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2009                       | 6906024                             | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2009164309                    |                                | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                     |                                       |   |               |                                  |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|---|---------------|----------------------------------|--------------|
| Asthenia; Confusional State; Dizziness; Drug Interaction; Feeling Abnormal; Limb Injury; Localised Infection; Loss Of Consciousness; Pain In Extremity; Tremor; Withdrawal Syndrome | Humira                                | S |               | 1 In 2 Wk                        | Not Reported |
|                                                                                                                                                                                     | Vicodin                               | S | Oral          | 5/500, 3 In 1 D, As Required     | Not Reported |
|                                                                                                                                                                                     | Tetanus Antitoxin                     | S | Intramuscular | Once                             | Not Reported |
|                                                                                                                                                                                     | Celebrex                              | S | Oral          | 200 Mg, 1x/Day                   | Pfizer       |
|                                                                                                                                                                                     | Lyrica                                | S | Oral          | 50 Mg, 2x/Day                    | Pfizer       |
|                                                                                                                                                                                     | Clindamycin Phosphate                 | S | Oral          | 100 Mg, 3x/Day                   | Pfizer       |
|                                                                                                                                                                                     | Lexapro                               | S | Oral          | 20 Mg, 1x/Day                    | Not Reported |
|                                                                                                                                                                                     | Chlormezanone                         | S |               |                                  | Not Reported |
|                                                                                                                                                                                     | Amitriptyline                         | S | Oral          | 75 Mg, 1x/Day At Night           | Not Reported |
|                                                                                                                                                                                     | Rizatriptan Benzoate                  | S | Oral          | 10 Mg, 1x/Day                    | Not Reported |
|                                                                                                                                                                                     | Cyclobenzaprine Hydrochloride         | S | Oral          | 10 Mg, Every 8 Hours As Required | Not Reported |
|                                                                                                                                                                                     | Bupropion                             | S | Oral          | 150 Mg, 1x/Day                   | Not Reported |
|                                                                                                                                                                                     | Minocycline\Minocycline Hydrochloride | S | Oral          | 100 Mg, 2x/Day                   | Not Reported |

| <u>FDA Received Date</u>                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 09-Feb-2009                                              | 6914849              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003823           |                                 | 51 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Intentional Overdose; Suicide Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | (20 Mg, Once), Oral             |                 | Not Reported |                |
|                                                          | Alcohol              |                    |                    | S               | Oral                 | Unknown Amount Of Alcohol, Oral |                 | Not Reported |                |
|                                                          | Zopiclone            |                    |                    | S               | Oral                 | (97.5 Mg, Once), Oral           |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 09-Feb-2009                             | 6914909              | EXPEDITED (15-DAY) | Y                  | HO              | 1000003820           |                             | 96 YR           | Female       | DNK            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Chloride Decreased; Culture Urine | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                         | Urbanyl              |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                       |   |              |
|---------------------------|-----------------------|---|--------------|
| Positive; Escherichia     | Cordarone             | C | Not Reported |
| Infection; Fall; General  | Mediatusyl (Capsules) | C | Not Reported |
| Physical Health           |                       |   |              |
| Deterioration; Heart Rate |                       |   |              |
| Decreased;                |                       |   |              |
| Hyponatraemia             |                       |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2009              | 6915797       | EXPEDITED (15-DAY) | Y                  | HO              | 1000003834           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|-----------------------------|------------------------------------|-----------------|------------------------------|
| Disorientation; Hepatic<br>Encephalopathy; Hepatitis<br>Fulminant; Sleep Disorder | Escitalopram Oxalate       |              |            | S           | Oral                        | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported                 |
|                                                                                   | Nitrazepam                 |              |            | S           | Oral                        | 7.5 Mg (7.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |
|                                                                                   | Morphine Sulfate           |              |            | S           | Oral                        | 60 (60 ,1 In 1 D) ,Oral            |                 | Not Reported                 |
|                                                                                   | Atrovent                   |              |            | S           | Respiratory<br>(inhalation) | Respiratory (Inhalation)           |                 | Not Reported                 |
|                                                                                   | Durogesic                  |              |            | S           | Transdermal                 | (75 Mcg) ,Transdermal              |                 | Not Reported                 |
|                                                                                   | Buprenorphine              |              |            | S           | Transdermal                 | (35 Mcg) ,Transdermal              |                 | Not Reported                 |
|                                                                                   | Primperan<br>Dexketoprofen |              |            | S<br>S      |                             | 25 Mg                              |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2009              | 6906182       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-<br>SYNTHELABO-<br>A02200900243 |                      | 74 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Fall; Gait<br>Disturbance; Muscular<br>Weakness;<br>Rhabdomyolysis | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                    | Ceftazidime          |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                                                    | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                    | Bromazepam           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                    | Bromazepam           |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                                      |   |         |     |              |
|--|------------------------------------------------------|---|---------|-----|--------------|
|  | Spironolactone                                       | S | Oral    |     | Not Reported |
|  | Furosemide                                           | S | Oral    |     | Not Reported |
|  | Doliprane                                            | C | Unknown | Unk | Not Reported |
|  | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C | Unknown | Unk | Not Reported |
|  | Tareg                                                | C | Oral    | Unk | Not Reported |
|  | Inexium                                              | C | Unknown | Unk | Not Reported |
|  | Previscan (Fluindione)                               | C | Oral    | Unk | Not Reported |
|  | Maxidrol                                             | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2009                                                   | 6914469        | DIRECT           | N                  | HO, LT, RI      |                      |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Haematemesis;<br>Screaming; Vomiting | Lexapro        |                  |                    | S               |                      | 1/2 Tablet Every Day | 2 WEEK          | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 11-Feb-2009              | 6691999                 | EXPEDITED (15-DAY) | N                  | OT              | A0736099A            |                      | 63 YR           | Male            | USA            |
| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Anxiety; Aphasia; | Wellbutrin              |                    |                    | S               | Oral                 |                      | 4 YR            | Glaxosmithkline |                |
| Asbestosis; Attention    | Xanax                   |                    |                    | S               | Unknown              |                      | 4 YR            | Not Reported    |                |
| Deficit/Hyperactivity    | Seroquel                |                    |                    | S               | Unknown              |                      | 4 YR            | Not Reported    |                |
| Disorder; Back Pain;     | Lexapro                 |                    |                    | S               | Unknown              |                      | 3 YR            | Not Reported    |                |
| Blood Cholesterol        | Restoril                |                    |                    | S               | Unknown              |                      | 4 YR            | Not Reported    |                |
| Abnormal; Blood Pressure | Cymbalta                |                    |                    | S               | Unknown              |                      | 4 YR            | Not Reported    |                |
| Increased; Blood         | Zoloft                  |                    |                    | S               |                      |                      |                 | Not Reported    |                |
| Triglycerides Abnormal;  | Neurontin               |                    |                    | S               |                      |                      |                 | Glaxosmithkline |                |
| Bruxism; Communication   | Trazodone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported    |                |
| Disorder; Confusional    | Effexor                 |                    |                    | S               |                      |                      |                 | Not Reported    |                |
| State; Constipation;     | Lisinopril              |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| Decreased Appetite;      |                         |                    |                    |                 |                      |                      |                 | Not Reported    |                |
| Depression; Drug         |                         |                    |                    |                 |                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                           |   |                 |
|-----------------------------|---------------------------|---|-----------------|
| Dependence; Dyskinesia;     | Fenofibrate               | C | Not Reported    |
| Emotional Distress;         | Levothyroxine             | C | Glaxosmithkline |
| Feeling Abnormal;           | Ambien                    | C | Not Reported    |
| Hallucination; Head Injury; | Hydrochlorothiazide       | C | Not Reported    |
| Headache; Hyperhidrosis;    | Acetaminophen\Hydrocodone | C | Not Reported    |
| Hypertension;               | Bitartrate                |   |                 |
| Hypothyroidism; Insomnia;   | Carisoprodol              | C | Not Reported    |
| Intentional Overdose;       |                           |   |                 |
| Lethargy; Loss Of           |                           |   |                 |
| Personal Independence In    |                           |   |                 |
| Daily Activities; Memory    |                           |   |                 |
| Impairment; Mental          |                           |   |                 |
| Disorder; Muscle            |                           |   |                 |
| Twitching; Night Sweats;    |                           |   |                 |
| Nightmare; Overdose;        |                           |   |                 |
| Pain; Pallor; Pancreatitis; |                           |   |                 |
| Panic Reaction; Paranoia;   |                           |   |                 |
| Performance Status          |                           |   |                 |
| Decreased; Pyrexia;         |                           |   |                 |
| Regurgitation; Renal        |                           |   |                 |
| Failure; Restless Legs      |                           |   |                 |
| Syndrome; Road Traffic      |                           |   |                 |
| Accident; Sedation;         |                           |   |                 |
| Seizure; Sleep Apnoea       |                           |   |                 |
| Syndrome; Sleep             |                           |   |                 |
| Disorder; Stress; Suicidal  |                           |   |                 |
| Ideation; Suicide Attempt;  |                           |   |                 |
| Tachycardia; Tardive        |                           |   |                 |
| Dyskinesia; Terminal        |                           |   |                 |
| Insomnia; Thyroid           |                           |   |                 |
| Disorder; Tremor; Urinary   |                           |   |                 |
| Incontinence; Vomiting;     |                           |   |                 |
| Weight Decreased;           |                           |   |                 |
| Withdrawal Syndrome         |                           |   |                 |

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 11-Feb-2009                | 6901579              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003576           |                      | 66 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Interaction; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, At     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                     |                      |                    |                    |                 |                      |                                          |                 |              |                                             |  |  |              |  |  |
|-------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|---------------------------------------------|--|--|--------------|--|--|
| Dyspepsia; Nausea;<br>Tardive Dyskinesia                                            |                      |                    | Itopride           |                 |                      | S                                        |                 |              | Bedtime), Oral<br>50 Mg (50 Mg, At Bedtime) |  |  | Not Reported |  |  |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                              |  |  |              |  |  |
| 11-Feb-2009                                                                         | 6907528              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003680           |                                          | 34 YR           | Female       | DEU                                         |  |  |              |  |  |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                                             |  |  |              |  |  |
| Coma; Diarrhoea;<br>Intentional Overdose;<br>Mydriasis; Seizure;<br>Suicide Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1280 Mg, Once, Oral                      |                 | Not Reported |                                             |  |  |              |  |  |
|                                                                                     | Seroquel             |                    |                    | S               | Oral                 | Oral                                     |                 | Not Reported |                                             |  |  |              |  |  |
|                                                                                     | Alcohol              |                    |                    | S               | Oral                 | Oral                                     |                 | Not Reported |                                             |  |  |              |  |  |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                              |  |  |              |  |  |
| 11-Feb-2009                                                                         | 6913013              | EXPEDITED (15-DAY) | Y                  | DE              | 1000003786           |                                          | 55 YR           | Female       | BEL                                         |  |  |              |  |  |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                                             |  |  |              |  |  |
| Completed Suicide                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral         |                 | Not Reported |                                             |  |  |              |  |  |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                              |  |  |              |  |  |
| 11-Feb-2009                                                                         | 6916343              | EXPEDITED (15-DAY) | Y                  | CA              | 1000003842           |                                          | < 1 DAY         | Male         | NLD                                         |  |  |              |  |  |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                                             |  |  |              |  |  |
| Hypospadias; Maternal<br>Drugs Affecting Foetus                                     | Lexapro              |                    |                    | S               | Transplacental       | 10 Mg (10 Mg,1 In 1<br>D),Transplacental |                 | Not Reported |                                             |  |  |              |  |  |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>                              |  |  |              |  |  |
| 11-Feb-2009                                                                         | 6919985              | EXPEDITED (15-DAY) | Y                  | HO              | 1000003838           |                                          | 74 YR           | Male         | FRA                                         |  |  |              |  |  |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                                             |  |  |              |  |  |
| Diarrhoea; Gastrointestinal<br>Disorder; Headache;<br>Hyponatraemia; Malaise;       | Escitalopram Oxalate |                    |                    | S               | Oral                 | (10 Mg),Oral                             |                 | Not Reported |                                             |  |  |              |  |  |
|                                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1                      |                 | Not Reported |                                             |  |  |              |  |  |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                |  |  |   |  |         |  |  |              |
|----------|----------------|--|--|---|--|---------|--|--|--------------|
| Vomiting |                |  |  |   |  | D),Oral |  |  |              |
|          | Imovane        |  |  | C |  |         |  |  | Not Reported |
|          | Levothyrox     |  |  | C |  |         |  |  | Not Reported |
|          | Fosamax        |  |  | C |  |         |  |  | Not Reported |
|          | Pantestone     |  |  | C |  |         |  |  | Not Reported |
|          | Hydrocortisone |  |  | C |  |         |  |  | Not Reported |
|          | Minirin        |  |  | C |  |         |  |  | Not Reported |
|          | Lanzor         |  |  | C |  |         |  |  | Not Reported |
|          | Ercefuryl      |  |  | C |  |         |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2009              | 6920078       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003860           |                      | 70 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>General Physical Health<br>Deterioration;<br>Hyponatraemia;<br>Leukocytosis; Respiratory<br>Distress; Somnolence | Escitalopram Oxalate                 |              |            | S           | Oral         | 5 Dosage Forms (5<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                           | Buscapina (10 Milligram,<br>Tablets) |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                                                           | Morphine Hydrochloride(Tablets)      |              |            | C           |              |                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2009              | 6750799       | EXPEDITED (15-DAY) | Y                  | DS, OT          | 1000000599           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Blood Albumin Decreased;<br>Cognitive Disorder; Drug<br>Interaction; Dyskinesia;<br>Influenza Like Illness;<br>Memory Impairment;<br>Motor Dysfunction;<br>Platelet Count Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral          |                 | Not Reported |
|                                                                                                                                                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5mg, 1 In 1 D), Oral                |                 | Not Reported |
|                                                                                                                                                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral               |                 | Not Reported |
|                                                                                                                                                                                     | Disulfiram           |              |            | S           | Oral         | 228.5714 Mg (1600 Mg, 1<br>In 1 Wk), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2009              | 6915720       | DIRECT           | Y                  |                 |                      |                      | 85 YR      | Female     | USA            |

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| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Drug Ineffective; Drug Intolerance                                                                                                                 | Lexapro                                  |                    |                    | S               | Oral                 | 10 Mg Daily Po                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2009                                                                                                                                        | 6917008                                  | DIRECT             | Y                  | HO              |                      |                                                 | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Serotonin Syndrome                                                                                                               | Zyvox                                    |                    |                    | S               | Oral                 | 600mg Bid Po                                    | 14 DAY          | Pfizer       |                |
|                                                                                                                                                    | Lexapro                                  |                    |                    | S               | Oral                 | 20mg Daily Po                                   | 7 MTH           | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2009                                                                                                                                        | 6918680                                  | EXPEDITED (15-DAY) | Y                  | DS              | 1000003882           |                                                 | 80 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Emotional Disorder                                                                                                       | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                   |                 | Not Reported |                |
|                                                                                                                                                    | Calchichew D3 Forte                      |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                    | Betahistine                              |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                    | Alendronic Acid                          |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                    | Vitamin B12                              |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                                                    | Lansoprazole                             |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2009                                                                                                                                        | 6918734                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000003905           |                                                 | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Creatinine Renal Clearance Decreased; Disorientation; Drug Level Below Therapeutic; Fall; Hypertonia; Hypokalaemia; Orthostatic | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                   |                 | Not Reported |                |
|                                                                                                                                                    | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               | Oral                 | 3 Dosage Forms (1 Dosage Forms, 3 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                    | Aricept (Tablets)                        |                    |                    | C               |                      |                                                 |                 | Not Reported |                |

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|                      |                               |   |              |
|----------------------|-------------------------------|---|--------------|
| Hypotension; Posture | Hydrochlorothiazide/Valsartan | C | Not Reported |
| Abnormal; Status     | Cacit D3                      | C | Not Reported |
| Epilepticus          | Fosamax                       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2009              | 6753453       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000000627           |                      | 26 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Alcohol Increased; | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Coma; Intentional        | Tranxene T-Tab       |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Overdose; Pneumonia      | Anafranil            |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Aspiration; Pneumonia    | Cyamemazine          |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Staphylococcal; Suicide  |                      |              |            |             |              |                    |                 |              |
| Attempt; Toxicity To     |                      |              |            |             |              |                    |                 |              |
| Various Agents           |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2009              | 6820392       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001660           |                      | 65 YR      | Male       | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia;               | Escitalopram Oxalate |              |            | S           | Oral         | (20 Mg), Oral      |                 | Not Reported |
| Atrioventricular Block;   | Levemir              |              |            | C           |              |                    |                 | Not Reported |
| Pallor; Refusal Of        | Novonorm             |              |            | C           |              |                    |                 | Not Reported |
| Treatment By Patient;     | Mediator             |              |            | C           |              |                    |                 | Not Reported |
| Syncope; Urinary          | Allopurinol          |              |            | C           |              |                    |                 | Not Reported |
| Incontinence; Ventricular | Triatec (Ramipril)   |              |            | C           |              |                    |                 | Not Reported |
| Tachycardia               | Aspirin Lysine       |              |            | C           |              |                    |                 | Not Reported |
|                           | Pravastatin          |              |            | C           |              |                    |                 | Not Reported |
|                           | Atenolol             |              |            | C           |              |                    |                 | Not Reported |
|                           | Lasix                |              |            | C           |              |                    |                 | Not Reported |
|                           | Xatral               |              |            | C           |              |                    |                 | Not Reported |
|                           | Proscar              |              |            | C           |              |                    |                 | Not Reported |
|                           | Noctamide            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2009              | 6909487       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003701           |                      | 76 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| Completed Suicide; Stress                                                         | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                   | Requip                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Sinemet                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2009                                                                       | 6919812                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000003923           |                                    | 87 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Cognitive Disorder; Confusional State; Disorientation; Urinary Retention | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral        |                 | Not Reported |                |
|                                                                                   | Topalgic [Tramadol Hydrochloride] |                    |                    | S               | Oral                 | 200 Mg (100 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                   | Atarax                            |                    |                    | S               | Oral                 | (100 Mg, As Needed), Oral          |                 | Not Reported |                |
|                                                                                   | Inipomp                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Furosemide                        |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Ramipril                          |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Aspirin Lysine                    |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Vastarel                          |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Creon                             |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Rocaltrol                         |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Allopurinol                       |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Lantus                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                   | Doliprane                         |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2009                                                                       | 6921030                           | EXPEDITED (15-DAY) | N                  | DE              | 1000003916           |                                    | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide; Death Of Relative                                    | Lexapro                           |                    |                    | S               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2009                                                                       | 6921514                           | DIRECT             | N                  | OT              |                      |                                    | 71 YR           | Male         | USA            |

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| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Seizure                                                                                                                                                                                                       | Lexapro                                                                                                             |                    |                    | S               | Oral                 | One Tablet By Mouth Per Day Po                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                      | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2009                                                                                                                                                                                                   | 6924649                                                                                                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000003915           |                                                 | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Aplasia; Azotaemia; Back Pain; Bone Marrow Failure; Bone Marrow Toxicity; Bronchoalveolar Lavage Abnormal; Influenza; Lung Disorder; Metabolic Acidosis; Pain; Rales; Renal Failure; Staphylococcal Infection | Escitalopram Oxalate                                                                                                |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D) ,Oral |                 | Not Reported |                |
|                                                                                                                                                                                                               | Cyamemazine                                                                                                         |                    |                    | S               | Oral                 | 75 Mg (25 Mg, 3 In 1 D), Oral                   |                 | Not Reported |                |
|                                                                                                                                                                                                               | Akineton                                                                                                            |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D) ,Oral |                 | Not Reported |                |
|                                                                                                                                                                                                               | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                      | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2009                                                                                                                                                                                                   | 6925202                                                                                                             | EXPEDITED (15-DAY) | Y                  | DE              | CHPA2009US01789      |                                                 | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning Deliberate                                                                                                                                                                       | Acetaminophen                                                                                                       |                    | Y                  | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                                                                                                                                               | Acetaminophen And Codeine                                                                                           |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                                                                                                                                               | Oxycodone (Oxycodone)                                                                                               |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                                                                                                                                               | Escitalopram Oxalate                                                                                                |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                                                                                                                                               | Levothyroxine Sodium                                                                                                |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                                                                                                                                               | Unspecified Ingredient                                                                                              |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                | Estradiol                   |                    | S                  | Oral            |                            | Oral                 |                 | Not Reported |                |
|------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
|                                                | Progesterone                |                    | S                  |                 |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2009                                    | 6911147                     | EXPEDITED (15-DAY) | N                  | HO              | ES-PURDUE-GBR_2009_0004856 |                      | 64 YR           | Male         | ESP            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Encephalopathy;<br>Hepatitis Fulminant | Morphine Sulfate            |                    |                    | S               | Oral                       | 60 Mg, Daily         | 7200 MIN        | Not Reported |                |
|                                                | Buprenorphine Hydrochloride |                    |                    | S               | Transdermal                | 35 Mcg, Q1h          |                 | Not Reported |                |
|                                                | Atrovent                    |                    |                    | S               | Respiratory (inhalation)   | 60 Capsules          |                 | Not Reported |                |
|                                                | Nitrazepam                  |                    |                    | S               | Oral                       | 75 Mg, Daily         | 4320 MIN        | Not Reported |                |
|                                                | Durogesic                   |                    |                    | S               | Transdermal                | 75 Mcg, Daily        | 12960 MIN       | Not Reported |                |
|                                                | Ketoprofen                  |                    |                    | S               | Oral                       | 25 Mg, Daily         | 7200 MIN        | Not Reported |                |
|                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                       | 20 Mg, Daily         | 11520 MIN       | Not Reported |                |
|                                                | Metoclopramide              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                | Ceftriaxone                 |                    |                    | S               | Intramuscular              | 1 Gram, Daily        | 5760 MIN        | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2009                                    | 6911475                     | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2009US05428            |                      | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Spina Bifida                                   | Clozaril                    |                    |                    | S               | Oral                       | 300 Mg/Day           |                 | Novartis     |                |
|                                                | Valium                      |                    |                    | S               | Oral                       | 6.5 Mg Daily         |                 | Not Reported |                |
|                                                | Lexapro                     |                    |                    | S               | Oral                       | 10 Mg Daily          |                 | Not Reported |                |
|                                                | Ms Contin                   |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2009                                    | 6913170                     | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2009GB04712            |                      |                 | Male         | GBR            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                |           |   |      |     |  |              |
|--------------------------------|-----------|---|------|-----|--|--------------|
| Electrocardiogram Qt Prolonged | Clozapine | S |      | Unk |  | Novartis     |
|                                | Ciprallex | S | Oral |     |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2009              | 6913352       | EXPEDITED (15-DAY) | N                  | HO, OT          | US-ROCHE-613546      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Anaemia; Bladder Neoplasm; Dystonia; Hypersensitivity | Peginterferon Alfa-2a   |              |            | S           | Unknown      | Form: Pre-Filled Syringe |                 | Roche        |
|                                                       | Ribavirin               |              |            | S           | Unknown      |                          |                 | Roche        |
|                                                       | Meclizine               |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                       | Tramadol Hydrochloride  |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                       | Lexapro                 |              |            | S           | Unknown      |                          |                 | Not Reported |
|                                                       | Trazodone Hydrochloride |              |            | S           | Unknown      |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2009              | 6913589       | EXPEDITED (15-DAY) |                    | HO              | FR-ABBOTT-09P-056-0502983-00 |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agranulocytosis; Back Pain; Chest Pain; Influenza; Metabolic Acidosis; Renal Failure | Biperiden                                                                                                           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                      | Seroplex                                                                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                      | Tercian                                                                                                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                      | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      |                                                                                                                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Feb-2009              | 6926310       | EXPEDITED (15-DAY) | Y                  | OT              | 1000003934           |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |                      |                    |                    |                 |                                                               |                      |                 |                      |                |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| Anxiety; Seizure                                          |                      | Lexapro            |                    | S               |                                                               | 5 Mg; 10 Mg;         |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Feb-2009                                               | 6926328              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003961                                                    |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Post Procedural<br>Haemorrhage                            | Lexapro              |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Feb-2009                                               | 6915152              | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-ROXANE<br>LABORATORIES, INC.-<br>2009-RO-00138RO           |                      | 53 YR           | Male                 | CHE            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Akathisia;                                                | Lorazepam            |                    |                    | S               |                                                               | 1mg                  |                 | Roxane               |                |
| Choreoathetosis;                                          | Lamotrigine          |                    |                    | S               |                                                               | 300mg                |                 | Roxane               |                |
| Cognitive Disorder;                                       | Lithium Sulfate      |                    |                    | S               |                                                               |                      |                 | Not Reported         |                |
| Delusion; Drug Interaction;                               | Amisulpride          |                    |                    | S               |                                                               | 800mg                |                 | Not Reported         |                |
| Dysarthria; Myoclonus;                                    | Escitalopram Oxalate |                    |                    | S               |                                                               | 20mg                 |                 | Not Reported         |                |
| Toxicity To Various<br>Agents; Transaminases<br>Increased |                      |                    |                    |                 |                                                               |                      |                 |                      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Feb-2009                                               | 6915196              | EXPEDITED (15-DAY) | Y                  | HO              | ES-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2009-<br>ES-00 |                      | 64 YR           | Male                 | ESP            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatic Encephalopathy;<br>Hepatitis Fulminant            | Atrovent             |                    |                    | S               | Respiratory<br>(inhalation)                                   |                      |                 | Boehringer Ingelheim |                |
|                                                           | Dormicum (Midazolam) |                    |                    | S               | Oral                                                          | 75mg                 |                 | Not Reported         |                |
|                                                           | Durogesic            |                    |                    | S               | Transdermal                                                   | 75mcg                |                 | Not Reported         |                |
|                                                           | Ketoprofen           |                    |                    | S               | Oral                                                          | 25mg                 |                 | Not Reported         |                |
|                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                                                          | 20mg                 |                 | Not Reported         |                |



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|                              |   |               |            |              |
|------------------------------|---|---------------|------------|--------------|
| Morphine Sulfate             | S | Oral          | 60mg       | Not Reported |
| Metoclopramide Hydrochloride | S | Oral          |            | Not Reported |
| Rocephin                     | S | Intramuscular | 1 G/3,5 MI | Not Reported |
| Buprenorphine                | S | Transdermal   |            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2009              | 6929299       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003303           |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cataract; Coordination Abnormal; Dizziness; Nausea | Lexapro              |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                    | Aricept              |              |            | C           |              |                               |                 | Not Reported |
|                                                    | Celebrex             |              |            | C           |              |                               |                 | Not Reported |
|                                                    | Aspirin              |              |            | C           |              |                               |                 | Not Reported |
|                                                    | Glucosamine(Tablets) |              |            | C           |              |                               |                 | Not Reported |
|                                                    | Namenda              |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2009              | 6929325       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000004799           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Haematoma; Paraplegia; Spinal Cord Haemorrhage | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                | Zantac (Tablets)     |              |            | C           |              |                               |                 | Not Reported |
|                                                | Movicol              |              |            | C           |              |                               |                 | Not Reported |
|                                                | Zestoretic           |              |            | C           |              |                               |                 | Not Reported |
|                                                | Lipitor              |              |            | C           |              |                               |                 | Not Reported |
|                                                | Tavanic              |              |            | C           |              |                               |                 | Not Reported |
|                                                | Myolastan (Tablets)  |              |            | C           |              |                               |                 | Not Reported |
|                                                | Dafalgan (Tablets)   |              |            | C           |              |                               |                 | Not Reported |
|                                                | Sifrol (Tablets)     |              |            | C           |              |                               |                 | Not Reported |
|                                                | Trazolan (Tablets)   |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2009              | 6871738       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003184           |                      | 76 YR      | Male       | NLD            |

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| <u>Preferred Term</u>                                                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------|-----------------|--------------|----------------|
| Completed Suicide                                                                               | Lexapro            |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D),Oral     |                 | Not Reported |                |
|                                                                                                 | Temazepam          |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                                                 | Oxazepam           |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                                                 | Dormicum (Tablets) |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                                                 | Nexium (Tablets)   |                    |                    | C               |                       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2009                                                                                     | 6871748            | EXPEDITED (15-DAY) | Y                  | DE              | 1000003187            |                                  | 47 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                               | Lexapro            |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                 | Temazepam          |                    |                    | C               |                       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2009                                                                                     | 6916531            | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20090204798 |                                  | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Glucose Decreased; Blood Glucose Increased; Dyspepsia; Irritable Bowel Syndrome | Risperdal          |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                                                                 | Lexapro            |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                                                                 | Strattera          |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2009                                                                                     | 6917199            | EXPEDITED (15-DAY) | Y                  | OT              | PHEH2009US01757       |                                  | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Laboratory Test Abnormal; Renal Impairment                                        | Femara             |                    |                    | S               | Oral                  | 2.5 Mg, Qd                       |                 | Novartis     |                |
|                                                                                                 | Synthroid          |                    |                    | S               |                       | Unk                              | 3650 DAY        | Not Reported |                |
|                                                                                                 | Lipitor            |                    |                    | S               |                       | Unk                              | 1825 DAY        | Not Reported |                |
|                                                                                                 | Lexapro            |                    |                    | S               |                       | Unk                              | 244 DAY         | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |   |     |         |              |
|-----------------|---|-----|---------|--------------|
| Calcium         | S | Unk | 730 DAY | Not Reported |
| Neurontin       | S | Unk |         | Not Reported |
| Antidepressants | S | Unk |         | Not Reported |
| Hormones Nos    | S |     |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2009              | 6918131       | NON-EXPEDITED    |                    |                 | US-ABBOTT-08P-163-0494375-00 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Dizziness; Flushing; Muscle Spasms; Muscle Twitching; Night Sweats; Paraesthesia; Tension | Simcor                 |              |            | S           |              | 500mg/20mg         |                 | Not Reported |
|                                                                                                      | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                      | Xanax                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Allegra                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                      | Asa                    |              |            | C           |              | At Times           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2009              | 6918355       | NON-EXPEDITED    |                    |                 | US-ABBOTT-09P-163-0496261-00 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Flushing              | Simcor         |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Metformin      |              |            | C           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | C           |              |                    |                 | Not Reported |
|                       | Asa            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 25-Feb-2009              | 6681144       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2008051192 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Amnesia; Anger; Asbestosis; Blood Cholesterol Increased; Blood Triglycerides | Xanax          |              |            | S           |              |                    |                 | Pfizer     |
|                                                                              | Xanax          |              |            | S           |              |                    |                 | Pfizer     |
|                                                                              | Xanax          |              |            | S           |              |                    |                 | Pfizer     |
|                                                                              | Zoloft         |              |            | S           |              |                    |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                           |   |  |  |  |     |  |              |
|-----------------------------|---------------------------|---|--|--|--|-----|--|--------------|
| Abnormal; Bruxism;          | Zoloft                    | S |  |  |  |     |  | Pfizer       |
| Depression; Feeling         | Neurontin                 | S |  |  |  |     |  | Pfizer       |
| Abnormal; Hallucination;    | Neurontin                 | S |  |  |  |     |  | Pfizer       |
| Hyperhidrosis;              | Trazodone Hydrochloride   | S |  |  |  |     |  | Not Reported |
| Hypertension;               | Seroquel                  | S |  |  |  |     |  | Not Reported |
| Hypothyroidism; Incorrect   | Wellbutrin                | S |  |  |  |     |  | Not Reported |
| Dose Administered;          | Lexapro                   | S |  |  |  |     |  | Not Reported |
| Insomnia; Pain;             | Restoril                  | S |  |  |  |     |  | Not Reported |
| Pancreatitis; Panic Attack; | Cymbalta                  | S |  |  |  | Unk |  | Not Reported |
| Paranoia; Pyrexia; Renal    | Effexor                   | S |  |  |  | Unk |  | Not Reported |
| Failure; Road Traffic       |                           |   |  |  |  |     |  |              |
| Accident; Seizure; Sleep    | Lisinopril                | C |  |  |  |     |  | Not Reported |
| Apnoea Syndrome;            | Fenofibrate               | C |  |  |  |     |  | Not Reported |
| Suicide Attempt;            | Fenofibrate               | C |  |  |  |     |  | Not Reported |
| Tachycardia; Tardive        | Levothyroxine             | C |  |  |  |     |  | Not Reported |
| Dyskinesia; Treatment       | Ambien                    | C |  |  |  |     |  | Not Reported |
| Noncompliance; Urinary      | Hydrochlorothiazide       | C |  |  |  |     |  | Not Reported |
| Incontinence; Vomiting;     | Acetaminophen\Hydrocodone | C |  |  |  |     |  | Not Reported |
| Weight Decreased;           | Bitartrate                |   |  |  |  |     |  |              |
| Withdrawal Syndrome         | Carisoprodol              | C |  |  |  |     |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 25-Feb-2009              | 6920099       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | AU-<br>ELI_LILLY_AND_COMP<br>ANY-AU200902001897 |                      | 36 YR      | Female     | AUS            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|----------------------|-----------------|--------------|
| Drug Interaction;                            | Zyprexa              |              |            | S           |                                          | Unk, Unknown         |                 | Unknown      |
| Intentional Overdose;                        | Antibiotics          |              |            | C           | Intravenous (not<br>otherwise specified) | Unk, Unknown         |                 | Not Reported |
| Neuroleptic Malignant<br>Syndrome; Pneumonia | Zyprexa              |              |            | S           |                                          | 10 Mg, X 30 = 300 Mg |                 | Unknown      |
| Aspiration; Somnolence                       | Chlorpromazine       |              |            | S           |                                          | Unk, Unknown         |                 | Not Reported |
|                                              | Chlorpromazine       |              |            | S           |                                          | 100 Mg, X 7 = 700 Mg |                 | Not Reported |
|                                              | Escitalopram Oxalate |              |            | S           |                                          | Unk, Unknown         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2009              | 6915666       | EXPEDITED (15-DAY) | Y                  | HO, LT          | AU-AMGEN-US333842    |                      | 46 YR      | Male       | AUS            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------|------------------------------------------------|-----------------|--------------|----------------|
| Drug Interaction;<br>Headache; Mouth<br>Ulceration; Respiratory<br>Tract Infection;<br>Thrombocytopenia                 | Enbrel               |                    |                    | S               | Subcutaneous                | 25mg 2 Vials Once A<br>Week                    |                 | Not Reported |                |
|                                                                                                                         | Valproate Sodium     |                    |                    | C               | Unknown                     |                                                |                 | Not Reported |                |
|                                                                                                                         | Lithium              |                    |                    | C               | Unknown                     | Unknown                                        |                 | Not Reported |                |
|                                                                                                                         | Lexapro              |                    |                    | S               | Unknown                     | 20mg                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2009                                                                                                             | 6920664              | EXPEDITED (15-DAY) | Y                  | HO              | ES-ROCHE-616181             |                                                | 64 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Encephalopathy;<br>Hepatitis Fulminant                                                                          | Rocephin             |                    |                    | S               | Intramuscular               |                                                |                 | Roche        |                |
|                                                                                                                         | Midazolam            |                    |                    | S               | Oral                        |                                                |                 | Roche        |                |
|                                                                                                                         | Metoclopramide       |                    |                    | S               | Oral                        |                                                |                 | Not Reported |                |
|                                                                                                                         | Buprenorphine        |                    |                    | S               | Transdermal                 |                                                |                 | Not Reported |                |
|                                                                                                                         | Atrovent             |                    |                    | S               | Respiratory<br>(inhalation) |                                                |                 | Not Reported |                |
|                                                                                                                         | Durogesic            |                    |                    | S               | Transdermal                 | Drug Name Reported As:<br>Durogesic Matrix 75. |                 | Not Reported |                |
|                                                                                                                         | Dexketoprofen        |                    |                    | S               | Oral                        |                                                |                 | Not Reported |                |
|                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                        |                                                |                 | Not Reported |                |
|                                                                                                                         | Morphine             |                    |                    | S               | Oral                        |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2009                                                                                                             | 6932331              | EXPEDITED (15-DAY) | Y                  | HO              | 1000004845                  |                                                | 74 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation; Bundle<br>Branch Block Right;<br>Disorientation; Fall;<br>Hepatitis Cholestatic;<br>Rhabdomyolysis | Escitalopram Oxalate |                    |                    | S               | Oral                        | 20 Mg (20 Mg, 1 In 1 D),<br>Oral               |                 | Not Reported |                |
|                                                                                                                         | Furosemide           |                    |                    | S               | Oral                        | 40 Mg (40 Mg, 1 In 1 D),<br>Oral               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      |   |             |                                                              |              |
|------------------------------------------------------|---|-------------|--------------------------------------------------------------|--------------|
| Spironolactone                                       | S | Oral        | 50 Mg (50 Mg, 1 In 1 D),<br>Oral                             | Not Reported |
| Bromazepam                                           | S | Oral        | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral        | Not Reported |
| Bromazepam                                           | S | Oral        | 0.25 Dosage Forms (0.25<br>Dosage Forms, 1 In 1 D),<br>Oral  | Not Reported |
| Stilnox                                              | S | Oral        | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral        | Not Reported |
| Nitroglycerin                                        | S | Transdermal | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Transdermal | Not Reported |
| Hydrocortisone Butyrate                              | C |             |                                                              | Not Reported |
| Locoid                                               | C |             |                                                              | Not Reported |
| Previclan (Fluindione)                               | C |             |                                                              | Not Reported |
| Inexium                                              | C |             |                                                              | Not Reported |
| Tareg                                                | C |             |                                                              | Not Reported |
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C |             |                                                              | Not Reported |
| Doliprane                                            | C |             |                                                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Feb-2009              | 6934047       | EXPEDITED (15-DAY) | Y                  | HO              | CHPA2009US04672      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Analgesic Drug Level<br>Increased; Hepatotoxicity;<br>International Normalised<br>Ratio Increased; Overdose | Acetaminophen\Diphenhydramin<br>e Hydrochloride |              | Y          | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                             | Escitalopram Oxalate                            |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                             | Zolpidem                                        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2009              | 6922149       | NON-EXPEDITED    | N                  |                 | A0722886A            |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                 |                                                                                         |                                 |                                          |                                                                           |                                       |                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------------|------------------------------------------|---------------------------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Diplopia; Drug Hypersensitivity; Dry Mouth; Dysgeusia; Emotional Disorder; Nervousness; Rash; Rash Pruritic; Rhinorrhoea; Somnolence; Stress; Tension; Tinnitus | Lamictal<br>Paxil<br>Lunesta<br>Ambien<br>Lexapro<br>Unspecified Ingredient<br>Vitamins | S<br>S<br>S<br>S<br>S<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br><br><br> | 25mg Per Day<br>10mg Per Day<br>3mg At Night<br>10mg At Night<br><br><br> | <br>1 YR<br>2 DAY<br><br><br><br><br> | Glaxosmithkline<br>Glaxosmithkline<br>Glaxosmithkline<br>Not Reported<br>Not Reported<br>Glaxosmithkline<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------------|------------------------------------------|---------------------------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2009              | 6922230       | NON-EXPEDITED    | N                  |                 | A0725838A            |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Screen Positive  | Lamictal       |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2009              | 6922405       | NON-EXPEDITED    | N                  |                 | A0732290A            |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Fatigue; Weight Increased | Lamictal               |              |            | S           | Oral         | 50mg Per Day       |                 | Glaxosmithkline |
|                           | Lexapro                |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |
|                           | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2009              | 6922457       | NON-EXPEDITED    | N                  |                 | A0733893A            |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Rash                  | Lamictal       |              |            | S           | Oral         | 300mg Per Day      | 6 MTH           | Glaxosmithkline |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |
|                       | Strattera      |              |            | S           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|-----------------|----------------|
| 27-Feb-2009                                                                                                    | 6923658                | NON-EXPEDITED      | N                  |                 | A0714332A            |                                       | 67 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Nausea                                                                                       | Imitrex                |                    |                    | S               | Subcutaneous         | 6mg As Required                       |                 | Glaxosmithkline |                |
|                                                                                                                | Lexapro                |                    |                    | S               | Oral                 | 10mg Per Day                          | 2 DAY           | Not Reported    |                |
|                                                                                                                | Sumatriptan Succinate  |                    |                    | C               |                      |                                       |                 | Glaxosmithkline |                |
|                                                                                                                | Vitamin                |                    |                    | C               |                      |                                       |                 | Not Reported    |                |
|                                                                                                                | Calcium                |                    |                    | C               |                      |                                       |                 | Not Reported    |                |
|                                                                                                                | Prilosec               |                    |                    | C               |                      |                                       |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Feb-2009                                                                                                    | 6935265                | EXPEDITED (15-DAY) | Y                  | DE              | 1000004856           |                                       | 30 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>      |                |
| Asphyxia; Completed Suicide                                                                                    | Escitalopram Oxalate   |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D)               |                 | Not Reported    |                |
|                                                                                                                | Seroquel               |                    |                    | S               | Oral                 | 600 Mg (600 Mg, 1 In 1 D), Oral       |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Feb-2009                                                                                                    | 6935276                | EXPEDITED (15-DAY) | Y                  | HO              | 1000004849           |                                       | 78 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>      |                |
| Altered State Of Consciousness; Asthenia; Confusional State; Drug Interaction; Fall; Hypoglycaemia; Somnolence | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral         |                 | Not Reported    |                |
|                                                                                                                | Insulin Aspart         |                    |                    | S               | Subcutaneous         | 66 Iu (66 Iu, 1 In 1 D), Subcutaneous |                 | Not Reported    |                |
|                                                                                                                | Celectol               |                    |                    | S               | Oral                 | 200 Mg (200 Mg, 1 In 1 D), Oral       |                 | Not Reported    |                |
|                                                                                                                | Telfast                |                    |                    | C               |                      |                                       |                 | Not Reported    |                |
|                                                                                                                | Previscan (Fluindione) |                    |                    | C               |                      |                                       |                 | Not Reported    |                |



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| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------|---------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Mar-2009                                | 6901978                   | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000003575                    |                               | 61 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide;<br>Intentional Overdose | Escitalopram Oxalate      |                           |                             | S                        |                               | Oral                          |                          | Not Reported        |                         |
|                                            | Levothyroxin              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Acetaminophen             |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Codeine                   |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Oxycodone                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Diphenhydramine           |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Estradiol                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Progesterone              |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Unspecified Ingredient    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Mar-2009                                | 6904616                   | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000003616                    |                               | 40 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide;<br>Intentional Overdose | Escitalopram Oxalate      |                           |                             | S                        | Oral                          | Ingestion                     |                          | Not Reported        |                         |
|                                            | Acetaminophen\Hydrocodone |                           |                             | S                        | Oral                          | Ingestion                     |                          | Not Reported        |                         |
|                                            | Bitartrate                |                           |                             |                          |                               |                               |                          |                     |                         |
|                                            | Bupropion                 |                           |                             | S                        | Oral                          | Ingestion                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Mar-2009                                | 6905677                   | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000003573                    |                               | 82 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide;<br>Intentional Overdose | Escitalopram Oxalate      |                           |                             | S                        | Oral                          | Oral                          |                          | Not Reported        |                         |
|                                            | Percocet                  |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                            | Trazodone Hydrochloride   |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Mar-2009                                | 6914148                   | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000003735                    |                               | 49 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Cardiac Arrest; Completed Suicide; Intentional Overdose; Respiratory Arrest | Escitalopram Oxalate       |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                             | Acetaminophen              |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Propoxyphene Hydrochloride |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Unspecified Ingredient     |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Meloxicam                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Celecoxib                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2009                                                                 | 6914191                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000003790           |                               | 77 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hallucinations, Mixed; Myoclonus; Posture Abnormal       | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                             | Thalidomide                |                    |                    | S               | Oral                 | 25 Mg (25 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                             | Rytmonorm (Tablets)        |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Cortone Acetato (Tablets)  |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Lasix                      |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Folina (Tablets)           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Benxol                     |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Allopurinol                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                             | Eprex                      |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2009                                                                 | 6916914                    | EXPEDITED (15-DAY) | Y                  | DE              | 1000003739           |                               | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide; Intentional Overdose          | Escitalopram Oxalate       |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                             | Acetaminophen              |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Cyclobenzaprine            |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Bupropion                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Alcohol                    |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Nifedipine                 |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                             | Piroxicam                  |                    |                    | S               |                      |                               |                 | Not Reported |                |

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| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2009                                    | 6920820                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000003749           |                      | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Overdose            | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                | Bupropion               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Alcohol                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Tramadol Hydrochloride  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2009                                    | 6923256                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000003746           |                      | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Intentional Overdose        | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                | Atenolol                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Amlodipine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Trazodone Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Duloxetine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Losartan                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2009                                    | 6924634                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000003743           |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose                    | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                | Quetiapine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2009                                    | 6934626                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000004933           |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Intentional | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                | Alprazolam              |                    |                    | S               |                      |                      |                 | Not Reported |                |

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|                              |               |   |              |
|------------------------------|---------------|---|--------------|
| Overdose; Respiratory Arrest | Lorazepam     | S | Not Reported |
|                              | Acetaminophen | S | Not Reported |
|                              | Quetiapine    | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2009              | 6539207       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2008007185 |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams;                                                              | Chantix                             |              |            | S           |              | Unk                | 19 DAY          | Pfizer       |
| Agitation; Drug Ineffective;                                                  | Altace                              |              |            | C           |              |                    |                 | Not Reported |
| Drug Interaction; Loss Of Personal Independence In Daily Activities; Malaise; | Triamterene And Hydrochlorothiazide |              |            | C           |              |                    |                 | Not Reported |
| Mental Disorder; Nausea;                                                      | Acetylsalicylic Acid                |              |            | C           |              |                    |                 | Not Reported |
| Personality Change;                                                           | Lexapro                             |              |            | S           |              | 10 Mg, 1x/Day      |                 | Not Reported |
| Suicidal Behaviour;                                                           | Lexapro                             |              |            | S           |              |                    |                 | Not Reported |
| Suicidal Ideation                                                             |                                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2009              | 6864208       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003052           |                      | 30 YR      | Male       | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Agitation; Completed Suicide | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2009              | 6890070       | EXPEDITED (15-DAY) | Y                  | DE              | 1000003496           |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Completed Suicide; Drug Screen Positive; Gun Shot Wound; Mood Altered | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1in 1 D), Oral |                 | Not Reported |
|                                                                       | Ambien         |              |            | C           |              |                              |                 | Not Reported |
|                                                                       | Lunesta        |              |            | C           |              |                              |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 04-Mar-2009                                                                                                                      | 6914147                     | EXPEDITED (15-DAY) | Y                  | DE              | 1000003737           |                              | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                                                                                       | Escitalopram Oxalate        |                    |                    | S               |                      | Ingestes & Aspirated         |                 | Not Reported |                |
|                                                                                                                                  | Alprazolam                  |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Lamotrigine                 |                    |                    | S               |                      | Ingested & Aspirated         |                 | Not Reported |                |
|                                                                                                                                  | Gabapentin                  |                    |                    | S               |                      | Ingested & Aspirated         |                 | Not Reported |                |
|                                                                                                                                  | Alcohol                     |                    |                    | S               |                      | Ingested & Aspirated         |                 | Not Reported |                |
|                                                                                                                                  | Unspecified Ingredient      |                    |                    | S               |                      | Ingested & Aspirated         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2009                                                                                                                      | 6932061                     | EXPEDITED (15-DAY) | Y                  | DE              | GXKR2009US01983      |                              | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Loss Of<br>Consciousness;<br>Pneumonia; Pulmonary<br>Congestion; Toxicity To<br>Various Agents;<br>Unresponsive To Stimuli | Dextromethorphan            |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Temazepam                   |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Zyprexa                     |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Lexapro                     |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Ambien                      |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Alcohol                     |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  |                             |                    |                    |                 |                      | Excessive Amount,<br>Unknown |                 |              |                |
|                                                                                                                                  | Naproxen (Naproxen)         |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Risperdal                   |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Lithium (Lithium)           |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                  | Metocarbamol (Metocarbamol) |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2009                                                                                                                      | 6941012                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000004966           |                              |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Road Traffic Accident;<br>Seizure                                                                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                 | Oral                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 05-Mar-2009                                                                                                                                                                                                                         | 6941423              | DIRECT             | N                  | OT              |                      |                                                                                                  | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Chills;<br>Conversion Disorder; Drug<br>Dependence; General<br>Physical Health<br>Deterioration; Incorrect<br>Product Administration<br>Duration; Muscle<br>Twitching; Nausea;<br>Palpitations; Paraesthesia;<br>Tremor | Lexapro              |                    |                    | S               |                      |                                                                                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2009                                                                                                                                                                                                                         | 6942341              | DIRECT             | N                  |                 |                      |                                                                                                  | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Feeling<br>Abnormal; Nervousness                                                                                                                                                                                         | Lexapro              |                    |                    | S               | Oral                 | 20mg 1 A Day Po                                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2009                                                                                                                                                                                                                         | 6942758              | EXPEDITED (15-DAY) | Y                  | OT              | 1000004985           |                                                                                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability; Personality<br>Change; Suicidal Ideation                                                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral<br>; 10 Mg (10 Mg, 1 In 1<br>D),Oral; 15 Mg (15 Ma, 1<br>In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Escitalopram Oxalate |                    |                    | S               |                      | 5 Mg (5 Mg, 1 In 1 D),Oral;<br>10 Mg (10 Mg, 1 In 1<br>D),Oral                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |                              |              |
|----------------------|---|------|------------------------------|--------------|
| Escitalopram Oxalate | S | Oral | 15 Mg (15 Mg, 1 In 1 D),Oral | Not Reported |
| Escitalopram Oxalate | S |      | 5 Mg (5 Mg, 1 In 1 D),Oral   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2009              | 6873480       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003214           |                      | 24 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Aggression; Alcohol Use; Intentional Overdose; Seizure; Somnolence; Suicide Attempt; Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | 600-1000 Mg (Once), Oral        |                 | Not Reported |
|                                                                                               | Sertindole           |              |            | S           | Oral         | 1200 Mg (1200 Mg, Once), Oral   |                 | Not Reported |
|                                                                                               | Caffeine             |              |            | S           | Oral         | 2 Gm (2 Gm, Once), Oral         |                 | Not Reported |
|                                                                                               | Ibuprofen Lysine     |              |            | S           | Oral         | 10 Tablets (Once), Oral         |                 | Not Reported |
|                                                                                               | Alcohol              |              |            | S           | Oral         | 300-500 MI Of Wine (Once), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2009              | 6905763       | EXPEDITED (15-DAY) | Y                  | DE, OT          | 1000003664           |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Condition Aggravated; Fall; Parkinsonism; Pulmonary Embolism; Wheelchair User | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                               | Modopar              |              |            | C           |              |                             |                 | Not Reported |
|                                                                               | Ogast                |              |            | C           |              |                             |                 | Not Reported |
|                                                                               | Lactulose            |              |            | C           |              |                             |                 | Not Reported |
|                                                                               | Practazin            |              |            | C           |              |                             |                 | Not Reported |
|                                                                               | Anti-Parkinson Drugs |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2009              | 6943456       | EXPEDITED (15-DAY) | N                  | HO              | 1000004996           |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Coma; Facial Bones Fracture; Fall; Fatigue; | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D ), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |                                    |   |              |
|-------------------------------|------------------------------------|---|--------------|
| Headache; Thyroid<br>Neoplasm | Norvasc                            | C | Not Reported |
|                               | Diovan (Tablets)                   | C | Not Reported |
|                               | Fosamax                            | C | Not Reported |
|                               | Advair (Aerosol For Inhalation)    | C | Not Reported |
|                               | Combivent (Aerosol For Inhalation) | C | Not Reported |
|                               | Calcium (Tablets)                  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2009              | 7377498       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_62485_2009       |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Acetaminophen And Codeine                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Oxycodone                                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Escitalopram Oxalate                        |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Levothyroxine                               |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Unspecified Ingredient                      |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Acetaminophen\Diphenhydramine Hydrochloride |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Estradiol                                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Unspecified Ingredient                      |              |            | S           | Oral         | Df Oral            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2009              | 6933430       | EXPEDITED (15-DAY) | Y                  | OT              | 1000004934           |                      | 49 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                   | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Acute Generalised<br>Exanthematous<br>Pustulosis; Dermatitis<br>Bullous | Escitalopram Oxalate               |              |            | S           | Oral         | 10 Mg (10 Mg, 1in 1 D),<br>Oral   |                 | Not Reported |
|                                                                         | Escitalopram Oxalate               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1d),<br>Oral   |                 | Not Reported |
|                                                                         | Acetaminophen\Codeine<br>Phosphate |              |            | S           |              | (As Required)                     |                 | Not Reported |
|                                                                         | Celecoxib                          |              |            | S           |              | 200-400 Mg/Day (1-2<br>Times/Day) |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |                           |              |
|------------------------------|---|---------------------------|--------------|
| Esomeprazole                 | S | (40 Mg, As Required)      | Not Reported |
| Mebeverine Hydrochloride     | S |                           | Not Reported |
| Chondroitin Sulfate (Bovine) | S | 800 Mg (800 Mg, 1 In 1 D) | Not Reported |
| Humira                       | S |                           | Not Reported |
| Eltroxin                     | C |                           | Not Reported |
| Arava                        | C |                           | Not Reported |

| <u>FDA Received Date</u>                        | <u>Case #</u>                                                                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 09-Mar-2009                                     | 7175203                                                                                                                     | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200900387 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>                                                                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Propoxyphene Hydrochloride<br>And Acetaminophen<br>Escitalopram Oxalate<br>Unspecified Ingredient<br>Meloxicam<br>Celecoxib |                    |                    | S               | Oral                                              |                      |                 | Tyco         |                |
|                                                 |                                                                                                                             |                    |                    | S               | Oral                                              |                      |                 | Not Reported |                |
|                                                 |                                                                                                                             |                    |                    | S               | Oral                                              |                      |                 | Not Reported |                |
|                                                 |                                                                                                                             |                    |                    | S               | Oral                                              |                      |                 | Not Reported |                |
|                                                 |                                                                                                                             |                    |                    | S               | Oral                                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Mar-2009                                                         | 6946375              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005047           |                                                                    |                 | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Self-Injurious Ideation;<br>Therapeutic Product Effect<br>Decreased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Mar-2009                                     | 6946379              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005019           |                      |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional<br>Self-Injury; Malaise | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| 10-Mar-2009                                                                                                                                            | 6950204              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005058            |                               | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Cold; Morbid Thoughts; Panic Attack; Violence-Related Symptom                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2009                                                                                                                                            | 6908800              | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-20090202630 |                               | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness Bilateral                                                                                                                                     | Risperdal            |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                                                        | Lexapro              |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                                                        | Wellbutrin XL        |                    |                    | S               | Oral                  | 450 (Units Unspecified) Qd    |                 | Not Reported |                |
|                                                                                                                                                        | Synthroid            |                    |                    | C               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                                                        | Lithium Carbonate    |                    |                    | C               | Unknown               | 600 (Units Unspecified) Bid   |                 | Not Reported |                |
|                                                                                                                                                        | Provigil             |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2009                                                                                                                                            | 6949476              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005050            |                               | 25 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Amnesia; Anger; Anxiety; Decreased Appetite; Dizziness; Fatigue; Feeling Abnormal; Headache; Hyperhidrosis; Nausea; Nervousness; Suicidal | Escitalopram Oxalate |                    |                    | S               | Oral                  | Oral                          |                 | Not Reported |                |

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Ideation; Tremor;  
Violence-Related  
Symptom

| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Mar-2009                                    | 6944380              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003195           |                                                                    | 55 YR           | Female       | DNK            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Somnolence;<br>Syncope               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
|                                                |                      |                    |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                   |                 |              |                |
|                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                | Tanakan              |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                                | Memantine (Tablets)  |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2009                                    | 6950377              | EXPEDITED (15-DAY) | Y                  | HO              | 1000005062           |                                                                    | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Exfoliative Rash;<br>Overdose; Suicide Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
|                                                | Tropatepine          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
|                                                | Depakote             |                    |                    | S               |                      | 100 Mg (100 Mg, 1 In 1 D)                                          |                 | Not Reported |                |
|                                                | Bromazepam           |                    |                    | S               | Oral                 | 120 Mg (120 Mg, Once),<br>Oral                                     |                 | Not Reported |                |
|                                                | Loxapac              |                    |                    | S               | Oral                 | 100 Mg (100 Mg, Once),<br>Oral                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 13-Mar-2009                                                            | 6947224        | DIRECT             | N                  | DE, OT          |                      |                                  | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                      | Seroquel       |                    |                    | S               |                      | Unknown                          |                 | Not Reported |                |
|                                                                        | Lexapro        |                    |                    | S               |                      | Unknown                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Mar-2009                                                            | 6954283        | EXPEDITED (15-DAY) | N                  | OT              | 1000005097           |                                  | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Screaming; Seizure                                                     | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                        | Dilantin       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                        | Lantus         |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                        | Synthroid      |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                        | Actos          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2009                                                            | 6948526        | DIRECT             |                    |                 |                      |                                  | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Urticaria                                                   | Prozac         |                    |                    | S               |                      | 4-1-08 - 5-7-08                  |                 | Not Reported |                |
|                                                                        | Lexapro        |                    |                    | S               |                      | 3-12-08 - 4-2-08                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2009                                                            | 6950510        | EXPEDITED (15-DAY) | Y                  | HO              | 1000005068           |                                  | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia Megaloblastic;<br>Diarrhoea; Fall; Nausea;<br>Weight Decreased | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |      |                                                                                                    |              |
|---------------------|---|------|----------------------------------------------------------------------------------------------------|--------------|
| Lexapro             | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                                   | Not Reported |
| Lexapro             | S | Oral | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                     |   | Oral | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D),<br>Oral |              |
|                     |   | Oral | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D),<br>Oral |              |
| Aspirin             | C |      |                                                                                                    | Not Reported |
| Metformin (Tablets) | C |      |                                                                                                    | Not Reported |
| Hydrochlorothiazide | C |      |                                                                                                    | Not Reported |
| Lipitor             | C |      |                                                                                                    | Not Reported |
| Lisinopril          | C |      |                                                                                                    | Not Reported |
| Detrol              | C |      |                                                                                                    | Not Reported |
| Atenolol            | C |      |                                                                                                    | Not Reported |
| Fosamax             | C |      |                                                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2009              | 7175264       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200900464 |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen\Hydrocodone<br>Bitartrate |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Trazodone Hydrochloride                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2009              | 6954877       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005132           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                  |                      |   |      |                                  |              |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Feeling Abnormal;<br>Hallucination, Visual;<br>Intentional Self-Injury;<br>Restlessness; Sleep<br>Disorder; Unevaluable<br>Event | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2009              | 6957976       | EXPEDITED (15-DAY) | Y                  | DE              | 1000005241           |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2009              | 6958797       | EXPEDITED (15-DAY) | Y                  | DE              | 1000005184           |                      | 70 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Zyprexa              |              |            | S           |              |                    |                 | Not Reported |
|                       | Bromazepam           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Mar-2009              | 6541632       | EXPEDITED (15-DAY) | Y                  | HO              | US-PFIZER INC-<br>2008005876 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram T Wave<br>Inversion; Hypotension;<br>Sinus Tachycardia | Detrol La               |              |            | S           | Oral         | 4 Mg, 1x/Day       | 828 DAY         | Pfizer       |
|                                                                          | Lexapro                 |              |            | S           | Oral         | 10 Mg, 1x/Day      | 18 DAY          | Not Reported |
|                                                                          | Reboxetine              |              |            | S           | Oral         | 1 Mg, 1x/Day       |                 | Pfizer       |
|                                                                          | Thiamine                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                          | Folic Acid              |              |            | C           | Oral         | Qd                 |                 | Not Reported |
|                                                                          | Multivitamins           |              |            | C           | Oral         | 1,Qd               |                 | Not Reported |
|                                                                          | Lisinopril              |              |            | C           | Oral         | 1,Qd               |                 | Not Reported |
|                                                                          | Verapamil Hydrochloride |              |            | C           | Oral         | 1,Qd               |                 | Not Reported |

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|                         |   |               |                 |              |
|-------------------------|---|---------------|-----------------|--------------|
| K-Dur                   | C | Oral          |                 | Not Reported |
| Magnesium Oxide         | C | Oral          | 2 Tabs,Bid      | Not Reported |
| Synthroid               | C | Oral          | Qd              | Not Reported |
| Amitiza                 | C | Oral          | Bid             | Not Reported |
| Cyanocobalamin          | C | Intramuscular | Qmo             | Not Reported |
| Metoprolol              | C | Oral          | 1,Bid           | Not Reported |
| Asa                     | C | Oral          | Qd              | Not Reported |
| Celebrex                | C |               | 1,Qd            | Not Reported |
| Protonix                | C |               | 1,Qd            | Not Reported |
| Premarin                | C |               | 1,Qd            | Not Reported |
| Tramadol Hydrochloride  | C |               | 1,Q 6 Hours Prn | Not Reported |
| Trazodone Hydrochloride | C |               | 1,Qhs           | Not Reported |
| Amitriptyline           | C |               | 1,Qpm           | Not Reported |
| Potassium Chloride      | C |               | 1,Qd            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2009              | 6941011       | EXPEDITED (15-DAY) | Y                  | OT              | 1000004984           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u>                     | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|-------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Hyperhidrosis; Muscle Twitching; Vomiting | Lexapro           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                           | Protium (Tablets) |              |            | C           |              |                               |                 | Not Reported |
|                                           | Larig (Tablets)   |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2009              | 6955915       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005204           |                      | 67 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Aspartate Aminotransferase Increased; Blood Calcium Decreased; Depressive | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, In 1 D), Oral |                 | Not Reported |
|                                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                  |                   |   |      |                                              |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---|------|----------------------------------------------|--------------|
| Delusion;<br>Electrocardiogram<br>Repolarisation<br>Abnormality;<br>Electrocardiogram ST<br>Segment Elevation;<br>Extrapyramidal Disorder;<br>Femoral Neck Fracture;<br>Generalised Tonic-Clonic<br>Seizure; Hyponatraemia;<br>International Normalised<br>Ratio Decreased; Sinus<br>Bradycardia | Valproate Sodium  | S | Oral | Oral<br>1200 Mg (1200 Mg, 1 In 1<br>D), Oral | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Omeprazole        | S | Oral | 40 Mg (40 Mg, 1 In 1 D),<br>Oral             | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Haldol            | S | Oral | 1 Mg (1 Mg, 1 In 1 D), Oral                  | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Haldol            | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral                  | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Haldol            | S | Oral | 2 Mg (2 Mg, 1 In 1 D), Oral                  | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Seroquel          | S | Oral | 50 Mg (50 Mg, 1 In 1 D),<br>Oral             | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Seroquel          | S | Oral | 25 Mg (25 Mg, 1 In 1 D),<br>Oral             | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Tavor [Lorazepam] | C |      |                                              | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Concor            | C |      |                                              | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Simvahehexal      | C |      |                                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2009              | 6808462       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001460           |                      | 34 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Fatigue; Obsessive<br>Thoughts; Overdose;<br>Sedation | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg,1 In 1<br>D),Oral                                  |                 | Not Reported |
|                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 20 Mg (20 Mg,1<br>In 1 D),Oral |                 | Not Reported |
|                                                       |                      |              |            |             | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 20 Mg (20 Mg,1<br>In 1 D),Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Mar-2009              | 6947904       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200900477 |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                           |                         |   |      |              |
|---------------------------|-------------------------|---|------|--------------|
| Cardio-Respiratory Arrest | Tramadol Hydrochloride  | S | Oral | Tyco         |
|                           | Bupropion Hydrochloride | S | Oral | Not Reported |
|                           | Alcohol                 | S | Oral | Not Reported |
|                           | Escitalopram Oxalate    | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                           | <u>Country</u> |
|--------------------------|------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|--------------------------------------|----------------|
| 20-Mar-2009              | 6947907                                                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200900482 |                      | 40 YR           | Male                                 | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                           |                |
| Completed Suicide        | Acetaminophen\Hydrocodone<br>Bitartrate<br>Bupropion<br>Escitalopram Oxalate |                    |                    | S<br>S<br>S     | Oral<br>Oral<br>Oral                              |                      |                 | Tyco<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 20-Mar-2009                                                                                   | 6955013            | DIRECT           | Y                  |                 |                      |                      |                 | Unknown                      | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Circumstance Or<br>Information Capable Of<br>Leading To Medication<br>Error; Medication Error | Namenda<br>Lexapro |                  |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>                                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------------|----------------------|-----------------------|-----------------|------------------------------------------------------------------------------|----------------|
| 20-Mar-2009                                                                             | 6955120                                             | EXPEDITED (15-DAY) | Y                  | OT                    | DSA_33316_2009       |                       | 47 YR           | Female                                                                       | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>                                                                   |                |
| Anxiety; Disorientation;<br>Drug Interaction;<br>Dysphagia; Dyspnoea;<br>Fall; Insomnia | Xenazine<br>Lexapro<br>Invega<br>Depakote<br>Deplin |                    |                    | S<br>S<br>C<br>C<br>C | Oral                 | 6.25 Mg Qd Oral<br>Df |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                    |                        |                    |                    |                 |                       |                               |                 |              |                |
|--------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| Namenda                                                            |                        |                    | C                  |                 |                       | Not Reported                  |                 |              |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2009                                                        | 6956195                | EXPEDITED (15-DAY) | Y                  | OT              | 1000005245            |                               | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Blood Creatine Phosphokinase Increased; Pain           | Escitalopram Oxalate   |                    |                    | S               | Oral                  | 10 Mg (10 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Mar-2009                                                        | 6956206                | EXPEDITED (15-DAY) | Y                  | OT              | 1000005280            |                               |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus | Escitalopram Oxalate   |                    |                    | S               | Transplacental        | Transplacental                |                 | Not Reported |                |
|                                                                    | Subutex                |                    |                    | S               | Transplacental        | Transplacental                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2009                                                        | 6913333                | EXPEDITED (15-DAY) | Y                  | DS              | 1000003759            |                               | 61 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Ageusia                                                            | Escitalopram Oxalate   |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2009                                                        | 6948669                | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20090303572 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Bladder Neoplasm; Dystonia; Pharyngeal Oedema             | Tramadol Hydrochloride |                    |                    | S               | Unknown               |                               |                 | Not Reported |                |
|                                                                    | Ribavirin              |                    |                    | S               | Unknown               |                               |                 | Not Reported |                |
|                                                                    | Pegasys                |                    |                    | S               |                       |                               |                 | Not Reported |                |

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|                                                                                                                                                                                                                                                              | Meclizine                      |                    | S                  | Unknown         |                          |                                         |                 | Not Reported |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                                                                              | Lexapro                        |                    | S                  | Unknown         |                          |                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Trazodone Hydrochloride        |                    | S                  | Unknown         |                          |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                                                                                                                                                                  | 6840682                        | EXPEDITED (15-DAY) | Y                  | OT              | 1000001769               |                                         | 80 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Pleural Effusion                                                                                                                                                                                                                                             | Escitalopram Oxalate           |                    |                    | S               | Oral                     | 5 Gtt (5 Gtt, 1 In 1 D), Oral           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Xanax                          |                    |                    | C               |                          |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                                                                                                                                                                  | 6902811                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003606               |                                         | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia Neonatal; Aortic Valve Disease; Biotin Deficiency; Blood Pressure Decreased; Heart Rate Increased; Infantile Apnoea; Maternal Drugs Affecting Foetus; Meconium In Amniotic Fluid; Neonatal Respiratory Depression; Neonatal Seizure; Sepsis Neonatal | Lexapro                        |                    |                    | S               | Transplacental           | 10 Mg (10 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Klonopin                       |                    |                    | C               |                          |                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Lortab                         |                    |                    | C               |                          |                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                              | Hepatitis B Vaccine(Injection) |                    |                    | C               |                          |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                     | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                                                                                                                                                                  | 6931374                        | EXPEDITED (15-DAY) | Y                  | HO              | IT-AVENTIS-200911900GDDC |                                         | 57 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                                                                                                                                                                                                                          | Arava                          |                    |                    | S               | Oral                     |                                         |                 | Aventis      |                |
|                                                                                                                                                                                                                                                              | Arava                          |                    |                    | S               | Oral                     | Dose: 5 Mg Even                         |                 | Aventis      |                |

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|                                                                                                              |                         |                    |                    |                    |                              |                      |                 |              |                |
|--------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|--------------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                              |                         |                    |                    | Days/10mg Odd Days |                              |                      |                 |              |                |
|                                                                                                              | Arava                   |                    | S                  | Oral               |                              |                      |                 | Aventis      |                |
|                                                                                                              | Cipralex                |                    | S                  | Oral               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Cipralex                |                    | S                  | Oral               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Nebivolol Hydrochloride |                    | C                  | Oral               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Medrol                  |                    | C                  | Oral               |                              |                      |                 | Not Reported |                |
|                                                                                                              | Omeprazole              |                    | C                  | Oral               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                  | 6949654                 | EXPEDITED (15-DAY) | N                  | HO, OT             | US-PFIZER INC-2009182620     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Neoplasm;<br>Hypersensitivity                                                                        | Meclizine Hydrochloride |                    |                    | S                  |                              |                      |                 | Pfizer       |                |
|                                                                                                              | Trazodone Hydrochloride |                    |                    | S                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Tramadol Hydrochloride  |                    |                    | S                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Interferon Alfa-2a      |                    |                    | S                  |                              | 180 Ug, Weekly       | 13 DAY          | Not Reported |                |
|                                                                                                              | Lexapro                 |                    |                    | S                  |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                  | 6950210                 | EXPEDITED (15-DAY) |                    | OT                 | PHEH2009US02691              |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Blood Pressure Increased;<br>Decreased Appetite; Drug<br>Interaction; Extrasystoles | Lopresor                |                    |                    | S                  | Oral                         | 25 Mg, Qid           |                 | Novartis     |                |
|                                                                                                              | Lexapro                 |                    |                    | S                  | Oral                         | 5 Mg, Qd             |                 | Not Reported |                |
|                                                                                                              | Valium                  |                    |                    | C                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Klonopin                |                    |                    | C                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Ativan                  |                    |                    | C                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Synthroid               |                    |                    | C                  |                              |                      |                 | Not Reported |                |
|                                                                                                              | Effexor                 |                    |                    | C                  |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2009                                                                                                  | 6950422                 | EXPEDITED (15-DAY) | Y                  | HO                 | NO-ABBOTT-09P-122-0562791-00 |                      |                 | Male         | NOR            |

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| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Lipoatrophy;<br>Lipodystrophy Acquired | Kaletra        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Epivir         |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Videx          |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Ciprallex      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2009              | 6957202       | EXPEDITED (15-DAY) | N                  | OT              | 1000005376           |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pelvic Congestion;<br>Thrombosis; Uterine Cyst;<br>Vaginal Haemorrhage | Lexapro        |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                                                        |                |              |            |             | Oral         | See Image          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2009              | 6957618       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005392           |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                  | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anuria; Epistaxis; Oedema<br>Peripheral; Renal Failure | Escitalopram Oxalate                      |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                        | Levothyroxine (100 Microgram,<br>Tablets) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2009              | 6958946       | DIRECT           | N                  | CA, OT          |                      |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|------------|
| Atrial Septal Defect; Lung<br>Disorder; Maternal Drugs<br>Affecting Foetus; Neonatal<br>Disorder; Premature Baby | Lexapro        |              |            | S           | Oral         | 1 A Day Po 6-9 Months |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2009              | 6951594       | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-621957      |                      | 51 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                                               | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|---------------------------------------------------------------------------|-----------------|----------------------|----------------|
| Drug Interaction;<br>Dysarthria; Hypertension;<br>Intentional Product Misuse                                        | Klonopin                    |                    |                    | S               | Oral                                                          |                                                                           |                 | Roche                |                |
|                                                                                                                     | Inderal                     |                    |                    | C               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Allegra-D                   |                    |                    | C               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Lotensin                    |                    |                    | C               |                                                               | Drug Reported: Lotension                                                  |                 | Not Reported         |                |
|                                                                                                                     | Ritalin                     |                    |                    | S               | Unknown                                                       |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Lexapro                     |                    |                    | S               | Oral                                                          |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Lexapro                     |                    |                    | S               | Oral                                                          |                                                                           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 26-Mar-2009                                                                                                         | 6959381                     | DIRECT             | N                  | LT              |                                                               |                                                                           | 16 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Condition Aggravated;<br>Depression; Suicidal<br>Ideation                                                           | Lexapro                     |                    |                    | S               | Oral                                                          | 10mg Once A Day Po                                                        |                 | Forest               |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>                                                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Mar-2009                                                                                                         | 6954818                     | EXPEDITED (15-DAY) |                    | OT              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2009-<br>DE-02 |                                                                           |                 | Female               | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Akathisia; Drug Ineffective;<br>Dyskinesia; Hyperphagia;<br>Oculogyric Crisis; Suicide<br>Attempt; Weight Increased | Pramipexole Dihydrochloride |                    |                    | S               |                                                               | Starting Dose Of 0.125<br>Mg, Titrated To 1.5 Mg<br>Over The Next 4 Weeks |                 | Boehringer Ingelheim |                |
|                                                                                                                     | Trazodone Hydrochloride     |                    |                    | S               |                                                               | 150mg                                                                     |                 | Not Reported         |                |
|                                                                                                                     | Trazodone Hydrochloride     |                    |                    | S               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Lamotrigine                 |                    |                    | S               |                                                               | 50mg                                                                      |                 | Not Reported         |                |
|                                                                                                                     | Escitalopram Oxalate        |                    |                    | S               |                                                               | 20mg                                                                      |                 | Not Reported         |                |
|                                                                                                                     | Zolpidem                    |                    |                    | S               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Temazepam                   |                    |                    | S               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Alprazolam                  |                    |                    | S               |                                                               |                                                                           |                 | Not Reported         |                |
|                                                                                                                     | Levothyroxine               |                    |                    | C               |                                                               | 150mcg                                                                    |                 | Not Reported         |                |

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|                                                       |                         |                    |                    |                 |                      |                                  |                 |              |                |
|-------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Calcium Supplement                                    |                         |                    | C                  |                 |                      | Not Reported                     |                 |              |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Mar-2009                                           | 6961230                 | DIRECT             | Y                  | HO              |                      |                                  | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Seizure; Serotonin<br>Syndrome | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg Daily Po                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2009                                           | 6965633                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000005501           |                                  | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity Vasculitis                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                       | Stresam                 |                    |                    | S               |                      | 1 To 4 Dr Daily (As              |                 | Not Reported |                |
|                                                       | Clonidine Hydrochloride |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                       | Celectol                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2009                                           | 6966973                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000005522           |                                  | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Abdominal Pain; Vomiting     | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                       | Magne B6                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                       | Levothyrox              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2009                                           | 6969788                 | DIRECT             | N                  | OT              |                      |                                  | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                          |         |   |      |      |                      |                      |              |
|----------------------------------------------------------------------------------------------------------|---------|---|------|------|----------------------|----------------------|--------------|
| Asthenia; Disturbance In Attention; Educational Problem; Exercise Tolerance Decreased; Therapy Cessation | Lexapro | S | Oral | Oral | 5mg/5ml 1 Per Day Po | 5mg/5ml 1 Per Day Po | Not Reported |
|----------------------------------------------------------------------------------------------------------|---------|---|------|------|----------------------|----------------------|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Apr-2009                       | 6958779                 | EXPEDITED (15-DAY)        | Y                           | DE                       | US-ABBOTT-09P-163-0564051-00  |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                 | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Apr-2009                                                                                     | 6958841                 | EXPEDITED (15-DAY)        | N                           | HO, OT                   | US-WATSON-2009-01994          |                               | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaemia; Bladder Neoplasm; Blood Urine Present; Dyskinesia; Hypersensitivity; Pharyngeal Oedema | Trazodone Hydrochloride |                           |                             | S                        | Unknown                       | Unk                           |                          |                     | Watson                  |
|                                                                                                 | Meclizine Hydrochloride |                           |                             | S                        | Unknown                       | Unk                           |                          |                     | Watson                  |
|                                                                                                 | Tramadol Hydrochloride  |                           |                             | S                        | Unknown                       | Unk                           |                          |                     | Watson                  |
|                                                                                                 | Peginterferon Alfa-2a   |                           |                             | S                        | Unknown                       | 180 Ug, 1/Week                | 13 DAY                   |                     | Not Reported            |
|                                                                                                 | Ribavirin               |                           |                             | S                        | Unknown                       | 1000 Mg, Daily                | 13 DAY                   |                     | Not Reported            |
|                                                                                                 | Lexapro                 |                           |                             | S                        | Unknown                       | Unk                           |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Apr-2009                       | 6966743                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000005572                    |                               | 25 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Seizure                           | Lexapro                 |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 02-Apr-2009                       | 6966749                 | EXPEDITED (15-DAY)        | Y                           | DE                       | 2009S1004727                  |                               | 25 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                      |   |              |
|-------------------------|----------------------|---|--------------|
| Alcohol Poisoning;      | Zyprexa              | S | Not Reported |
| Pneumonia; Pulmonary    | Temazepam            | S | Not Reported |
| Congestion; Toxicity To | Dextromethorphan     | S | Not Reported |
| Various Agents          | Hydrobromide         |   |              |
|                         | Escitalopram Oxalate | S | Not Reported |
|                         | Ambien               | S | Not Reported |
|                         | Lithium              | C | Not Reported |
|                         | Risperdal            | C | Not Reported |
|                         | Lexapro              | C | Not Reported |
|                         | Naproxen             | C | Not Reported |
|                         | Methocarbamol        | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2009              | 6967927       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005564           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Abdominal Pain Upper;   | Escitalopram Oxalate |              |            | S           | Oral         | 1000 Mg (1000mg, Once),   |                 | Not Reported |
| Dizziness; Fatigue;     |                      |              |            |             |              | Oral                      |                 |              |
| Intentional Overdose;   | Alcohol              |              |            | S           | Oral         | 1/2 Bottle Of Hard Liquor |                 | Not Reported |
| Nausea; Suicide Attempt |                      |              |            |             |              | (35-40%) (Once), Oral     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2009              | 6970602       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005553           |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Accidental Overdose;      | Lexapro          |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), |                 | Not Reported |
| Cerebrovascular Accident; |                  |              |            |             | Oral         | Oral; 8-9 Tablets        |                 |              |
| Overdose                  |                  |              |            |             |              | 30 Mg (30 Mg, 1 In 1 D), |                 |              |
|                           |                  |              |            |             |              | Oral; 8-9 Tablets        |                 |              |
|                           | Ambien           |              |            | C           |              |                          |                 | Not Reported |
|                           | Xanax            |              |            | C           |              |                          |                 | Not Reported |
|                           | Lamictal         |              |            | C           |              |                          |                 | Not Reported |
|                           | Neurontin        |              |            | C           |              |                          |                 | Not Reported |
|                           | Pain Patch (Nos) |              |            | C           |              |                          |                 | Not Reported |
|                           | Lisinopril       |              |            | C           |              |                          |                 | Not Reported |
|                           | Amitriptyline    |              |            | C           |              |                          |                 | Not Reported |
|                           | Oxycontin        |              |            | C           |              |                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                          |                    |                    |                 |                      |                         |                 |              |                |
|----------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| Oxygen                     |                          | C                  |                    |                 |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2009                | 6970637                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000005573           |                         | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                    | Lexapro                  |                    |                    | S               |                      |                         |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2009                | 6987802                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000005468           |                         | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                    | Lexapro                  |                    |                    | S               |                      |                         |                 |              | Not Reported   |
|                            | Lamictal                 |                    |                    | C               |                      |                         |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2009                | 6958657                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000005307           |                         | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;         | Lexapro                  |                    |                    | S               |                      |                         |                 |              | Not Reported   |
| Dilatation Ventricular;    | Zyprexa                  |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D) |                 |              | Not Reported   |
| Toxicity To Various Agents | Seroquel                 |                    |                    | S               |                      |                         |                 |              | Not Reported   |
|                            | Trazodone                |                    |                    | S               |                      |                         |                 |              | Not Reported   |
|                            | Benadryl                 |                    |                    | S               |                      |                         |                 |              | Not Reported   |
|                            | Dilantin                 |                    |                    | S               |                      |                         |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2009                | 6958677                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000005305           |                         | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;         | Lexapro                  |                    |                    | S               |                      |                         |                 |              | Not Reported   |
| Pneumonia; Toxicity To     | Mirtazapine              |                    |                    | S               |                      |                         |                 |              | Not Reported   |
| Various Agents             | Sertraline Hydrochloride |                    |                    | S               |                      |                         |                 |              | Not Reported   |
|                            | Amitriptyline            |                    |                    | S               |                      |                         |                 |              | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |              |
|--------------------------|---|--------------|
| Zolpidem                 | S | Not Reported |
| Lorazepam                | S | Not Reported |
| Trazodone                | S | Not Reported |
| Phenytoin                | S | Not Reported |
| Aciclovir                | S | Not Reported |
| Zyprexa                  | S | Not Reported |
| 2.5 Mg (2.5 Mg,1 In 1 D) |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Apr-2009              | 6958683       | EXPEDITED (15-DAY) | Y                  | DE              | 1000005306           |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Death; Drug      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Level Increased; Skin       | Zyprexa        |              |            | S           |              |                    |                 | Not Reported |
| Injury; Toxicity To Various | Fluoxetine     |              |            | S           |              |                    |                 | Not Reported |
| Agents                      | Kemadrin       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Apr-2009              | 6959757       | EXPEDITED (15-DAY) | Y                  | HO              | US-ASTRAZENECA-2009UW07689 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Condition      | Zestoretic               |              |            | S           | Oral         | 20/12.5 Mg         |                 | Not Reported |
| Aggravated; Dysarthria;  | Desvenlafaxine Succinate |              |            | S           | Oral         |                    | 107 DAY         | Not Reported |
| Headache; Hypertension;  | Ibuprofen                |              |            | S           |              |                    |                 | Not Reported |
| Hypokalaemia; Mental     | Lyrica                   |              |            | S           |              |                    |                 | Not Reported |
| Status Changes; Multiple | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |
| Drug Therapy             | Clonazepam               |              |            | S           |              |                    |                 | Not Reported |
|                          | Abilify                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                          | Fluticasone              |              |            | S           |              | 2 Sprays Daily     |                 | Not Reported |
|                          | Loratadine               |              |            | S           |              |                    |                 | Not Reported |
|                          | Vicodin                  |              |            | S           |              | 5/500              |                 | Not Reported |
|                          | Ambien                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Vivelle                  |              |            | S           |              | 0.1 Mg             |                 | Not Reported |
|                          | Robaxin                  |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2009                                                    | 6959999              | EXPEDITED (15-DAY) | Y                  | OT              | GB-TEVA-189544ISR    |                      | 31 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Bladder Anomaly; Pulmonary Malformation; Stillbirth | Amitriptyline        |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
|                                                                | Amitriptyline        |                    |                    | S               |                      |                      |                 | Teva         |                |
|                                                                | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2009                                                                                         | 6961889        | EXPEDITED (15-DAY) | Y                  | DE              | 1000005304           |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Fall; Loss Of Consciousness; Pneumonia; Pulmonary Congestion; Toxicity To Various Agents | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Zyprexa        |                    |                    | S               |                      | (10 Mg)              |                 | Not Reported |                |
|                                                                                                     | Lithium        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Risperdal      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Ambien         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Temazepam      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Naproxen       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Methocarbamol  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Alcohol        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 03-Apr-2009                                                                                                                                                           | 6961937        | EXPEDITED (15-DAY) | Y                  | DE              | 1000005308           |                         | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Death; Alcohol Use; Antipsychotic Drug Level Above Therapeutic; Arteriosclerosis; Hepatic Steatosis; Pulmonary Oedema; Snoring; Toxicity To Various Agents | Lexapro        |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                       | Zyprexa        |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                       | Lunesta        |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                       | Seroquel       |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                       | Vistaril       |                    |                    | S               |                      |                         |                 | Not Reported |                |
|                                                                                                                                                                       | Depakote       |                    |                    | S               |                      |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
|--------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|------------------|----------------|
| 03-Apr-2009                                                                                | 6963793                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000005476                                          |                      |                 | Male             | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Acute Abdomen; Condition Aggravated; Drug Interaction; Lipoatrophy; Lipodystrophy Acquired | Escitalopram Oxalate     |                    |                    | S               | Oral                                                | Oral                 |                 | Not Reported     |                |
|                                                                                            | Kaletra                  |                    |                    | S               | Oral                                                | Oral                 |                 | Not Reported     |                |
|                                                                                            | Lamivudine               |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
|                                                                                            | Didanosine               |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 06-Apr-2009                                                                                | 6961673                  | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-09P-163-0566011-00                        |                      | 42 YR           | Male             | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Toxicity To Various Agents                                                                 | Escitalopram Oxalate     |                    |                    | S               | Unknown                                             |                      |                 | Not Reported     |                |
|                                                                                            | Zyprexa                  |                    |                    | S               | Unknown                                             |                      |                 | Not Reported     |                |
|                                                                                            | Eszopiclone              |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
|                                                                                            | Quetiapine               |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
|                                                                                            | Hydroxyzine              |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
|                                                                                            | Valproate Semisodium     |                    |                    | S               |                                                     |                      |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 07-Apr-2009                                                                                | 6962139                  | EXPEDITED (15-DAY) | Y                  | HO              | SE-ELI_LILLY_AND_COMP<br>ANY-SE200903002257         |                      | 40 YR           | Female           | SWE            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |
| Major Depression                                                                           | Duloxetine Hydrochloride |                    |                    | S               | Oral                                                | 60 Mg, Unk           |                 | Eli Lilly And Co |                |
|                                                                                            | Escitalopram Oxalate     |                    |                    | S               | Unknown                                             | 10 Mg, Daily (1/D)   |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 07-Apr-2009                                                                                | 6962819                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | CA-ROXANE<br>LABORATORIES, INC.-<br>2009-RO-00333RO |                      | 52 YR           | Male             | CAN            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                               |   |      |              |
|--------------------------|-------------------------------|---|------|--------------|
| Electrocardiogram Qt     | Morphine                      | S | 30mg | Roxane       |
| Prolonged;               | Morphine                      | S |      | Roxane       |
| Hyperkalaemia; Overdose; | Morphine                      | S |      | Roxane       |
| Sinus Tachycardia        | Morphine                      | S |      | Roxane       |
|                          | Ramipril                      | S | 5mg  | Roxane       |
|                          | Lorazepam                     | S |      | Roxane       |
|                          | Diazepam                      | S |      | Roxane       |
|                          | Citalopram                    | S |      | Roxane       |
|                          | Roxicet                       | S |      | Roxane       |
|                          | Escitalopram Oxalate          | S | 10mg | Not Reported |
|                          | Escitalopram Oxalate          | S |      | Not Reported |
|                          | Zopiclone                     | S | 15mg | Not Reported |
|                          | Zopiclone                     | S |      | Not Reported |
|                          | Oxycodone                     | S |      | Not Reported |
|                          | Oxycodone                     | S |      | Not Reported |
|                          | Calcium Gluconate             | C |      | Not Reported |
|                          | Insulin                       | C |      | Not Reported |
|                          | Sodium Polystyrene Sulphonate | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2009              | 6970446       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000005099           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Agitation; Blood Creatine Phosphokinase;                             | Escitalopram Oxalate |              |            | S           | Oral         | 80 Mg (80 Mg, Once),<br>Oral; Oral |                 | Not Reported |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Suicide Attempt | Ritalin              |              |            | S           | Oral         | 300 Mg (300 Mg, Once),<br>Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2009              | 6802723       | EXPEDITED (15-DAY) | Y                  | HO              | DE-PFIZER INC-<br>2008091240 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>            | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Liver Disorder | Lamotrigine               |              |            | S           |              |                    |                 | Not Reported |
|                                  | Lithium Carbonate         |              |            | C           |              |                    |                 | Not Reported |
|                                  | Ziprasidone Hydrochloride |              |            | S           | Oral         |                    |                 | Pfizer       |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |           |   |      |              |
|--|-----------|---|------|--------------|
|  | Sortis    | S | Oral | Pfizer       |
|  | Tilidine  | S |      | Not Reported |
|  | Cymbalta  | S |      | Not Reported |
|  | Cipralext | S |      | Not Reported |
|  | Seroquel  | S |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2009              | 6812641       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-PFIZER INC-2008090861 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                     | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Liver Disorder; Transaminases Increased | Zoloft                    |              |            | S           |              |                    |                 | Pfizer       |
|                                                           | Tilidine Hydrochloride    |              |            | S           |              |                    |                 | Not Reported |
|                                                           | Cymbalta                  |              |            | S           |              |                    |                 | Not Reported |
|                                                           | Lithium Carbonate         |              |            | C           |              |                    |                 | Not Reported |
|                                                           | Sortis                    |              |            | S           | Oral         |                    |                 | Pfizer       |
|                                                           | Ziprasidone Hydrochloride |              |            | S           |              |                    |                 | Pfizer       |
|                                                           | Lamotrigine               |              |            | S           |              |                    |                 | Not Reported |
|                                                           | Cipralext                 |              |            | S           |              |                    |                 | Not Reported |
|                                                           | Seroquel                  |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2009              | 6898476       | EXPEDITED (15-DAY) | Y                  | DS, OT          | 1000003546           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|-------------------------------------|-----------------|--------------|
| Developmental Delay; Developmental Hip Dysplasia; Failure To Thrive; Gait Inability; Hypospadias; Hypotonia; Maternal Drugs Affecting Foetus; Selective Eating Disorder; Umbilical Cord Around Neck; Weight Gain Poor | Lexapro        |              |            | S           | Transplacental | 5 Mg (5 Mg,1 In 1 D),Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 08-Apr-2009              | 6966738        | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000005560           |                                                                                          | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Lexapro        |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                          |                |                    |                    |                 | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral |                 |              |                |
|                          |                |                    |                    |                 | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral |                 |              |                |
|                          | Cymbalta       |                    |                    | S               | Oral                 | Oral                                                                                     |                 | Not Reported |                |
|                          | Ativan         |                    |                    | C               |                      |                                                                                          |                 | Not Reported |                |
|                          | Abilify        |                    |                    | C               |                      |                                                                                          |                 | Not Reported |                |
|                          | Remeron        |                    |                    | C               |                      |                                                                                          |                 | Not Reported |                |
|                          | Wellbutrin     |                    |                    | C               |                      |                                                                                          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 08-Apr-2009                                                                                                                                                                                                                  | 6970922                | EXPEDITED (15-DAY) | Y                  | HO              | 1000005611           |                           | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Blood Potassium Decreased; Confusional State; Dysarthria; Electrocardiogram St Segment Abnormal; Haematocrit Increased; Headache; Hypertension; Hypokalaemia; Mastoid Disorder; Mental Status Changes; White Blood | Lexapro                |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D)    |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Unspecified Ingredient |                    |                    | S               | Oral                 | (Daily),Oral              |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Ibuprofen              |                    |                    | S               |                      | 2400 Mg (800 Mg,3 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Lyrica                 |                    |                    | S               |                      | 75 Mg (75 Mg,1 In 1 D)    |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Clonazepam             |                    |                    | S               |                      | 2 Mg (1 Mg,2 In 1 D)      |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Abilify                |                    |                    | S               |                      | 30 Mg (15 Mg,2 In 1 D)    |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Fluticasone            |                    |                    | S               |                      | (2 Sprays Daily)          |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |            |   |             |                           |              |
|----------------------|------------|---|-------------|---------------------------|--------------|
| Cell Count Increased | Loratadine | S |             | 10 Mg (10 Mg,1 In 1 D)    | Not Reported |
|                      | Vicodin    | S |             | (Prn)                     | Not Reported |
|                      | Zestoretic | S |             | (Daily)                   | Not Reported |
|                      | Ambien     | S |             | 10 Mg (10 Mg,1 In 1 D)    | Not Reported |
|                      | Vivelle    | S | Transdermal | (0.1 Mg),Transdermal      | Not Reported |
|                      | Robaxin    | S |             | 2250 Mg (750 Mg,3 In 1 D) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2009              | 6971728       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005643           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Haematoma; Urinary Retention | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                              | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                              | Escitalopram Oxalate |              |            | S           | Oral         | (1 In 1 D), Oral              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2009              | 6959512       | EXPEDITED (15-DAY) | Y                  | HO              | 235567K07USA         |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Depressed Mood; Fall; Gait Disturbance; Injection Site Erythema; Injection Site Pain; Self-Injurious Ideation; Suicide Attempt | Rebif                              |              |            | S           | Subcutaneous | 44 Mcg, 3 In 1 Weeks, Subcutaneous |                 | Not Reported |
|                                                                                                                                | Lexapro                            |              |            | S           |              | 40 Mg, 20 Mg<br>40 Mg, 20 Mg       |                 | Not Reported |
|                                                                                                                                | Ibuprofen (Ibuprofen)              |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                | Synthroid                          |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                | Ocybutin<br>(Oxybutynin/00538901/) |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2009              | 6965479       | EXPEDITED (15-DAY) | N                  | DS, OT          | PHEH2009US03323      |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>               |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------------------|
| Disorientation; Headache;<br>Hyperacusis;<br>Hypersensitivity;<br>Hypothalamo-Pituitary<br>Disorder; Muscle Spasms;<br>Sensory Loss | Trileptal<br>Lexapro |              |            | S<br>S      |              |                    |                 | Novartis<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2009              | 6966681       | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-<br>2009UW01598 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u>                                                        | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |
|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|---------------------------------------------------------------------|--------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| Abdominal Distension;<br>Abdominal Pain; Blood<br>Pressure Increased;<br>Dyspepsia; Joint Swelling | Atenolol<br>Xyrem<br>Ramipril<br>Lexapro<br>Cymbalta<br>Simvastatin<br>Lyrica<br>Triamterene And<br>Hydrochlorothiazide |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S<br>C | Oral<br>Oral<br>Unknown<br>Unknown<br>Unknown<br>Unknown<br>Unknown |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2009              | 6975647       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005674           |                      | 87 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                                                                                                          | <u>Duration</u> | <u>Mfr</u>                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------|------------|------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------------|
| Gastric Ulcer;<br>Gastrointestinal<br>Haemorrhage;<br>Gastroesophageal Reflux<br>Disease; Haematemesis;<br>Haemoglobin Decreased;<br>Hiatus Hernia;<br>Oesophageal Mucosal | Escitalopram Oxalate<br>Aspirin<br>Aspirin<br>Aricept |              |            | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral<br>100 Mg 9100 Mg, 1 In 1<br>D), Oral<br>100 Mg 9100 Mg, 1 In 1<br>D), Oral<br>5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |                                                                                                                     |   |              |
|-------------|---------------------------------------------------------------------------------------------------------------------|---|--------------|
| Hyperplasia | Novonorm (Tablets)                                                                                                  | C | Not Reported |
|             | Triatec (Tablets)                                                                                                   | C | Not Reported |
|             | Norvasc                                                                                                             | C | Not Reported |
|             | Remeron                                                                                                             | C | Not Reported |
|             | Leponex (Tablets)                                                                                                   | C | Not Reported |
|             | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | C | Not Reported |
|             | Acidum Folicum (Tablets)                                                                                            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2009              | 6975649       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005676           |                      | 49 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Epilepsy              | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2009              | 6976703       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005675           |                      | 60 YR      | Female     | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|--------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Disturbance In Attention; Somnolence | Lexapro            |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                      | Anxicalm (Tablets) |              |            | C           |              |                               |                 | Not Reported |
|                                      | Lipitor            |              |            | C           |              |                               |                 | Not Reported |
|                                      | Zoton (Capsules)   |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2009              | 6970393       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2009FR13313      |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                             |   |      |                         |          |              |
|--------------------------|-----------------------------|---|------|-------------------------|----------|--------------|
| Blood Creatine           | Trileptal                   | S | Oral | 150 Mg, Bid             | 1890 DAY | Novartis     |
| Phosphokinase Increased; | Keppra                      | C |      | 1 Tablet Each Morning   |          | Not Reported |
| Blood Potassium          |                             |   |      | And 2 Each Evening      |          |              |
| Decreased; Blood         | Dipiperon                   | C |      | Xv Each Morning, X Each |          | Not Reported |
| Pressure Increased;      |                             |   |      | Midday And Xxv Each     |          |              |
| Hyponatraemia; Nausea;   |                             |   |      | Evening                 |          |              |
| Seizure; Vomiting        | Flupentixol Dihydrochloride | C |      | 20 Mg, Tiw              |          | Not Reported |
|                          | Tropatepine Hydrochloride   | C |      | 1 Each Morning          |          | Not Reported |
|                          | Escitalopram Oxalate        | S |      | 1 Each Morning          |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2009              | 6970467       | EXPEDITED (15-DAY) | N                  | OT              | A0777897A            |                      |            | Male       | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Amnesia; Depression;<br>Hallucination; Somnolence | Lamictal               |              |            | S           | Oral         |                    | 6 YR            | Glaxosmithkline |
|                                                   | Paxil                  |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                   | Klonopin               |              |            | S           |              |                    |                 | Not Reported    |
|                                                   | Lexapro                |              |            | S           |              |                    |                 | Not Reported    |
|                                                   | Bupropion              |              |            | S           |              |                    | 6 YR            | Teva            |
|                                                   | Humulin R              |              |            | C           |              |                    |                 | Not Reported    |
|                                                   | Spiriva                |              |            | C           |              |                    |                 | Not Reported    |
|                                                   | Plavix                 |              |            | C           |              |                    |                 | Not Reported    |
|                                                   | Simvastatin            |              |            | C           |              |                    |                 | Not Reported    |
|                                                   | Unspecified Ingredient |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                   | Unspecified Ingredient |              |            | C           |              |                    |                 | Not Reported    |
|                                                   | Metoprolol             |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Apr-2009              | 6970499       | EXPEDITED (15-DAY) | Y                  | HO              | US-ABBOTT-09P-163-0566868-00 |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Condition<br>Aggravated; Dysarthria;<br>Headache; Hypertension; | Vicodin        |              |            | S           | Unknown      | 5/500 As Needed    |                 | Not Reported |
|                                                                           | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |                          |   |             |               |  |              |
|------------------------------------------------------------|--------------------------|---|-------------|---------------|--|--------------|
| Hypokalaemia; Mental Status Changes; Multiple Drug Therapy | Ibuprofen                | S | Unknown     |               |  | Not Reported |
|                                                            | Desvenlafaxine Succinate | S | Oral        |               |  | Not Reported |
|                                                            | Desvenlafaxine Succinate | S |             |               |  | Not Reported |
|                                                            | Abilify                  | S | Unknown     |               |  | Not Reported |
|                                                            | Ambien                   | S | Oral        |               |  | Not Reported |
|                                                            | Clonazepam               | S | Unknown     |               |  | Not Reported |
|                                                            | Fluticasone              | S | Unknown     | Sprays        |  | Not Reported |
|                                                            | Loratadine               | S | Unknown     |               |  | Not Reported |
|                                                            | Lyrica                   | S | Oral        |               |  | Not Reported |
|                                                            | Methocarbamol            | S | Unknown     |               |  | Not Reported |
|                                                            | Vivelle                  | S | Transdermal |               |  | Not Reported |
|                                                            | Zestoretic               | S | Unknown     | 20/12.5 Daily |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2009              | 6978597       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005706           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amimia; Dyskinesia; Extrapyramidal Disorder; Eyelid Function Disorder; Muscular Weakness; Parkinsonism | Escitalopram Oxalate   |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                        | Unspecified Ingredient |              |            | S           |              | (15 Mg)            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2009              | 6978695       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005713           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Drug Interaction; Fall; Psychomotor Retardation | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                            | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 16-Apr-2009                                                                  | 6985715                                                                 | EXPEDITED (15-DAY) | N                  | OT              | CHPA2009US09086      |                                 |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Dizziness; Dyspnoea                                             | Acetaminophen\Diphenhydramine Hydrochloride\Phenylephrine Hydrochloride |                    | Y                  | S               | Oral                 | 6 Tsp, Once/Single, Oral        |                 | Not Reported |                |
|                                                                              | Acetaminophen\Dextromethorphan\Phenylephrine                            |                    |                    | S               | Oral                 | 6 Tsp, Once/Single, Oral        |                 | Not Reported |                |
|                                                                              | Lexapro                                                                 |                    |                    | S               |                      | Oral                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                  | 6924656                                                                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000003933           |                                 | 72 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Hypovolaemic Shock; Upper Gastrointestinal Haemorrhage | Escitalopram Oxalate                                                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                              | Terbinafine                                                             |                    |                    | S               | Oral                 | 250 Mg (250 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                              | Sifrol (Tablets)                                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                              | Motilium                                                                |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                              | Madopar (Tablets)                                                       |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                              | Nebilet (Tablets)                                                       |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                              | Lyrinel Oros (Tablets)                                                  |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                              | Seroquel                                                                |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                  | 6932334                                                                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000004847           |                                 | 61 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Conjunctival Haemorrhage; Episcleritis                                       | Escitalopram Oxalate                                                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                              | Pariet                                                                  |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                      | Lorazepam          |                    | C               |                      |                                                                                         |                 |              | Not Reported   |
|----------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                        |                      | Stilnox            |                    | C               |                      |                                                                                         |                 |              | Not Reported   |
|                                                                                        |                      | Avlocardyl         |                    | C               |                      |                                                                                         |                 |              | Not Reported   |
|                                                                                        |                      | Colchicine         |                    | C               |                      |                                                                                         |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                            | 6959885              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005420           |                                                                                         | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Tachycardia                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                                                                                    |                 | Not Reported |                |
|                                                                                        | Aspirin              |                    |                    | S               | Oral                 | Oral                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                            | 6976336              | DIRECT             | Y                  | OT              |                      |                                                                                         | 86 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased                                                                 | Lexapro              |                    |                    | S               | Oral                 | 10mg Qd Po                                                                              |                 | Forest       |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                            | 6977964              | EXPEDITED (15-DAY) | Y                  | CA              | 1000005711           |                                                                                         |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting<br>Foetus; Pelvi-Ureteric<br>Obstruction;<br>Pyelocaliectasis | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental, 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
|                                                                                        |                      |                    |                    |                 | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental, 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                 |              |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Apr-2009                                                                            | 6978144              | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2009GB04313      |                                                                                         | 66 YR           | Female       | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| Depressed Level Of Consciousness; Drug Interaction; Sedation; Somnolence              | Clonidine Transdermal System |                    |                    | S               |                          | Qd                            |                 | Not Reported |                |
|                                                                                       | Escitalopram Oxalate         |                    |                    | S               |                          | 5 Mg, Qd                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2009                                                                           | 6517385                      | EXPEDITED (15-DAY) | Y                  | HO, OT          | IN-PFIZER INC-2007107508 |                               | 56 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Interaction; Hypomania; Serotonin Syndrome                     | Sertraline Hydrochloride     |                    |                    | S               |                          |                               | 35 DAY          | Pfizer       |                |
|                                                                                       | Amlodipine                   |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                                       | Trazodone Hydrochloride      |                    |                    | S               |                          |                               | 35 DAY          | Not Reported |                |
|                                                                                       | Lithium Carbonate            |                    |                    | S               |                          |                               |                 | Pfizer       |                |
|                                                                                       | Phenytoin Sodium             |                    |                    | S               |                          |                               |                 | Pfizer       |                |
|                                                                                       | Escitalopram Oxalate         |                    |                    | S               |                          |                               | 7 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2009                                                                           | 6808022                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000001459               |                               | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention; Urinary Tract Disorder; Uterine Leiomyoma                          | Escitalopram Oxalate         |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2009                                                                           | 6943357                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000005044               |                               | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased; Blood Thyroid Stimulating Hormone Increased; Gynaecomastia | Escitalopram Oxalate         |                    |                    | S               |                          | 15 Mg (15 Mg,1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                       | Escitalopram Oxalate         |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 21-Apr-2009                                                                 | 6955086              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005113           |                                                                    | 61 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Oedema;<br>Respiratory Distress;<br>Wrong Product<br>Administered  | Escitalopram Oxalate |                    |                    | S               |                      |                                                                    |                 | Not Reported |                |
|                                                                             | Nimesulide           |                    |                    | S               |                      |                                                                    |                 | Not Reported |                |
|                                                                             | Loxapine             |                    |                    | S               | Oral                 | Oral                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2009                                                                 | 6974316              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000005649           |                                                                    | 28 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Intentional<br>Overdose; Sopor; Suicide<br>Attempt; Tachycardia | Escitalopram Oxalate |                    |                    | S               | Oral                 | 160 Mg (160<br>Mg,Once),Oral ; Oral                                |                 | Not Reported |                |
|                                                                             | Mirtazapine          |                    |                    | S               | Oral                 | 240 Mg (240<br>Mg,Once),Oral                                       |                 | Not Reported |                |
|                                                                             | Tavor (Lorazepam)    |                    |                    | S               | Oral                 | 20 Mg (20 Mg,Once),Oral                                            |                 | Not Reported |                |
|                                                                             | Alcohol              |                    |                    | S               | Oral                 | (Once),Oral                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2009                                                                 | 6981226              | EXPEDITED (15-DAY) | Y                  | OT              | 1000004813           |                                                                    | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;<br>Eye Pain; Headache                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                             |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                             | Seroquel             |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                                                             | Temesta (Tablets)    |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------------------|-----------------|------------------------------|----------------|
| 21-Apr-2009                                                                                                                          | 6983710                                          | DIRECT             | N                  | OT              |                              |                                                 | 43 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aphasia; Decreased Appetite; Headache; Nausea                                                                                        | Lexapro                                          |                    |                    | S               | Oral                         | 1 Tablet 1x Day Po                              |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Apr-2009                                                                                                                          | 7378900                                          | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000005780                   |                                                 | 71 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aortic Valve Incompetence; Cardiac Failure; Left Ventricular Dysfunction; Mitral Valve Incompetence; Pulmonary Arterial Hypertension | Escitalopram Oxalate<br>Benfluorex Hydrochloride |                    |                    | S<br>S          | Oral                         | 3 Dosage Forms (3 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                             | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 22-Apr-2009                                                                                                                          | 6968549                                          | EXPEDITED (15-DAY) | Y                  | OT              | DE-ABBOTT-09P-062-0566920-00 |                                                 | 28 YR           | Male                         | DEU            |
| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aggression; Intentional Overdose; Sopor; Suicide Attempt; Tachycardia                                                                | Ciprallex                                        |                    |                    | S               | Oral                         | Overdose: 160mg (10mg, 16 In 1 Day)             |                 | Not Reported                 |                |
|                                                                                                                                      | Mirtazapine                                      |                    |                    | S               | Oral                         | Overdose: 240mg (30 Mg, 8 In 1 Day)             |                 | Not Reported                 |                |
|                                                                                                                                      | Tavor (Lorazepam)                                |                    |                    | S               | Oral                         | Overdose: 20 Mg (0.5 Mg, 40 In 1 Day)           |                 | Not Reported                 |                |
|                                                                                                                                      | Alcohol                                          |                    |                    | S               | Oral                         | Overdose: Unknown Amount (1.3 Per Mille)        |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 22-Apr-2009                                                                                                                                      | 6981317                                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000005826           |                                                                                              | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; General Physical Health Deterioration; Pyrexia; Visual Impairment                                                                     | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | 5 Mg (5mg, 1 In 1 D), Oral                                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2009                                                                                                                                      | 6981382                                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000005796           |                                                                                              | 84 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Overdose; Pelvic Fracture; Urinary Retention                                                                                               | Lexapro                                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral, 30 Mg (30 Mg, 1 In 1 D), Oral, |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2009                                                                                                                                      | 6981786                                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000005822           |                                                                                              | 34 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma Scale Abnormal; Deep Vein Thrombosis; Eschar; Hypothermia; Hypotonia; Intentional Overdose; Mydriasis; Pneumonia Aspiration; Rhabdomyolysis | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
|                                                                                                                                                  | Alprazolam                                          |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
|                                                                                                                                                  | Nordazepam                                          |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
|                                                                                                                                                  | Aceprometazine\Meprobamate                          |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
|                                                                                                                                                  | Zopiclone                                           |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
|                                                                                                                                                  | Acepromazine\Aceprometazine\Clorazepate Dipotassium |                    |                    | S               | Oral                 | Oral                                                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2009                                                                                                                                      | 6985142                                             | DIRECT             | N                  |                 |                      |                                                                                              | 44 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------|-----------------|--------------|----------------|
| Anxiety; Confusional State; Crying; Eye Disorder; Fear; Formication; Heart Rate Increased; Hyperacusis; Impaired Driving Ability; Mental Impairment; Nausea; Photophobia; Tremor | Lexapro              |                    |                    | S               | Oral                                     | 10mg 1 Tablet Daily Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2009                                                                                                                                                                      | 6985357              | DIRECT             | N                  | DE              |                                          |                          | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Completed Suicide; Gun Shot Wound; Mood Swings                                                                                                                       | Lexapro              |                    |                    | S               | Oral                                     | Once Dailey Po           |                 | Not Reported |                |
|                                                                                                                                                                                  | Xanax                |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                                                                                                                                                                  | Ambien               |                    |                    | C               |                                          |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2009                                                                                                                                                                      | 6962502              | EXPEDITED (15-DAY) | N                  | DE              | US-BRISTOL-MYERS SQUIBB COMPANY-14574263 |                          | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                                                                                                     | Abilify              |                    |                    | S               | Oral                                     |                          | 4 YR            | Not Reported |                |
|                                                                                                                                                                                  | Lexapro              |                    |                    | S               | Oral                                     |                          |                 | Not Reported |                |
|                                                                                                                                                                                  | Atenolol             |                    |                    | C               |                                          |                          |                 | Not Reported |                |
|                                                                                                                                                                                  | Prevacid             |                    |                    | C               |                                          |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2009                                                                                                                                                                      | 6973126              | EXPEDITED (15-DAY) | Y                  | OT              | 1000005655                               |                          | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Atrial Fibrillation; Cachexia;                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 15 Mg (15 Mg, 1 In 1 D), |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                          |                      |   |      |                                  |                                          |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|----------------------------------|------------------------------------------|--------------|
| Cardiac Fibrillation;<br>Decreased Appetite;<br>Personality Change;<br>Restlessness; Sinus<br>Bradycardia; Sinus<br>Tachycardia;<br>Supraventricular<br>Extrasystoles; Ventricular<br>Extrasystoles; Weight<br>Decreased | Escitalopram Oxalate | S | Oral | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral         | Not Reported |
|                                                                                                                                                                                                                          | Seroquel             | S | Oral | Oral                             | 650 Mg (650 Mg, 1 In 1 D),<br>Oral; Oral | Not Reported |
|                                                                                                                                                                                                                          |                      |   | Oral | Oral                             | 650 Mg (650 Mg, 1 In 1 D),<br>Oral; Oral |              |
|                                                                                                                                                                                                                          | Seroquel             | S | Oral | See Image                        | See Image                                | Not Reported |
|                                                                                                                                                                                                                          |                      |   | Oral | See Image                        | See Image                                |              |
|                                                                                                                                                                                                                          |                      |   | Oral | See Image                        | See Image                                |              |
|                                                                                                                                                                                                                          |                      |   | Oral | See Image                        | See Image                                |              |
|                                                                                                                                                                                                                          |                      |   | Oral | See Image                        | See Image                                |              |
|                                                                                                                                                                                                                          |                      |   | Oral | See Image                        | See Image                                |              |
|                                                                                                                                                                                                                          | Zyprexa              | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                                          | Not Reported |
|                                                                                                                                                                                                                          | Zyprexa              | S | Oral | (1 In 1 D), Oral                 |                                          | Not Reported |
|                                                                                                                                                                                                                          | Akineton             | S | Oral | 2 Mg (2 Mg, 1 In 1 D), Oral      |                                          | Not Reported |
|                                                                                                                                                                                                                          | Zopiclone            | S |      |                                  |                                          | Not Reported |
|                                                                                                                                                                                                                          | Pantozol             | C |      |                                  |                                          | Not Reported |
|                                                                                                                                                                                                                          | Diazepam             | C |      |                                  |                                          | Not Reported |
|                                                                                                                                                                                                                          | Levothyroxine Sodium | C |      |                                  |                                          | Not Reported |
|                                                                                                                                                                                                                          | Osteo Plus           | C |      |                                  |                                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Apr-2009              | 6973245       | EXPEDITED (15-DAY) | N                  | OT              | DE-PFIZER INC-<br>2009195648 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety Disorder;<br>Asthenia; Drug Interaction;<br>Mania; Tremor | Ziprasidone Hydrochloride |              |            | S           | Oral         | 40-60mg/Day        |                 | Pfizer       |
|                                                                   | Ziprasidone Hydrochloride |              |            | S           | Oral         | 80mg/Day           |                 | Pfizer       |
|                                                                   | Ziprasidone Hydrochloride |              |            | S           |              |                    |                 | Pfizer       |
|                                                                   | Escitalopram Oxalate      |              |            | S           | Oral         | 10mg/Day           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Apr-2009              | 6976913       | EXPEDITED (15-DAY) | Y                  | HO, LT          | AU-B.I.<br>PHARMACEUTICALS,I |                      |            | Male       | AUS            |

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NC./RIDGEFIELD-2009-  
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| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Hyponatraemia; Malaise | Micardis             |              |            | S           |              | 40mg               |                 | Boehringer Ingelheim |
|                        | Escitalopram Oxalate |              |            | S           | Oral         | 10mg               |                 | Not Reported         |
|                        | Colgout              |              |            | C           | Oral         | 500mcg             |                 | Not Reported         |
|                        | Movicol              |              |            | C           |              |                    |                 | Not Reported         |
|                        | Mylanta              |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2009              | 6983732       | DIRECT           | Y                  | OT              |                      |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Hypertension;<br>Serotonin Syndrome;<br>Tachycardia | Linezolid            |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2009              | 6984168       | DIRECT           |                    |                 |                      |                      | 33 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Medication Error; Product<br>Dispensing Error | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                               | Lipitor        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Apr-2009              | 6985253       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005858           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Suicide Attempt | Escitalopram Oxalate |              |            | S           | Oral         | 1000 Mg (1000 Mg, Once),<br>Oral; Oral |                 | Not Reported |
|                                          | Alcohol              |              |            | S           | Oral         | (Once), Oral                           |                 | Not Reported |

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| <u>FDA Received Date</u>                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
| 24-Apr-2009                                             | 6987185                      | EXPEDITED (15-DAY) | Y                  | HO              | 1000005916               |                             | 79 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health Deterioration;<br>Hyponatraemia | Escitalopram Oxalate         |                    |                    | S               | Oral                     | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                         | Citalopram Hydrobromide      |                    |                    | S               | Oral                     | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                         | Citalopram                   |                    |                    | S               | Oral                     | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                         | Amiodarone                   |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Minisintrom                  |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Amlodipine                   |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Seretide                     |                    |                    | C               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2009                                             | 6806476                      | EXPEDITED (15-DAY) | Y                  | HO              | DE-PFIZER INC-2008091321 |                             |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                   | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Interaction;<br>Somnolence               | Venlafaxine Hydrochloride    |                    |                    | S               | Oral                     |                             | 19 DAY          | Not Reported |                |
|                                                         | Quilonorm                    |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Novodigal (Digoxin)          |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Enalapril Maleate            |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Furosemide                   |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Piretanide                   |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Kalinor (Potassium Chloride) |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Godamed                      |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Creon                        |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                         | Ziprasidone Hydrochloride    |                    |                    | S               | Oral                     |                             |                 | Pfizer       |                |
|                                                         | Cipralext                    |                    |                    | S               |                          |                             |                 | Not Reported |                |
|                                                         | Remergil                     |                    |                    | S               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2009                                             | 6985889                      | DIRECT             | Y                  |                 |                          |                             | 52 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>                   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------------------|-----------------|------------------------------|----------------|
| Decreased Appetite;<br>Depression; Dysgeusia;<br>Fatigue; Hypophagia;<br>Irritability; Lethargy;<br>Mental Impairment;<br>Pollakiuria; Tongue<br>Discolouration; Vomiting                                                                                                          | Effexor Xr          |                    |                    | S               | Oral                 | 37.5 Mg Daily (2x) Oral                                                                              |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                                                    | Lexapro             |                    |                    | S               | Oral                 | 37.5 Mg Daily (2x) Oral<br>10 Mg 1 X Oral                                                            |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 27-Apr-2009                                                                                                                                                                                                                                                                        | 6986609             | EXPEDITED (15-DAY) | N                  | OT              | 1000001578           |                                                                                                      | 32 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abdominal Discomfort;<br>Anxiety; Depressed Mood;<br>Feeling Abnormal;<br>Inappropriate Schedule Of<br>Product Administration;<br>Muscular Weakness;<br>Obsessive Thoughts;<br>Product Dose Omission;<br>Self-Injurious Ideation;<br>Therapy Cessation;<br>Treatment Noncompliance | Lexapro             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 20 Mg (20 Mg, 1<br>In 1 D), Oral |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                                                    |                     |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 20 Mg (20 Mg, 1<br>In 1 D), Oral |                 |                              |                |
|                                                                                                                                                                                                                                                                                    |                     |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 20 Mg (20 Mg, 1<br>In 1 D), Oral |                 |                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Apr-2009                                                                                                                                                                                                                                                                        | 6910170             | EXPEDITED (15-DAY) | Y                  | HO              | 1000003722           |                                                                                                      | 51 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Interaction;<br>Dysarthria; Hypertension;<br>Malaise                                                                                                                                                                                                                          | Lexapro             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral                                                                      |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                                                    | Lexapro             |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1<br>D),Oral                                                                       |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                                                                    | Ritalin<br>Klonopin |                    |                    | S<br>S          | Oral                 | 2 Mg (0.5 Mg,4 In 1                                                                                  |                 | Not Reported<br>Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                |                    |                    |                 |                                  |                                  | D),Oral         |              |                |
|----------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------------------|-----------------|--------------|----------------|
|                            |                                | Inderal            |                    | C               |                                  |                                  |                 |              | Not Reported   |
|                            |                                | Lotension          |                    | C               |                                  |                                  |                 |              | Not Reported   |
|                            |                                | Allegra-D          |                    | C               |                                  |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2009                | 6953720                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000005156                       |                                  | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Vomiting          | Lexapro                        |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2009                | 6967713                        | EXPEDITED (15-DAY) | Y                  | OT              | DE-ABBOTT-09P-062-<br>0566917-00 |                                  | 33 YR           | Female       | DEU            |
| <u>Preferred Term</u>      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Atrial         | Akineton                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Fibrillation;              | Escitalopram Oxalate           |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Supraventricular           | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Extrasystoles; Ventricular | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Extrasystoles              | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Seroquel                       |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Zyprexa                        |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
|                            | Zopiclone                      |                    |                    | C               | Oral                             |                                  |                 | Not Reported |                |
|                            | Pantozol (Pantoprazole Sodium) |                    |                    | C               | Oral                             |                                  |                 | Not Reported |                |
|                            | Diazepam                       |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
|                            | Levothyroxine Sodium           |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
|                            | Calcium Carbonate              |                    |                    | C               |                                  |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 28-Apr-2009                                                                                        | 6972494                | EXPEDITED (15-DAY) | Y                  | DS              | 1000005598           |                                                                                              | 32 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Chorioretinopathy                                                                                  | Escitalopram Oxalate   |                    |                    | S               | Oral                 | (20 Mg),Oral                                                                                 |                 | Not Reported |                |
|                                                                                                    | Lithium Carbonate      |                    |                    | C               |                      |                                                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2009                                                                                        | 6986715                | DIRECT             | N                  | OT              |                      |                                                                                              | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Family Stress; Impaired Work Ability; Paraesthesia; Quality Of Life Decreased; Tinnitus            | Lexapro                |                    |                    | S               | Oral                 | Now: .5mg Daily Po                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2009                                                                                        | 6987558                | EXPEDITED (15-DAY) | Y                  | DE, HO, LT, OT  | 1000003679           |                                                                                              | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Coma; Drug Interaction; Fall; Head Injury; Subdural Haematoma                   | Escitalopram Oxalate   |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D), 10 Mg (10mg1 In 1 D)<br>20 Mg (20 Mg,1 In 1 D), 10 Mg (10mg1 In 1 D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2009                                                                                        | 6436152                | EXPEDITED (15-DAY) | Y                  | DE              | S07-IRL-05115-01     |                                                                                              | 64 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Arteriosclerosis Coronary Artery; Completed Suicide; Hepatic Steatosis; Intentional Overdose; Left | Lexapro                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                                                |                 | Not Reported |                |
|                                                                                                    | Unspecified Ingredient |                    |                    | S               |                      | Once                                                                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                                                                                |        |                              |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------|------------------------------|
| Ventricular Hypertrophy;<br>Pneumonia; Poisoning;<br>Pulmonary Oedema | Lipostat (Pravastatin Sodium)<br>(Pravastatin Sodium)<br>Zispin (Mirtazapine)<br>(Mirtazapine) | C<br>C | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2009              | 6982158       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2009-02802 |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Temazepam                        |              |            | S           |              | Unk                |                 | Watson       |
|                            | Lexapro                          |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Ambien                           |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Zyprexa                          |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Alcohol                          |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Dextromethorphan<br>Hydrobromide |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2009              | 6989392       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005945           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| General Physical Health<br>Deterioration; Overdose;<br>Suicidal Ideation; Suicide<br>Attempt; Unresponsive To<br>Stimuli; Withdrawal<br>Syndrome | Escitalopram Oxalate   |              |            | S           |              | 60 Mg (60 Mg, 1in 1 D) |                 | Not Reported |
|                                                                                                                                                  | Risperdal              |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                                                  | Tiaprid                |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                                                  | Tramadol Hydrochloride |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                                                                  | Eunerpan               |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-May-2009              | 6992571       | EXPEDITED (15-DAY) | N                  | HO              | 2008S1011439         |                      | 33 YR      | Female     | AUS            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Induced Labour; Maternal<br>Exposure During | Metoclopramide |              |            | S           | Oral         | 10 Mg;Q6h;Oral     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                      |   |      |                  |              |
|-------------------------------------------------------------|----------------------|---|------|------------------|--------------|
| Pregnancy; Premature Labour; Premature Rupture Of Membranes | Escitalopram Oxalate | S | Oral | 10 Mg;Daily;Oral | Not Reported |
|                                                             | Folic Acid           | C |      |                  | Not Reported |
|                                                             | Lysine               | C |      |                  | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 01-May-2009                       | 6992578                | EXPEDITED (15-DAY)        | N                           | HO                       | 2009S1006607                  |                               |                     | Male                | AUS                     |

| <a href="#">Preferred Term</a>                                                                                            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Jaundice Neonatal; Maternal Drugs Affecting Foetus; Neonatal Infection; Premature Labour; Temperature Regulation Disorder | Metoclopramide          |                       |                     | S                    | Transplacental        | 10 Mg;Q6h;Transplacental    |                          | Not Reported        |
|                                                                                                                           | Escitalopram Oxalate    |                       |                     | S                    | Transplacental        | 10 Mg;Daily;Transplacental  |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-May-2009                       | 6992566                | DIRECT                    | N                           | DE                       |                               |                               | 54 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anxiety; Decreased Appetite; Dysphagia; Fear; Nausea; Suicidal Ideation | Lexapro                 |                       |                     | S                    | Oral                  | 2-3/Day Po                  |                          | Forest              |
|                                                                         | Mirtazapine             |                       |                     | S                    | Oral                  | 15mg As Needed Po           |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 04-May-2009                       | 6992626                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000006038                    |                               | 25 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                             | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Antinuclear Antibody Positive; Arthralgia; Blood Creatine Phosphokinase Increased; Myalgia | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg,1 In 1 D),Oral |                          | Not Reported        |
|                                                                                            | Prazepam                |                       |                     | S                    | Oral                  | (As Required),Oral          |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-May-2009                       | 6541621                | EXPEDITED (15-DAY)        | Y                           |                          | US-BAYER-200812372GPV         |                               | 39 YR               | Female              | USA                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Toxicity To Various Agents                                                               | Aspirin                |                    | Y                  | S               | Unknown                                         |                                                                                                              |                 | Bayer        |                |
|                                                                                          | Acetaminophen          |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Ibuprofen              |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Bayer        |                |
|                                                                                          | Naproxen               |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Unspecified Ingredient |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Quetiapine             |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Escitalopram Oxalate   |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Caffeine               |                    |                    | S               |                                                 |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Fexofenadine           |                    |                    | S               | Unknown                                         |                                                                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2009                                                                              | 6986448                | EXPEDITED (15-DAY) | Y                  | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14602924 |                                                                                                              | 23 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Fatigue;<br>Hallucination, Auditory;<br>Pain In Extremity;<br>Somnolence | Abilify                |                    |                    | S               | Oral                                            | Initiated On<br>30mar09,10mg/D Dose<br>Increased To 15mg/D, On<br>21apr09, Again Dose<br>Increased To 20mg/D |                 | Not Reported |                |
|                                                                                          | Abilify                |                    |                    | S               | Oral                                            | Initiated On<br>30mar09,10mg/D Dose<br>Increased To 15mg/D, On<br>21apr09, Again Dose<br>Increased To 20mg/D |                 | Not Reported |                |
|                                                                                          | Abilify                |                    |                    | S               | Oral                                            | Initiated On<br>30mar09,10mg/D Dose<br>Increased To 15mg/D, On<br>21apr09, Again Dose<br>Increased To 20mg/D |                 | Not Reported |                |
|                                                                                          | Escitalopram Oxalate   |                    |                    | S               | Oral                                            |                                                                                                              |                 | Not Reported |                |
|                                                                                          | Zyprexa                |                    |                    | C               |                                                 | Dose Decreased To 5mg,<br>Then Withdrawn                                                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 05-May-2009                                     | 6993569                | DIRECT             |                    | OT              |                          |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Obsessive Thoughts; Suicidal Ideation | Lexapro                |                    |                    | S               |                          |                      | 6 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2009                                     | 6897398                | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2009159452 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Aggression                     | Chantix                |                    |                    | S               |                          | 1 Mg, 2x/Day         |                 | Pfizer       |                |
|                                                 | Lexapro                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Meclizine              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Unspecified Ingredient |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Flexeril               |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Klonopin               |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Compazine              |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Synthroid              |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Lortab                 |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                 | Amantadine             |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Folic Acid             |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Zanaflex               |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Fosamax                |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Methotrexate           |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Dextrose               |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Solu-Medrol            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Copaxone               |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                 | Calcium With Vitamin D |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |     |  |              |
|--------------------------|---|-----|--|--------------|
| Flonase                  | C |     |  | Not Reported |
| Oxybutynin Hydrochloride | C | Unk |  | Not Reported |
| Lisinopril               | C | Unk |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2009              | 6987915       | EXPEDITED (15-DAY) | N                  | OT              | PHEH2009US04143      |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Confusional State;<br>Disturbance In Attention;<br>Dizziness; Nausea;<br>Paraesthesia; Tinnitus | Reclast        |              |            | S           |              | Unk                            |                 | Novartis     |
|                                                                                                 | Lexapro        |              |            | S           | Oral         | 10 Mg, Qd                      |                 | Not Reported |
|                                                                                                 | Lexapro        |              |            | S           | Oral         | 20 Mg, Qd                      |                 | Not Reported |
|                                                                                                 | Lexapro        |              |            | S           | Oral         | 10 Mg Qd X 7 Days              |                 | Not Reported |
|                                                                                                 | Lexapro        |              |            | S           | Oral         | 10 Mg Every Other Day X 7 Days |                 | Not Reported |
|                                                                                                 | Lexapro        |              |            | S           | Oral         | 10 Mg, Qod                     | 8 DAY           | Not Reported |
|                                                                                                 | Wellbutrin     |              |            | C           |              | Unk                            |                 | Not Reported |
|                                                                                                 | Xanax          |              |            | C           |              | Unk                            |                 | Not Reported |
|                                                                                                 | Calcium        |              |            | C           |              | Unk                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2009              | 6993934       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006063           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Hyponatraemia   | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Lasix                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2009              | 6993969       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006061           |                      | 44 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                      |   |      |                               |  |              |
|-------------------------------------------------------------|----------------------|---|------|-------------------------------|--|--------------|
| Amnesia; Generalised Tonic-Clonic Seizure; Malaise; Seizure | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral |  | Not Reported |
|                                                             | Lexomil (Tablets)    | C |      |                               |  | Not Reported |
|                                                             | Cartrex              | C |      |                               |  | Not Reported |
|                                                             | Omeprazole           | C |      |                               |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2009              | 6994010       | DIRECT           | N                  | OT              |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Asthenia; Diarrhoea; Dizziness; Hyperhidrosis; Nausea | Lexapro        |              |            | S           |              | 20 Mg 1 Tablet Every Night At Bedtime, Once |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2009              | 6994982       | EXPEDITED (15-DAY) | N                  | DE              | 1000006099           |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2009              | 6910195       | EXPEDITED (15-DAY) | N                  | HO              | PHEH2009US01490      |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Dysarthria; Hypertension | Clonazepam     |              |            | S           |              | 0.5 Mg, Qid        |                 | Not Reported |
|                                            | Inderal        |              |            | C           |              | Unk                |                 | Not Reported |
|                                            | Lotensin       |              |            | C           |              | Unk                |                 | Not Reported |
|                                            | Allegra-D      |              |            | C           |              |                    |                 | Not Reported |
|                                            | Ritalin        |              |            | S           |              | Unk, Unk           |                 | Novartis     |
|                                            | Lexapro        |              |            | S           | Oral         | 10 Mg Daily        |                 | Not Reported |
|                                            | Lexapro        |              |            | S           | Oral         | 20mg Daily         |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 08-May-2009                                                                      | 6996101              | EXPEDITED (15-DAY) | Y                  | DE              | 1000006075                |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest                                                                   | Lexapro              |                    |                    | S               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2009                                                                      | 6799506              | EXPEDITED (15-DAY) | Y                  | HO              | 1000001287                |                      | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Candida Infection;<br>Pruritus; Rash Maculo-<br>Papular; Seborrhoeic<br>Keratosi | Escitalopram Oxalate |                    |                    | S               | Oral                      | (10 Mg), Oral        |                 | Not Reported |                |
|                                                                                  | Lansoprazole         |                    |                    | S               | Oral                      | Oral                 |                 | Not Reported |                |
|                                                                                  | Symbicort            |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Lescol               |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Aspirin Lysine       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Sectral              |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Spironolactone       |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Altizide             |                    |                    | C               |                           |                      |                 | Not Reported |                |
|                                                                                  | Laxomil              |                    |                    | C               |                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2009                                                                      | 6991001              | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-<br>20090501180 |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Strabismus                                                             | Flexeril             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Flexeril             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Lexapro              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Lexapro              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Cogentin             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Cogentin             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Seroquel             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Seroquel             |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Abilify              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Abilify              |                    |                    | S               |                           |                      |                 | Not Reported |                |
|                                                                                  | Vistaril             |                    |                    | S               |                           |                      |                 | Not Reported |                |

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|                                                                                        | Vistaril                 |                    |                    | S               |                      |                                                 |                 |              | Not Reported   |
|----------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
|                                                                                        | Lamictal                 |                    |                    | S               |                      |                                                 |                 |              | Not Reported   |
|                                                                                        | Lamictal                 |                    |                    | S               |                      |                                                 |                 |              | Not Reported   |
|                                                                                        | Albuterol Inhalers       |                    |                    | C               |                      |                                                 |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2009                                                                            | 6991537                  | EXPEDITED (15-DAY) | Y                  | HO              | US-WYE-H09179309     |                                                 | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysstasia; Eating Disorder; Fatigue; Insomnia; Movement Disorder; Unevaluable Event    | Pristiq Extended Release |                    |                    | S               | Oral                 | Unknown                                         |                 | Wyeth        |                |
|                                                                                        | Lexapro                  |                    |                    | S               |                      | Unknown                                         |                 | Lundbeck     |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2009                                                                            | 6996175                  | DIRECT             |                    |                 |                      |                                                 | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Angina Pectoris                                                                        | Lexapro                  |                    |                    | S               |                      |                                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2009                                                                            | 6997419                  | EXPEDITED (15-DAY) | Y                  | LT              | 1000005628           |                                                 | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Haematuria; Haemorrhagic Disorder; International Normalised Ratio Increased | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Oral                                            |                 | Not Reported |                |
|                                                                                        | Previscan (Fluindione)   |                    |                    | S               |                      | 0.75 Dosage Forms (0.75 Dosage Forms, 1 In 1 D) |                 | Not Reported |                |
|                                                                                        | Risperdal                |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2009                                                                            | 6996234                  | DIRECT             | Y                  | OT              |                      |                                                 | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |            |   |      |                            |              |
|-------------------------|------------|---|------|----------------------------|--------------|
| Abdominal Discomfort;   | Lexapro    | S | Oral | 20 Mg Once Daily Po        | Not Reported |
| Abdominal Pain;         | Citalopram | S | Oral | 20 Mg Three Times Daily Po | Not Reported |
| Eructation; Flatulence; |            |   |      |                            |              |
| Muscle Spasms; Nausea   |            |   |      |                            |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2009              | 6997765       | DIRECT           | Y                  | LT, OT          |                      |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;      | Lexapro        |              |            | S           | Oral         | 10mg Once Daily Po |                 | Not Reported |
| Abnormal Behaviour;        | Prozac         |              |            | S           |              |                    |                 | Not Reported |
| Aggression; Hallucination; |                |              |            |             |              |                    |                 |              |
| Mania; Vomiting            |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2009              | 6975598       | EXPEDITED (15-DAY) | Y                  | HO              | CA-GENENTECH-281154  |                      | 31 YR      | Female     | CAN            |

| <u>Preferred Term</u>                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Bradycardia; Neutropenia; Pleural Effusion | Avastin                 |              |            | S           | Intravenous (not otherwise specified) | 15 Mg/Kg, Q3w      | 20 DAY          | Genentech    |
|                                            | Trastuzumab             |              |            | S           | Intravenous (not otherwise specified) | 8 Mg/Kg, Q3w       |                 | Not Reported |
|                                            | Docetaxel               |              |            | S           | Intravenous (not otherwise specified) | 75 Mg/M2, Q3w      |                 | Not Reported |
|                                            | Carboplatin             |              |            | S           |                                       | 1 Unk, Q3w         |                 | Not Reported |
|                                            | Tylenol With Codeine    |              |            | S           | Unknown                               |                    |                 | Not Reported |
|                                            | Morphine                |              |            | S           | Unknown                               | 2.5 Mg, Unknown    | 5 DAY           | Not Reported |
|                                            | Cipralelex              |              |            | S           | Unknown                               | 10 Mg, Unknown     |                 | Not Reported |
|                                            | Ciprofloxacin           |              |            | S           | Oral                                  | 1000 Mg, Unknown   | 3 DAY           | Not Reported |
|                                            | Codeine                 |              |            | C           |                                       |                    |                 | Not Reported |
|                                            | Ammonium Chloride       |              |            | C           |                                       |                    |                 | Not Reported |
|                                            | Ceftazidime             |              |            | C           |                                       | Unk                | 2 DAY           | Not Reported |
|                                            | Codeine                 |              |            | C           |                                       | Unk                | 6 DAY           | Not Reported |
|                                            | Trazodone Hydrochloride |              |            | C           |                                       | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |     |       |              |
|-------------------------|---|-----|-------|--------------|
| Escitalopram Oxalate    | C | Unk |       | Not Reported |
| Docusate Sodium         | C | Unk | 6 DAY | Not Reported |
| Senna                   | C | Unk | 6 DAY | Not Reported |
| Lactulose               | C | Unk | 2 DAY | Not Reported |
| Mouthwash Nos           | C | Unk | 4 DAY | Not Reported |
| Gravol                  | C | Unk | 2 DAY | Not Reported |
| Simethicone             | C | Unk | 2 DAY | Not Reported |
| Piperacillin/Tazobactam | C | Unk |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2009              | 6989431       | EXPEDITED (15-DAY) | Y                  | HO              | GB-WYE-G03609809     |                      | 16 YR      | Male       | GBR            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Discomfort;     | Anadin Ibuprofen     |              |            | S           | Oral         |                    | 7 DAY           | Wyeth      |
| Abdominal Pain; Condition | Escitalopram Oxalate |              |            | S           | Oral         |                    | 7 DAY           | Unknown    |
| Aggravated; Diarrhoea;    | Amoxicillin          |              |            | C           |              | Unknown            |                 | Unknown    |
| Gastrointestinal          | Terbutaline Sulfate  |              |            | C           | Respiratory  | Unknown            |                 | Unknown    |
| Haemorrhage;              |                      |              |            |             | (inhalation) |                    |                 |            |
| Haematemesis              |                      |              |            |             |              |                    |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2009              | 6999254       | DIRECT           |                    |                 |                      |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;   | Lexapro        |              |            | S           | Oral         | 10mg Daily Po      |                 | Not Reported |
| Asthma; Musculoskeletal |                |              |            |             |              |                    |                 |              |
| Chest Pain; Nausea;     |                |              |            |             |              |                    |                 |              |
| Somnolence; Vomiting    |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2009              | 7001388       | DIRECT           | N                  | OT              |                      |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                 |         |   |    |              |
|---------------------------------------------------------------------------------------------------------------------------------|---------|---|----|--------------|
| Anxiety; Burning Sensation; Decreased Appetite; Feeling Abnormal; Feeling Jittery; Insomnia; Mental Disorder; Unevaluable Event | Zoloft  | S | 50 | Not Reported |
|                                                                                                                                 | Lexapro | S | 10 | Not Reported |

| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| 14-May-2009                                    | 7002976              | EXPEDITED (15-DAY) | N                  |                 | 2009S1007640         |                                                     | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Chills; Headache; Weight Decreased | Alprazolam           |                    |                    | S               | Oral                 | 2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral |                 | Not Reported |                |
|                                                |                      |                    |                    |                 | Oral                 | 2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral |                 |              |                |
|                                                |                      |                    |                    |                 | Oral                 | 2.5 Mg; Twice A Day; Oral, 0.5 Mg; At Bedtime; Oral |                 |              |                |
|                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | At Bedtime; Oral                                    |                 | Not Reported |                |
|                                                | Lipitor              |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                | Benicar              |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                | Evista               |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                | Synthroid            |                    |                    | C               |                      |                                                     |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 15-May-2009                                                             | 6805527                     | EXPEDITED (15-DAY) | Y                  | HO              | THQ2008A02085        |                      | 71 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Candida Infection; Pruritus; Rash Maculo-Papular; Seborrhoeic Keratosis | Lansoprazole (Lansoprazole) |                    |                    | S               | Oral                 |                      | 21 DAY          | Not Reported |                |
|                                                                         | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                         | Aspirin Lysine              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Acebutolol Hydrochloride    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Spironolactone              |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Altizide                    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Bromazepam                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Omeprazole Sodium           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                         | Promoterol Fumarate,        |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                        | Budesonide         |                    |                 |                      |                          |                 |              |                |
|-----------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
|                             |                        | Fluvastatin        |                    | C               |                      |                          |                 |              | Not Reported   |
|                             |                        | Budesonide         |                    | C               |                      |                          |                 |              | Not Reported   |
| <u>FDA Received Date</u>    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2009                 | 6993943                | EXPEDITED (15-DAY) | Y                  | HO              | 09GB001089           |                          | 16 YR           | Male         | GBR            |
| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;       | Ibuprofen              |                    | Y                  | S               | Oral                 | 400 Mg Tid Oral          |                 | Not Reported |                |
| Abdominal Pain;             | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Qd Oral            |                 | Not Reported |                |
| Diarrhoea; Gastrointestinal | Amoxicillin Trihydrate |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Haemorrhage                 | Terbutaline Sulfate    |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2009                 | 7003232                | EXPEDITED (15-DAY) | Y                  | HO              | 1000006183           |                          | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysstasia; Gait Inability;  | Lexapro                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |                |
| Neuropathy Peripheral       |                        |                    |                    |                 |                      | Oral                     |                 |              |                |
|                             | Aricept                |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Levothyroxine          |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Lisinopril             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Vivelle Dot            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Clonidine              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Namenda                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2009                 | 7004444                | EXPEDITED (15-DAY) | Y                  | HO              | 1000006225           |                          | 76 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema; Pruritus          | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg Oral               |                 | Not Reported |                |
| Generalised; Rash           | Tahoe                  |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Papular                     | Plavix                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                             | Pariet                 |                    |                    | C               |                      |                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------------|-----------------|--------------|----------------|
| 18-May-2009                                                                                                                                                        | 6949991                     | EXPEDITED (15-DAY) | Y                  | DE              | 1000005098                |                                  | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose                                                                                                                                                | Escitalopram Oxalate        |                    |                    | S               |                           | (20 Mg) ; (20 Mg)                |                 | Not Reported |                |
|                                                                                                                                                                    | Amitriptyline Hydrochloride |                    |                    | S               |                           | (25 Mg)                          |                 | Not Reported |                |
|                                                                                                                                                                    | Tylenol With Codeine        |                    |                    | S               |                           |                                  |                 | Not Reported |                |
|                                                                                                                                                                    | Diazepam                    |                    |                    | C               |                           |                                  |                 | Not Reported |                |
|                                                                                                                                                                    | Seroquel                    |                    |                    | C               |                           |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                                                                        | 6980337                     | EXPEDITED (15-DAY) | N                  | HO              | 1000005842                |                                  | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Fall;<br>Transient Ischaemic<br>Attack; Upper Limb<br>Fracture                                                                                        | Lexapro                     |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                    | Metoprolol                  |                    |                    | C               |                           |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                                                                        | 6993929                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000006046                |                                  | 57 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Bacterial Test Positive;<br>Blood Chloride<br>Decreased;<br>Hyponatraemia; Monocyte<br>Count Increased; Nocturia;<br>Oliguria; White Blood Cell<br>Count Increased | Escitalopram Oxalate        |                    |                    | S               | Ophthalmic                | 10 Mg (10 Mg,1 In 1<br>D),Oral   |                 | Not Reported |                |
|                                                                                                                                                                    | Mavik                       |                    |                    | C               |                           |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                                                                        | 6996807                     | EXPEDITED (15-DAY) | Y                  | OT              | US-JNJFOC-<br>20090502781 |                                  | 25 YR           | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Aggression; Condition<br>Aggravated; Drug<br>Interaction; Paranoia;<br>Psychotic Disorder | Haloperidol               |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
|                                                                                                                  | Haloperidol               |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
|                                                                                                                  | Ziprasidone Hydrochloride |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
|                                                                                                                  | Ziprasidone Hydrochloride |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate      |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
|                                                                                                                  | Varenicline               |                    |                    | S               | Unknown              |                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                      | 7003461                   | DIRECT             | N                  | LT, RI, OT      |                      |                                                     | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Family Stress;<br>Headache; Loss Of<br>Employment; Nausea                                             | Lexapro                   |                    |                    | S               | Oral                 | 1 Daily Po                                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                      | 7005981                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000006233           |                                                     | 54 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Conjunctivitis; Pruritus;<br>Rash Erythematous; Skin<br>Exfoliation                                              | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral                      |                 | Not Reported |                |
|                                                                                                                  | Phenobarbital             |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms,1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                                                                                  | Seresta                   |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-May-2009                                                                                                      | 7006163                   | EXPEDITED (15-DAY) | Y                  | DE, OT          | 1000006190           |                                                     | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Enzyme                                                                                                   | Lexapro                   |                    |                    | S               |                      |                                                     |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2009              | 7006659       | EXPEDITED (15-DAY) | Y                  | OT              | 1000006217           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder;<br>Dyskinesia; Heart Rate<br>Increased; Tremor | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2009              | 6966970       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000005505           |                      | 47 YR      | Female     | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|------------------------------|
| Generalised Tonic-Clonic<br>Seizure | Escitalopram Oxalate    |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                          |                 | Not Reported                 |
|                                     | Citalopram Hydrobromide |              |            | S           | Oral         | Oral                                                      |                 | Not Reported                 |
|                                     | Citalopram Hydrobromide |              |            | S           | Oral         | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported                 |
|                                     | Prazepam<br>Cymemazine  |              |            | C<br>C      |              |                                                           |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2009              | 7005331       | DIRECT           | N                  | OT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Confusional State;<br>Depressed Mood; Drug<br>Withdrawal Syndrome;<br>Dystonia; Fatigue; Hot<br>Flush; Hyperhidrosis;<br>Impaired Work Ability;<br>Influenza Like Illness;<br>Insomnia; Memory | Effexor Xr     |              |            | S           | Oral         | 150 Mg. 2 Times A Day Po<br>Several Years |                 | Not Reported |
|                                                                                                                                                                                                | Lexapro        |              |            | S           | Oral         | 20 Mg. 2 At Bedtime Po<br>Several Years   |                 | Forest       |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Impairment; Muscular  
Weakness; Myalgia;  
Nausea; Paraesthesia;  
Tearfulness; Vomiting;  
Weight Decreased

| <u>FDA Received Date</u>                                                       | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|-----------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 20-May-2009                                                                    | 7005519                     | DIRECT           | Y                  |                 |                      |                               | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hot Flush                                                             | Lexapro                     |                  |                    | S               | Oral                 | 1 Daily Po                    |                 | Forest       |                |
|                                                                                | Celexa                      |                  |                    | S               | Oral                 | 1 Daily Po                    |                 | Dr Reddys    |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2009                                                                    | 6907599                     | NON-EXPEDITED    | N                  | OT              | 2008S1022493         |                               | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Drug Dependence; Drug Withdrawal Syndrome; Malaise; Somnolence | Fentanyl Transdermal System |                  |                    | S               | Transdermal          | 50 Ug;Every Hour; Transdermal |                 | Not Reported |                |
|                                                                                | Fentanyl Transdermal System |                  |                    | S               | Transdermal          | 25 Ug;Every Hour;Transdermal  |                 | Not Reported |                |
|                                                                                | Fentanyl Transdermal System |                  |                    | S               | Transdermal          | 12 Ug;Every Hour;Transdermal  |                 | Not Reported |                |
|                                                                                | Lisinopril                  |                  |                    | S               | Oral                 | 20 Mg;Daily;Oral              |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate        |                  |                    | S               | Oral                 | 20 Mg;Daily;Oral              |                 | Not Reported |                |
|                                                                                | Atenolol                    |                  |                    | S               | Oral                 | 50 Mg;Daily;Oral              |                 | Not Reported |                |
|                                                                                | Amlodipine                  |                  |                    | S               | Oral                 | 10 Mg;Daily;Oral              |                 | Not Reported |                |
|                                                                                | Pepcid                      |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Omeprazole                  |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Potassium Chloride          |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Hydrochlorothiazide         |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Metformin Hydrochloride     |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Ferrous Sulfate             |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Vitamin D Nos               |                  |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                      |                      |                    |                    |                              |                      |                                            |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|------------------------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
| Asa<br>Zolof                                                                                                                                         |                      | C<br>C             |                    | Not Reported<br>Not Reported |                      |                                            |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2009                                                                                                                                          | 6978089              | EXPEDITED (15-DAY) | Y                  | HO                           | 1000005704           |                                            | 17 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma;<br>Fall; Generalised Tonic-<br>Clonic Seizure; Loss Of<br>Consciousness; Malaise;<br>Postictal State; Skin<br>Abrasion           | Escitalopram Oxalate |                    |                    | S                            | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral           |                 | Not Reported |                |
|                                                                                                                                                      | Escitalopram Oxalate |                    |                    | S                            | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2009                                                                                                                                          | 7007566              | DIRECT             | N                  | OT                           |                      |                                            | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bladder Disorder;<br>Condition Aggravated;<br>Ulcer                                                                                                  | Lexapro              |                    |                    | S                            |                      | 5 Mg (Liquid) Daily<br>5 Mg (Liquid) Daily |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2009                                                                                                                                          | 7009109              | EXPEDITED (15-DAY) | N                  | OT                           | 1000006285           |                                            | 30 DAY          | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Hypoventilation;<br>Irritability; Maternal Drugs<br>Affecting Foetus; Middle<br>Insomnia; Muscle<br>Twitching; Respiratory<br>Rate Increased | Lexapro              |                    |                    | S                            | Transplacental       | 20 Mg (20 Mg),<br>Transplacental           |                 | Not Reported |                |
|                                                                                                                                                      | Allerx               |                    |                    | C                            |                      |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2009                                                                                                                                          | 7007383              | DIRECT             | N                  |                              |                      |                                            | 41 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------|-----------------|--------------|----------------|
| Bruxism; Euphoric Mood; Eye Movement Disorder; Headache; Insomnia; Jaw Disorder; Muscle Twitching; Tic | Lexapro              |                    |                    | S               | Oral                     | 10 Mg -1 Pill- Daily Po          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2009                                                                                            | 7011091              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006274               |                                  | 16 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Abdominal Pain;                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
| Diarrhoea; Gastrointestinal Haemorrhage;                                                               | Ibuprofen            |                    |                    | S               | Oral                     | 1200 Mg (400 Mg, 3 In 1 D), Oral |                 | Not Reported |                |
| Haematemesis; Self-Medication                                                                          | Amoxicillin          |                    |                    | C               |                          |                                  |                 | Not Reported |                |
|                                                                                                        | Terbutaline Sulfate  |                    |                    | C               |                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2009                                                                                            | 6996225              | EXPEDITED (15-DAY) | Y                  | HO              | GB-RANBAXY-2009RR-24025  |                                  | 16 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Abdominal Pain;                                                                  | Ibuprofen            |                    |                    | S               | Oral                     | 400 Mg, Tid                      | 7 DAY           | Ranbaxy      |                |
| Diarrhoea; Gastrointestinal Haemorrhage;                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg, Qd                        | 7 DAY           | Not Reported |                |
| Haematemesis                                                                                           | Amoxicillin          |                    |                    | C               |                          |                                  |                 | Not Reported |                |
|                                                                                                        | Terbutaline Sulfate  |                    |                    | C               | Respiratory (inhalation) |                                  |                 | Not Reported |                |
|                                                                                                        | Paracetamol          |                    |                    | C               |                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2009                                                                                            | 6950332              | EXPEDITED (15-DAY) | Y                  | DE              | 1000005088               |                                  | 61 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |                      |   |      |                                  |              |
|------------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Completed Suicide;<br>Delusion; Insomnia | Escitalopram Oxalate | S | Oral | 10 Mg 910 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                          | Adalat Cc            | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2009              | 7008971       | DIRECT           | N                  | LT, OT          |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Communication Disorder;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Speech<br>Disorder | Lexapro        |              |            | S           | Oral         | 20mg 1 X Day Po    |                 | Not Reported |
|                                                                                                        | Lexapro        |              |            | S           | Oral         | 10 Mg 1 X Day Po   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2009              | 7009013       | DIRECT           | N                  | OT              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Condition Aggravated;<br>Depression; Suicidal<br>Ideation; Therapy Non-<br>Responder | Lexapro        |              |            | S           | Oral         | 20 Mg 1 Daily Po Approx.<br>Feb To May 2009 |                 | Not Reported |
|                                                                                                                | Klonopin       |              |            | C           |              |                                             |                 | Not Reported |
|                                                                                                                | Lamictal       |              |            | C           |              |                                             |                 | Not Reported |
|                                                                                                                | Zanaflex       |              |            | C           |              |                                             |                 | Not Reported |
|                                                                                                                | Diovan Hct     |              |            | C           |              |                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2009              | 7004357       | EXPEDITED (15-DAY) | Y                  | OT              | 1000006208           |                      | 17 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Depression; Fatigue; Initial<br>Insomnia; Restlessness;<br>Sleep Disorder;<br>Somnolence; Suicidal<br>Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------|-----------------|--------------|----------------|
| 28-May-2009                                                                                                                                                                             | 7005303              | EXPEDITED (15-DAY) | Y                  | OT              | ZA-JNJFOC-20090505630 |                                  | 19 YR           | Male         | ZAF            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar I Disorder;<br>Condition Aggravated;<br>Disturbance In Attention                                                                                                                | Risperdal            |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                                                                                                                                         | Risperidone          |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                                                                                                                                         | Ciprallex            |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
|                                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Unknown               |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2009                                                                                                                                                                             | 7013606              | EXPEDITED (15-DAY) | N                  | OT              | 1000006326            |                                  | 29 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Drug Withdrawal<br>Syndrome; Headache;<br>Insomnia; Nausea;<br>Paraesthesia; Piloerection;<br>Sensory Disturbance;<br>Sexual Dysfunction;<br>Suicidal Ideation | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                         | Remeron              |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                                                                                                                                                         | Xanor (Tablets)      |                    |                    | C               |                       |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2009                                                                                                                                                                             | 6957171              | EXPEDITED (15-DAY) | Y                  | HO              | 1000003730            |                                  | 15 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus; Weight<br>Decreased                                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                  | 5-20 Mg/Day, Oral                |                 | Not Reported |                |
|                                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2009                                                                                                                                                                             | 6988364              | EXPEDITED (15-DAY) | Y                  | HO              | 1000005939            |                                  | 19 YR           | Male         | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------|-----------------|--------------|----------------|
| Drug Abuse; Rash Erythematous; White Blood Cell Count Increased     | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-May-2009                                                         | 7015632              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006443           |                                                         | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Urinary Retention                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg (30 Mg, 1 In 1 D), Oral                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2009                                                         | 7016684              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006495           |                                                         | 71 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Withdrawal Syndrome; Loss Of Consciousness          | Lexapro              |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                     |                      |                    |                    |                 | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral |                 |              |                |
|                                                                     | Seroquel             |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
|                                                                     | Omeprazol (Tablets)  |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
|                                                                     | Famotidine           |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
|                                                                     | Metamucil (Tablets)  |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2009                                                         | 6836296              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000001773           |                                                         | 48 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Alcohol Withdrawal Syndrome; Anticonvulsant Drug Level | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D), Oral                           |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                        |                      |   |      |                                                                                                                                                                                                                                                                                                                                  |              |
|------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Below Therapeutic;<br>Depression; Drug<br>Interaction; Lumbar<br>Vertebral Fracture; Road<br>Traffic Accident; Seizure | Escitalopram Oxalate | S | Oral | 10 Mg (1 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg (10<br>Mg, 1 In 1 D), Oral<br>10 Mg (1 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg (10<br>Mg, 1 In 1 D), Oral<br>10 Mg (1 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg (10<br>Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                                        |                      |   | Oral |                                                                                                                                                                                                                                                                                                                                  |              |
|                                                                                                                        |                      |   | Oral |                                                                                                                                                                                                                                                                                                                                  |              |
|                                                                                                                        | Escitalopram Oxalate | S | Oral | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D, Oral<br>5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D, Oral                                                                                                                                                                                               | Not Reported |
|                                                                                                                        |                      |   | Oral |                                                                                                                                                                                                                                                                                                                                  |              |
|                                                                                                                        | Modafinil (Tablets)  | S | Oral | 200 Mg (200 Mg, 1 In 1 D),<br>Oral; 100 Mg 9100 Mg, 1<br>In 1 D)<br>200 Mg (200 Mg, 1 In 1 D),<br>Oral; 100 Mg 9100 Mg, 1<br>In 1 D)                                                                                                                                                                                             | Not Reported |
|                                                                                                                        |                      |   | Oral |                                                                                                                                                                                                                                                                                                                                  |              |
|                                                                                                                        | Modafinil (Tablets)  | S | Oral | 100 Mg (100 Mg, 1 In 1 D),<br>Oral                                                                                                                                                                                                                                                                                               | Not Reported |
|                                                                                                                        | Alcohol              | S |      |                                                                                                                                                                                                                                                                                                                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Jun-2009              | 7008743                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-TEVA-196331USA    |                      | 62 YR           | Male         | AUS            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Naltrexone Hydrochloride |                    |                    | S               |                      |                      |                 | Barr         |                |
|                          | Escitalopram Oxalate     |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jun-2009              | 7016501       | EXPEDITED (15-DAY) | Y                  | DE              | 1000006541           |                      | 43 YR      | Male       | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------------------|--------------------------|---------------------|-------------------------|
| Completed Suicide;<br>Thermal Burn; Treatment<br>Noncompliance                                         | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg, Oral, 10 Mg (10<br>Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                                                                                        |                         |                           |                             |                          | Oral                          | 10 Mg, Oral, 10 Mg (10<br>Mg, 1 In 1 D), Oral |                          |                     |                         |
|                                                                                                        | Trazodone Hydrochloride |                           |                             | C                        |                               |                                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                 | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jun-2009                                                                                            | 7017930                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000006499                    |                                               | 51 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthenia; Fatigue;<br>Sedation; Urinary<br>Incontinence                                                | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 920 Mg), Oral                                 |                          | Not Reported        |                         |
|                                                                                                        | Diazepam                |                           |                             | S                        | Oral                          | (5 Mg), Oral                                  |                          | Not Reported        |                         |
|                                                                                                        | Celecoxib               |                           |                             | S                        | Oral                          | (200 Mg), Oral                                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                 | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jun-2009                                                                                            | 7024190                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000006532                    |                                               |                          | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Decreased Appetite; Dry<br>Mouth; Dysgeusia;<br>Dysphagia                                              | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral              |                          | Not Reported        |                         |
|                                                                                                        | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                 | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jun-2009                                                                                            | 7024609                 | DIRECT                    | N                           | OT                       |                               |                                               | 66 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Dreams;<br>Amnesia; Anhedonia;<br>Anxiety; Confusional<br>State;<br>Depersonalisation/Dereali | Lexapro                 |                           |                             | S                        |                               | Lexapro 10 Mg 1x                              |                          | Forest              |                         |
|                                                                                                        | Klonopin                |                           |                             | C                        |                               |                                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

sation Disorder; Dizziness;  
Emotional Disorder;  
Hypoaesthesia; Loss Of  
Employment; Nervous  
System Disorder; Pain In  
Extremity; Product Quality  
Issue; Screaming;  
Somnolence

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2009              | 7013725       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000006324           |                      | 54 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Gastrointestinal Sounds<br>Abnormal; Intentional<br>Overdose;<br>Rhabdomyolysis; Sopor;<br>Suicide Attempt | Escitalopram Oxalate |              |            | S           | Oral         | Once, Oral               |                 | Not Reported |
|                                                                                                            | Zopiclone            |              |            | S           | Oral         | 75 Mg (75 Mg, Once) Oral |                 | Not Reported |
|                                                                                                            | Imipramine           |              |            | S           | Oral         | Oral                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2009              | 7010534       | EXPEDITED (15-DAY) | Y                  | OT              | 090520-0000710       |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accommodation Disorder;<br>Diplopia; Pupillary Reflex<br>Impaired; Strabismus;<br>Visual Acuity Reduced | Cogentin                      |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                                                         | Cyclobenzaprine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Quetiapine Fumarate           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Aripiprazole                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Hydroxyzine Pamoate           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Lamotrigine                   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                         | Albuterol                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2009              | 7018031       | DIRECT           | Y                  | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       |         |   |      |             |              |
|-------------------------------------------------------|---------|---|------|-------------|--------------|
| Abnormal Behaviour;<br>Amnesia; Personality<br>Change | Lexapro | S | Oral | 20mg Bid Po | Not Reported |
|-------------------------------------------------------|---------|---|------|-------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jun-2009              | 7023032       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006593           |                      | 82 YR      | Male       | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety; Epistaxis;<br>Haematochezia; Sleep<br>Disorder | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                         | Coumadin       |              |            | S           |              |                                  |                 | Not Reported |
|                                                         | Vitamins       |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Atenolol       |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Amlodipine     |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Quinapril      |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Digoxin        |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Hyzaar         |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Welchol        |              |            | C           |              |                                  |                 | Not Reported |
|                                                         | Gemfibrozil    |              |            | C           |              |                                  |                 | Not Reported |
| Metformin Hydrochloride                                 |                |              | C          |             |              |                                  | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2009              | 7013107       | NON-EXPEDITED    | N                  |                 | A0743970A            |                      |            | Male       | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Sexual Dysfunction;<br>Tachyphylaxis | Wellbutrin XI  |              |            | S           | Oral         | 300mg Per Day      |                 | Glaxosmithkline |
|                                      | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                      | C-Pap          |              |            | C           |              |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2009              | 7013177       | NON-EXPEDITED    | N                  |                 | A0752544A            |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Exercise Lack Of      | Wellbutrin XI  |              |            | S           | Oral         | 150mg Twice Per Day |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                       |                      |                    |                    |                 |                      |                               |                 |                 |                |  |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|-----------------|----------------|--|
| Lexapro                                                                                                                               |                      |                    | S                  |                 | Oral                 |                               | 20mg Per Day    |                 | Not Reported   |  |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 08-Jun-2009                                                                                                                           | 7013222              | NON-EXPEDITED      | N                  |                 | A0758554A            |                               | 37 YR           | Female          | USA            |  |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Dizziness                                                                                                                             | Wellbutrin XI        |                    |                    | S               | Oral                 | 300mg Per Day                 | 26 WEEK         | Glaxosmithkline |                |  |
|                                                                                                                                       | Lexapro              |                    |                    | S               | Unknown              |                               |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 08-Jun-2009                                                                                                                           | 7022630              | DIRECT             | N                  | OT              |                      |                               | 49 YR           | Male            | USA            |  |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Burning Sensation; Chest Pain; Disturbance In Attention; Ejaculation Failure; Fatigue; Hyperhidrosis; Pain In Extremity; Paraesthesia | Lexapro              |                    |                    | S               | Oral                 | 10mg Once Daily Po            |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 08-Jun-2009                                                                                                                           | 7024858              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006616           |                               |                 | Female          | DNK            |  |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Angle Closure Glaucoma                                                                                                                | Escitalopram Oxalate |                    |                    | S               |                      |                               |                 | Not Reported    |                |  |
|                                                                                                                                       | Benzodiazepine       |                    |                    | C               |                      |                               |                 | Not Reported    |                |  |
| <u>FDA Received Date</u>                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |  |
| 09-Jun-2009                                                                                                                           | 6881439              | EXPEDITED (15-DAY) | Y                  | OT              | 1000003347           |                               | 70 YR           | Male            | DNK            |  |
| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |  |
| Myelodysplastic Syndrome; Pancytopenia                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |  |

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|                      |   |      |                                  |              |
|----------------------|---|------|----------------------------------|--------------|
| Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
| Zolpidem             | C |      |                                  | Not Reported |
| Bromazepam           | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2009              | 7027043       | EXPEDITED (15-DAY) | Y                  | OT              | 1000006377           |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Accidental Overdose;<br>Product Dispensing Error;<br>Restless Legs Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                             | Seropram             |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2009              | 7028808       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006607           |                      | 89 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anaemia; Creatinine<br>Renal Clearance<br>Decreased; Gastric Ulcer<br>Haemorrhage | Escitalopram Oxalate                            |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                   | Aspirin Lysine                                  |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                   | Nitroderm                                       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Lasix                                           |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Imovane (Tablets)                               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Modopar (Capsules)                              |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Cardensiel                                      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Rivotril                                        |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Loxen (Nicardipine<br>Hydrochloride)            |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Aluminum Hydroxide And<br>Magnesium Trisilicate |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                   | Efferalgan (Tablets)                            |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2009              | 7029097       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006614           |                      |            | Female     | FRA            |

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| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Disinhibition; Intentional Overdose | Escitalopram Oxalate |              |            | S           | Oral         | 28 Dosage Forms (28 Dosage Forms, Once), Oral                |                 | Not Reported |
|                                     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                     |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2009              | 7029172       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006612           |                      | 57 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cough; Haemoptysis; Haemorrhage; Metastases To Lung; Overdose; Prothrombin Level Abnormal | Escitalopram Oxalate   |              |            | S           | Oral         | 40 Mg (20 Mg, 2 In 1 D), Oral |                 | Not Reported |
|                                                                                           | Vandetanib             |              |            | S           |              |                               |                 | Not Reported |
|                                                                                           | Levothyrox             |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Equanil                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Seresta                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Aprovel                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Isoptin                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Seretide               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Unspecified Ingredient |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Ventolin               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Inexium                |              |            | C           |              |                               |                 | Not Reported |
|                                                                                           | Loperamide             |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2009              | 7029515       | EXPEDITED (15-DAY) | Y                  | HO              | DE-WYE-G03808809     |                      | 35 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Intentional Overdose; Respiratory Depression; Seizure; | Venlafaxine Hydrochloride   |              |            | S           | Oral         | Overdose           | 1 DAY           | Not Reported |
|                                                              | Amitriptyline Hydrochloride |              |            | S           | Oral         | Overdose           | 1 DAY           | Not Reported |

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| Suicide Attempt                                                                                                                             | Ciprallex               |                    | S                  | Oral            | Overdose             | 1 DAY                |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                             | Lyrica                  |                    | S                  | Oral            | Overdose             | 1 DAY                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2009                                                                                                                                 | 7030072                 | EXPEDITED (15-DAY) | Y                  | OT              | GB-WYE-G03792809     |                      | 30 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; International Normalised Ratio Increased                                                                                         | Effexor                 |                    |                    | S               | Oral                 |                      |                 |              | Not Reported   |
|                                                                                                                                             | Ciprallex               |                    |                    | S               |                      |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2009                                                                                                                                 | 6918681                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000003881           |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Caesarean Section; Dyspnoea; Infection; Maternal Drugs Affecting Foetus; Neonatal Tachypnoea                               | Escitalopram Oxalate    |                    |                    | S               | Transplacental       | Transplacental       |                 |              | Not Reported   |
|                                                                                                                                             | Flovent                 |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | Salbutamol (Salbutamol) |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | (Salbutamol)            |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                             | Advair Hfa              |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | Vitamins (Nos)          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| Zoloft                                                                                                                                      |                         |                    | C                  | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2009                                                                                                                                 | 6920261                 | EXPEDITED (15-DAY) | Y                  | OT              | S08-CAN-01736-01     |                      | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Labour; Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy; Premature Rupture Of Membranes; Type 2 Diabetes Mellitus | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 |              | Not Reported   |
|                                                                                                                                             | Flovent                 |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | Salbutamol (Salbutamol) |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | (Salbutamol)            |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                             | Advair Hfa              |                    |                    | C               |                      |                      |                 |              | Not Reported   |
|                                                                                                                                             | Vitamins (Nos)          |                    |                    | C               |                      |                      |                 |              | Not Reported   |
| Zoloft                                                                                                                                      |                         |                    | C                  | Not Reported    |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 11-Jun-2009                                                                                                                                                         | 6990685              | EXPEDITED (15-DAY) | N                  | OT              | 1000006012           |                                | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Coronary Artery Disease; Coronary Artery Occlusion; Crying; Irritability; Nervousness; Overdose; Pain In Extremity; Sensory Disturbance; Therapy Cessation | Lexapro              |                    |                    | S               | Oral                 | See Image                      |                 | Not Reported |                |
|                                                                                                                                                                     |                      |                    |                    |                 | Oral                 | See Image                      |                 |              |                |
|                                                                                                                                                                     |                      |                    |                    |                 | Oral                 | See Image                      |                 |              |                |
|                                                                                                                                                                     |                      |                    |                    |                 | Oral                 | See Image                      |                 |              |                |
|                                                                                                                                                                     | Amaryl               |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                     | Metoprolol           |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                     | Norvasc              |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                     | Crestor              |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                     | Lisinopril           |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                     | Advil                |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2009                                                                                                                                                         | 7030034              | EXPEDITED (15-DAY) | Y                  | OT              | 1000006656           |                                | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Chills; Drug Interaction; Gait Disturbance; Posture Abnormal                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                                                                                                     | Ziprasidone          |                    |                    | S               | Oral                 | 120 Mg (60 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                     | Ziprasidone          |                    |                    | S               | Oral                 | 80 Mg (40 Mg, 2 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                                                                                                     | Temesta (Lorazepam)  |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2009                                                                                                                                                         | 7031354              | EXPEDITED (15-DAY) | Y                  | OT              | 1000006655           |                                |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Repolarisation Abnormality                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral    |                 | Not Reported |                |
|                                                                                                                                                                     | Ace Inhibitor Nos    |                    |                    | C               |                      |                                |                 | Not Reported |                |



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| <u>FDA Received Date</u>                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-----------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| 11-Jun-2009                                         | 7032922                                | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2009GB06602                                 |                      | 30 YR           | Female                       | GBR            |
| <u>Preferred Term</u>                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Contusion; International Normalised Ratio Increased | Venlafaxine Hydrochloride<br>Ciprallex |                    |                    | S<br>S          | Oral                                            | Oral                 |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jun-2009                                         | 6831933                                | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14428775 |                      | 50 YR           | Male                         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Pulmonary Embolism; Thrombosis                      | Anafranil                              |                    |                    | S               | Oral                                            |                      |                 | Sandoz                       |                |
|                                                     | Abilify                                |                    |                    | S               | Oral                                            |                      |                 | Not Reported                 |                |
|                                                     | Abilify                                |                    |                    | S               | Oral                                            |                      |                 | Not Reported                 |                |
|                                                     | Escitalopram Oxalate                   |                    |                    | S               | Oral                                            | Tab                  |                 | Not Reported                 |                |
|                                                     | Cyamemazine                            |                    |                    | S               | Oral                                            |                      |                 | Not Reported                 |                |
|                                                     | Cyamemazine                            |                    |                    | S               | Oral                                            |                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jun-2009                                         | 6896844                                | EXPEDITED (15-DAY) | N                  | HO, LT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14484257 |                      | 50 YR           | Male                         | FRA            |
| <u>Preferred Term</u>                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Pulmonary Embolism                                  | Anafranil                              |                    |                    | S               |                                                 |                      |                 | Sandoz                       |                |
|                                                     | Abilify                                |                    |                    | S               | Oral                                            |                      |                 | Not Reported                 |                |
|                                                     | Cyamemazine                            |                    |                    | S               |                                                 |                      |                 | Not Reported                 |                |
|                                                     | Escitalopram Oxalate                   |                    |                    | S               |                                                 | Taken 1 Tablet Daily |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 12-Jun-2009                                         | 6992561                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000006036                                      |                      | 24 YR           | Male                         | FIN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------------|-----------------|--------------|
| Hyperbilirubinaemia   | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral, 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral, 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 |              |
|                       |                      |              |            |             | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral, 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 |              |
|                       | Xanor (Tablets)      |              |            | C           |              |                                                                                                    |                 | Not Reported |
|                       | Xanor (Tablets)      |              |            | C           |              |                                                                                                    |                 | Not Reported |
|                       | Propral (Tablets)    |              |            | C           |              |                                                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Jun-2009              | 7022145       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20090601633 |                      | 85 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Atrial<br>Flutter; Bradycardia;<br>Depressed Level Of<br>Consciousness; Drug<br>Interaction;                            | Galantamine Hydrobromide |              |            | S           | Unknown                     |                    |                 | Not Reported |
| Electrocardiogram Qt<br>Prolonged; Hypertension;<br>Malaise; Nervous System<br>Disorder; Torsade De<br>Pointes; Ventricular<br>Extrasystoles | Fluticasone              |              |            | S           | Respiratory<br>(inhalation) |                    |                 | Not Reported |
|                                                                                                                                              | Bromazepam               |              |            | S           | Oral                        |                    |                 | Not Reported |
|                                                                                                                                              | Paracetamol              |              |            | S           | Oral                        |                    |                 | Not Reported |
|                                                                                                                                              | Inipomp                  |              |            | S           | Oral                        |                    |                 | Not Reported |
|                                                                                                                                              | Coaprovel                |              |            | S           | Oral                        |                    |                 | Not Reported |
|                                                                                                                                              | Fluindione               |              |            | S           | Unknown                     |                    |                 | Not Reported |
|                                                                                                                                              | Ibandronic Acid          |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                                                                                                              | Levothyrox               |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                                                                                                              | Fluticasone              |              |            | C           | Unknown                     |                    |                 | Not Reported |
|                                                                                                                                              | Escitalopram Oxalate     |              |            | S           | Unknown                     |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------|-----------------|--------------|----------------|
| 15-Jun-2009                                                                    | 6993966                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000006062           |                                                                        | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Gastrointestinal Haemorrhage; Metrorrhagia; Nausea; Suicide Attempt | Escitalopram Oxalate              |                    |                    | S               | Oral                 | (20 Mg, Once), Oral                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2009                                                                    | 6997412                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000006120           |                                                                        | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                       | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                          |                 | Not Reported |                |
|                                                                                | Atarax                            |                    |                    | S               | Oral                 | 137.5 Mg (137.5 Mg, 1 In 1 D), Oral; 87.5 Mg (87.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                |                                   |                    |                    |                 | Oral                 | 137.5 Mg (137.5 Mg, 1 In 1 D), Oral; 87.5 Mg (87.5 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                | Influenza Virus Vaccine Nos       |                    |                    | S               |                      | 1 Dosage Forms (1 Dosage Forms, Once)                                  |                 | Not Reported |                |
|                                                                                | Topalgic (Tramadol Hydrochloride) |                    |                    | S               | Oral                 | 300 To 400 Mg Daily (1 In 1 D), Oral                                   |                 | Not Reported |                |
|                                                                                | Topalgic (Tramadol Hydrochloride) |                    |                    | S               | Oral                 | 300 Mg (300 Mg, 1 In 1 D), Oral; 350 Mg (350 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |
|                                                                                |                                   |                    |                    |                 | Oral                 | 300 Mg (300 Mg, 1 In 1 D), Oral; 350 Mg (350 Mg, 1 In 1 D), Oral       |                 |              |                |
|                                                                                | Amitriptyline                     |                    |                    | S               | Oral                 | 15 Mg (5 Mg, 3 In 1 D), Oral                                           |                 | Not Reported |                |
|                                                                                | Lovenox                           |                    |                    | C               |                      |                                                                        |                 | Not Reported |                |
|                                                                                | Aspegic [Acetylsalicylate Lysine] |                    |                    | C               |                      |                                                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                | Stilnox                  |                    |                    | C               |                      |                                  |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                                                                                                | Oracilline               |                    |                    | C               |                      |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2009                                                                                                                                                                                                                                                                    | 7011307                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000006380           |                                  | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Iron Decreased;<br>Coeliac Disease;<br>Complication Associated<br>With Device; Haemoglobin<br>Decreased; Vaginal<br>Haemorrhage                                                                                                                                          | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Mirena                   |                    |                    | S               | Intra-uterine        | (52 Mg), I.U.                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2009                                                                                                                                                                                                                                                                    | 7033287                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000006766           |                                  | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;<br>Bradycardia; Conduction<br>Disorder; Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Hypertension;<br>Loss Of Consciousness;<br>Malaise; Motor<br>Dysfunction; Nervous<br>System Disorder; Torsade<br>De Pointes; Ventricular<br>Extrasystoles | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Galantamine Hydrobromide |                    |                    | S               |                      | 24 Mg (24 Mg, 1 In 1 D)          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Coaprovel                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Fluindone                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Pantoprazole Sodium      |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Levothyrox               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Fluticasone              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Bromazepam               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Ibandronic Acid          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                | Paracetamol              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2009                                                                                                                                                                                                                                                                    | 6795932                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000000723           |                                  | 28 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus;<br>Maternal Exposure During                                                                                                                                                                                                                                 | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Otitis Media;  
Pre-Eclampsia; Pregnancy  
With Contraceptive Device

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2009              | 7025058       | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14661680 |                      | 82 YR      | Male       | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|---------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Anxiety; Epistaxis;<br>Haematochezia; Sleep<br>Disorder | Coumadin                |              |            | S           | Oral         | 1 Df = 50/12.5mg   |                 | Bristol Myers Squibb |
|                                                         | Lexapro                 |              |            | S           |              |                    |                 | Not Reported         |
|                                                         | Vitamins                |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Atenolol                |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Amlodipine              |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Quinapril               |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Digoxin                 |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Hyzaar                  |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Welchol                 |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Gemfibrozil             |              |            | C           |              |                    |                 | Not Reported         |
|                                                         | Metformin Hydrochloride |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2009              | 7030033       | DIRECT           | N                  | CA, HO, LT, RI  |                      |                      | 1 DAY      | Female     | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Congenital Pulmonary<br>Hypertension; Maternal<br>Drugs Affecting Foetus | Lexapro        |              |            | S           | Oral         | 10 Mg 1 Daily Po   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 17-Jun-2009              | 7026148       | EXPEDITED (15-DAY) | Y                  | OT              | GB-MYLANLABS-<br>2009S1009856 |                      | 30 YR      | Female     | GBR            |

| <u>Preferred Term</u>                        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Contusion; International<br>Normalised Ratio | Venlafaxine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                              | Cipralex                  |              |            | S           |              |                    |                 | Alphapharm   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased

| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>           | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|---------------------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 17-Jun-2009                                                                           | 7033218                   | DIRECT             | N                  |                           |                              |                      | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>               | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscular Weakness;<br>Musculoskeletal Stiffness;<br>Neuralgia; Pain                   | Lexapro                   |                    |                    | S                         | Oral                         | 15 Mg 1x Daily Po    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>           | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2009                                                                           | 7035439                   | EXPEDITED (15-DAY) | Y                  | LT, OT                    | 1000006795                   |                      | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>               | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional<br>Overdose; Respiratory<br>Depression; Seizure;<br>Suicide Attempt | Escitalopram Oxalate      |                    |                    | S                         | Oral                         | (Once), Oral; Oral   |                 | Not Reported |                |
|                                                                                       | Amitriptyline             |                    |                    | S                         | Oral                         | (Once), Oral         |                 | Not Reported |                |
|                                                                                       | Lyrica                    |                    |                    | S                         | Oral                         | (Once), Oral         |                 | Not Reported |                |
|                                                                                       | Venlafaxine Hydrochloride |                    |                    | S                         | Oral                         | (Once), Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>           | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jun-2009                                                                           | 7035190                   | DIRECT             | Y                  | CA, DS, HO, LT,<br>RI, OT |                              |                      | 20 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>               | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise; Overdose                                                                     | Geodon                    |                    |                    | S                         |                              | 100 Mg               |                 | Not Reported |                |
|                                                                                       | Lexapro                   |                    |                    | S                         |                              | 100mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>           | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2009                                                                           | 7003809                   | EXPEDITED (15-DAY) | N                  | OT                        | US-PFIZER INC-<br>2009215184 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>               | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Bladder<br>Disorder; Depression;                                  | Zoloft                    |                    |                    | S                         |                              |                      |                 | Pfizer       |                |
|                                                                                       | Lexapro                   |                    |                    | S                         |                              |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fibromyalgia;  
Gastroesophageal Reflux  
Disease; Pain

| <u>FDA Received Date</u>            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 19-Jun-2009                         | 7015634                                | EXPEDITED (15-DAY) | Y                  | LT              | 1000006445           |                                | 59 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Depression | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1in 1 D),Oral    |                 | Not Reported |                |
|                                     | Valsartan                              |                    |                    | S               | Oral                 | 80 Mg (80 Mg, 1 In 1 D) , Oral |                 | Not Reported |                |
|                                     | Rosuvastatine (Tablets)                |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                     | Levothyroxine(0.05 Milligram, Tablets) |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                     | Phenobarbital                          |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jun-2009                         | 7056612                                | NON-EXPEDITED      | N                  |                 | SPV1-2009-00991      |                                | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Rash                      | Vyvanse                                |                    |                    | S               | Oral                 | 20 Mg, 1x/Day:Qd, Oral         |                 | Not Reported |                |
|                                     | Lexapro                                |                    |                    | S               | Oral                 | 20 Mg, 1x/Day:Qd, Oral         |                 | Not Reported |                |
|                                     | Calcium (Calcium)                      |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                     | Vitamin D Nos (Vitamin D Nos)          |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2009                         | 6955720                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000005185           |                                | 21 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea                         | Lexapro                                |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral    |                 | Not Reported |                |
|                                     | Lexapro                                |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |
|                                     | Alprazolam                             |                    |                    | C               |                      |                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                         |                      |                    |                    |                 |                         |                             |                 |              |                |
|---------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|-----------------------------|-----------------|--------------|----------------|
| Psychotropics (Nos)                                                                                     |                      |                    | C                  |                 |                         | Not Reported                |                 |              |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2009                                                                                             | 6974766              | EXPEDITED (15-DAY) | N                  | HO              | 1000005494              |                             | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Depression;<br>Haematemesis; Throat<br>Irritation                                | Lexapro              |                    |                    | S               | Oral                    | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                         | Lexapro              |                    |                    | S               | Oral                    | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                         | Aspirin              |                    |                    | S               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Nexium               |                    |                    | C               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Benicar              |                    |                    | C               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Labetalol            |                    |                    | C               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Glyburide            |                    |                    | C               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Norvasc              |                    |                    | C               |                         |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2009                                                                                             | 7010488              | EXPEDITED (15-DAY) | Y                  | OT              | US-RANBAXY-2009RR-24496 |                             | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Drug Interaction; Low<br>Density Lipoprotein<br>Increased | Zocor                |                    |                    | S               |                         |                             |                 | Ranbaxy      |                |
|                                                                                                         | Levothyroxine Sodium |                    |                    | S               |                         | 0.05 Mg, Unk                |                 | Not Reported |                |
|                                                                                                         | Levothyroxine Sodium |                    |                    | S               |                         | 0.075 Mg, Qd                |                 | Not Reported |                |
|                                                                                                         | Levothyroxine Sodium |                    |                    | S               |                         | 0.1 Mg, Qd                  |                 | Not Reported |                |
|                                                                                                         | Levothyroxine Sodium |                    |                    | S               |                         | 0.125 Mg, Qd                |                 | Not Reported |                |
|                                                                                                         | Levothyroxine Sodium |                    |                    | S               |                         | 0.137 Mg, Qd                |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate |                    |                    | S               |                         | 5 Mg, Unk                   |                 | Not Reported |                |
|                                                                                                         | Vytorin              |                    |                    | S               |                         | 10/40 Mg                    |                 | Not Reported |                |
|                                                                                                         | Zetia                |                    |                    | S               |                         | Unk                         |                 | Not Reported |                |
|                                                                                                         | Crestor              |                    |                    | S               |                         | 5 Mg, Qd                    |                 | Not Reported |                |
|                                                                                                         | Iodine I-131         |                    |                    | C               |                         |                             |                 | Not Reported |                |
|                                                                                                         | Welchol              |                    |                    | C               |                         | Unk                         |                 | Not Reported |                |
|                                                                                                         | Warfarin Sodium      |                    |                    | C               |                         |                             |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jun-2009                                                                                                                                                                        | 7039869              | DIRECT             | Y                  |                 |                                  |                      | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Disturbance In Attention;<br>Dizziness; Drug<br>Withdrawal Syndrome;<br>Headache; Irritability;<br>Vertigo | Lexapro              |                    |                    | S               | Oral                             | 20 Mg Qd Po          |                 | Forest       |                |
|                                                                                                                                                                                    | Deplin               |                    |                    | C               |                                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Ambien               |                    |                    | C               |                                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2009                                                                                                                                                                        | 6790445              | EXPEDITED (15-DAY) | Y                  | OT              | DE-ABBOTT-08P-062-<br>0480950-00 |                      | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diabetes Mellitus; Otitis<br>Media; Pre-Eclampsia                                                                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                             |                      |                 | Not Reported |                |
|                                                                                                                                                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2009                                                                                                                                                                        | 7032430              | EXPEDITED (15-DAY) | Y                  |                 | US-MYLANLABS-<br>2009S1007640    |                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Chest Pain;<br>Chills; Drug Withdrawal<br>Syndrome; Dyskinesia;<br>Headache; Malaise;<br>Nausea; Retching;<br>Tremor; Weight<br>Decreased                                | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |
|                                                                                                                                                                                    | Alprazolam           |                    |                    | S               | Oral                             |                      |                 | Alphapharm   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |      |                     |
|----------------|---|------|---------------------|
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Alprazolam     | S | Oral | Alphapharm          |
| Lexapro        | S | Oral | 6 MTH<br>Alphapharm |
| Lipitor        | C | Oral | Not Reported        |
| Benicar        | C | Oral | Not Reported        |
| Evista         | C | Oral | Not Reported        |
| Synthroid      | C | Oral | Not Reported        |
| Cipro          | C |      | Not Reported        |
| Nitrofurantoin | C |      | Not Reported        |
| Azithromycin   | C |      | Not Reported        |
| Doxycycline    | C |      | Not Reported        |
| Omeprazole     | C |      | Not Reported        |
| Folic Acid     | C |      | Not Reported        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jun-2009              | 7040965       | DIRECT           | N                  | RI              |                      |                      | 32 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Testosterone Decreased; Erectile Dysfunction; Libido Decreased | Lexapro        |              |            | S           | Oral         | 1 Once A Day Po    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2009              | 6295116       | EXPEDITED (15-DAY) | Y                  | CA              | S07-FIN-01390-02     |                      | 1 DAY      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|----------------|----------------------|-----------------|--------------|
| Caesarean Section;    | Ciprallex      |              |            | S           | Transplacental | 10 Mg (10 Mg, Once A |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                                          |   |                      |  |  |  |  |  |              |
|------------------------------------------------------------------------|------------------------------------------|---|----------------------|--|--|--|--|--|--------------|
| Congenital Anomaly;<br>Dysmorphism; Maternal<br>Drugs Affecting Foetus | Selexid (Pevmecillinam<br>Hydrochloride) | S | Day), Transplacental |  |  |  |  |  | Not Reported |
|                                                                        | Ispaghula                                | S |                      |  |  |  |  |  | Not Reported |
|                                                                        | Laxoberon                                | S |                      |  |  |  |  |  | Not Reported |
|                                                                        | Xenical                                  | C |                      |  |  |  |  |  | Not Reported |
|                                                                        | Antepsin                                 | C |                      |  |  |  |  |  | Not Reported |
|                                                                        | Lansoprazole                             | C |                      |  |  |  |  |  | Not Reported |
|                                                                        | Tolterodine Tartrate                     | C |                      |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2009              | 6936419       | EXPEDITED (15-DAY) | N                  | DE              | 1000004976           |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Asphyxia;<br>Completed Suicide;<br>Depression; Pain | Lexapro        |              |            | S           | Oral         | (10 Mg), Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2009              | 7041346       | DIRECT           | N                  | RI              |                      |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Alopecia; Anxiety; Hair<br>Texture Abnormal;<br>Product Label Issue | Lexapro        |              |            | S           | Oral         | 15mg 1x Day Po     |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2009              | 7042988       | EXPEDITED (15-DAY) | Y                  | OT              | 1000006981           |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Alcohol Poisoning;<br>Intentional Overdose;<br>Suicide Attempt;<br>Tachycardia | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Tablets, Oral          |                 | Not Reported |
|                                                                                | Chlorprothixene Hydrochloride |              |            | S           |              | 500 Mg (50 Mg, 10 In 1 D) |                 | Not Reported |
|                                                                                | Seroquel                      |              |            | S           |              | 10 Tablets                |                 | Not Reported |
|                                                                                | Alcohol                       |              |            | S           | Oral         | Oral                      |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| 26-Jun-2009                                                                                                                                                                              | 7034359                 | EXPEDITED (15-DAY) | Y                  | HO              | CH-ROXANE<br>LABORATORIES, INC.-<br>2009-RO-00606RO |                                  | 80 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Central Nervous System<br>Lesion; Encephalopathy;<br>Toxicity To Various Agents                                                                                                          | Levetiracetam           |                    |                    | S               |                                                     |                                  |                 | Roxane       |                |
|                                                                                                                                                                                          | Levetiracetam           |                    |                    | S               |                                                     |                                  |                 | Roxane       |                |
|                                                                                                                                                                                          | Verapamil Hydrochloride |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Propranolol             |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Metformin Hydrochloride |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Oxazepam                |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Escitalopram Oxalate    |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Benserazide\Levodopa    |                    |                    | S               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Clonazepam              |                    |                    | C               |                                                     |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jun-2009                                                                                                                                                                              | 7045211                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000007010                                          |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Fear; Morbid Thoughts                                                                                                                                                                    | Escitalopram Oxalate    |                    |                    | S               | Oral                                                | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2009                                                                                                                                                                              | 6806546                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000001430                                          |                                  | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blepharitis; Chorioretinal<br>Disorder; Dry Eye; Eye<br>Pain; Headache;<br>Maculopathy; Overdose;<br>Vision Blurred; Visual<br>Acuity Reduced; Vitreous<br>Disorder; Weight<br>Increased | Lexapro                 |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1<br>D),Oral  |                 | Not Reported |                |
|                                                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                                                | 30 Mg (30 Mg, 1 In 1<br>D),Oral  |                 | Not Reported |                |
|                                                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                          | Wellbutrin              |                    |                    | S               | Oral                                                | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                                                                                                          | Wellbutrin              |                    |                    | C               |                                                     |                                  |                 | Not Reported |                |
|                                                                                                                                                                                          | Zocor                   |                    |                    | C               |                                                     |                                  |                 | Not Reported |                |

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|              |   |              |
|--------------|---|--------------|
| Xanax        | C | Not Reported |
| Gabapentin   | C | Not Reported |
| Topamax      | C | Not Reported |
| Indomethacin | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jun-2009              | 7044593       | DIRECT           | Y                  | OT              |                      |                      | 42 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Anxiety; Dry Mouth; Gait Inability; Headache; Hyperhidrosis; Hypertension; Palpitations; Panic Attack | Lexapro<br>Prozac |              |            | S<br>S      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jun-2009              | 7045097       | DIRECT           | N                  | OT              |                      |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Aggression; Mania     | Lexapro        |              |            | S           | Oral         | 10 Mg 1-Day Oral 15-20 Days |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2009              | 6906165       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ROCHE-612930      |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Extrapyramidal Disorder; Fall; Orthostatic Hypotension | Rivotril       |              |            | S           | Oral         |                                |                 | Roche        |
|                                                        | Bromazepam     |              |            | S           | Oral         |                                |                 | Roche        |
|                                                        | Amitriptyline  |              |            | S           | Oral         | Tdd Reported As 15 Doses Daily |                 | Roche        |
|                                                        | Vastarel       |              |            | S           | Unknown      |                                |                 | Not Reported |
|                                                        | Acetaminophen  |              |            | S           | Unknown      |                                |                 | Not Reported |
|                                                        | Atacand        |              |            | S           | Oral         |                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                        |   |         |              |
|--|------------------------|---|---------|--------------|
|  | LevomEPROMAZINE        | S | Oral    | Not Reported |
|  | Escitalopram Oxalate   | S | Unknown | Not Reported |
|  | Omeprazole             | C |         | Not Reported |
|  | Actonel                | C |         | Not Reported |
|  | Calcium Carbonate      | C |         | Not Reported |
|  | Previscan (Fluindione) | C |         | Not Reported |
|  | Symbicort              | C |         | Not Reported |
|  | Sinemet                | C |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2009              | 7036393       | EXPEDITED (15-DAY) | N                  | HO              | US-RB-017383-09      |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Mood Swings           | Suboxone       |              |            | S           | Sublingual   | Varying Dose Up To 12 Mg Daily |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Unknown      | Unknown Dose                   |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Unknown      | Unknown Dose                   |                 | Not Reported |
|                       | Seroquel       |              |            | S           | Unknown      | Unknown                        |                 | Not Reported |
|                       | Seroquel       |              |            | S           | Unknown      | Unknown                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 02-Jul-2009              | 7040080       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-2009232743 |                      | 27 YR      | Unknown    | FRA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Epilepsy              | Atarax                      |              |            | S           | Oral         | 137.5 Mg, Unk      | 3 DAY           | Pfizer       |
|                       | Atarax                      |              |            | S           | Oral         | 87.5 Mg, Unk       |                 | Pfizer       |
|                       | Influenza Virus Vaccine Nos |              |            | S           |              | Unk                | 1 DAY           | Not Reported |
|                       | Topalgic (France)           |              |            | S           | Oral         | 350 Mg, Unk        | 5 DAY           | Not Reported |
|                       | Topalgic (France)           |              |            | S           | Oral         | Unk                | 44 DAY          | Not Reported |
|                       | Topalgic (France)           |              |            | S           | Oral         | 300 Mg, Unk        |                 | Not Reported |
|                       | Amitriptyline Hydrochloride |              |            | S           | Oral         | 5 Mg, 3x/Day       |                 | Not Reported |
|                       | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |   |              |                 |              |
|-----------------------------------|---|--------------|-----------------|--------------|
| Lovenox                           | C | Subcutaneous | 4000 Iu, 1x/Day | Not Reported |
| Aspegic [Acetylsalicylate Lysine] | C |              | 100 Mg, Unk     | Not Reported |
| Oracilline                        | C |              | 2 Df, Unk       | Not Reported |
| Stilnox                           | C | Oral         | 0.5 Df, Unk     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jul-2009              | 7047868       | DIRECT           | N                  | HO, LT, RI      |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aggression; Agitation;                                                                                                                                                          | Lexapro        |              |            | S           |              | 10 Mg Daily        |                 | Forest     |
| Anger; Anxiety;                                                                                                                                                                 | Lexapro        |              |            | S           |              |                    |                 | Forest     |
| Depression; Emotional Disorder; Feeling Abnormal; General Physical Health Deterioration; Hypertension; Partner Stress; Serotonin Syndrome; Suicidal Ideation; Thinking Abnormal |                |              |            |             |              |                    |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2009              | 6992559       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006020           |                      | 61 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Amnesia; Base Excess Negative; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Glucose Increased; Blood Osmolarity Decreased; Blood Ph Decreased; Blood Urea Decreased; Carbon | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                    | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                    | Haldol               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                    | Albyl-E              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                    | Atacand              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                    | Sobril               |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                    | Persantine           |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                    | Paracetamol          |              |            | C           |              |                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                           |             |   |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|--------------|
| Dioxide Decreased;<br>Cerebral Atrophy;<br>Cerebral Infarction;<br>Generalised Tonic-Clonic<br>Seizure; Haemoglobin<br>Decreased;<br>Hyponatraemia; Injury;<br>Mean Cell Volume<br>Decreased; Overdose;<br>Oxygen Saturation<br>Decreased | Simvastatin | C | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2009              | 7050339       | EXPEDITED (15-DAY) | N                  | OT              | 1000007143           |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Breast Cancer In Situ;<br>Breast Cancer Recurrent;<br>Breast Pain; Breast<br>Swelling; Oestrogen<br>Receptor Assay Positive | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                             | Alprazolam     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                             | Prevacid       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                             | Singulair      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                             | Advil          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                             | Multivitamins  |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                             | Calcium        |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2009              | 7051494       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007161           |                      | 24 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Sopor; Suicide Attempt;<br>Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                 | Doxepin              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                 | Seroquel             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                 | Tavor (Lorazepam)    |              |            | S           | Oral         | Oral               |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-------------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 07-Jul-2009                                                                                                                                  | 6232629                    | EXPEDITED (15-DAY) | Y                  | OT              | S07-SWI-00279-01              |                                           | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;<br>Infection; Maternal<br>Exposure During<br>Pregnancy; Pregnancy                                                          | Cipralex                   |                    |                    | S               | Oral                          | Oral                                      |                 | Not Reported |                |
|                                                                                                                                              | Clonazepam                 |                    |                    | S               | Oral                          | 20 Mg (20 Mg), Oral                       |                 | Not Reported |                |
|                                                                                                                                              | Alcohol (Ethanol)          |                    |                    | S               | Oral                          | Oral                                      |                 | Not Reported |                |
|                                                                                                                                              | Lorazepam                  |                    |                    | S               | Oral                          | 2.5mg (2.5 Mg), Oral                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2009                                                                                                                                  | 6755074                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000000679                    |                                           | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Headache;<br>Incontinence; Lethargy;<br>Nuclear Magnetic<br>Resonance Imaging Brain<br>Abnormal; Seizure;<br>Unresponsive To Stimuli | Lexapro                    |                    |                    | S               | Oral                          | 10 Mg (10 Mg,1 In 1 D),<br>Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2009                                                                                                                                  | 7043308                    | EXPEDITED (15-DAY) | Y                  | OT              | DE-MYLANLABS-<br>2009S1011285 |                                           | 48 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura                                                                                                                                      | Lamotrigine                |                    |                    | S               | Oral                          | 200-0-250-0                               |                 | Not Reported |                |
|                                                                                                                                              | Oxcarbazepine              |                    |                    | S               | Oral                          |                                           |                 | Not Reported |                |
|                                                                                                                                              | Enalapril                  |                    |                    | S               | Oral                          | Daily Dose: 2 Df Dosage<br>Form Every Day |                 | Genpharm     |                |
|                                                                                                                                              | Metoprolol                 |                    |                    | S               | Oral                          | Daily Dose: 2 Df Dosage<br>Form Every Day |                 | Not Reported |                |
|                                                                                                                                              | Ferrous Sulfate\Folic Acid |                    |                    | S               | Oral                          | Daily Dose: 1 Df Dosage<br>Form Every Day |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |      |                                           |              |
|---------------------|---|------|-------------------------------------------|--------------|
| Simvastatin         | S | Oral | Daily Dose: 1 Df Dosage<br>Form Every Day | Not Reported |
| Baclofen            | S | Oral | Daily Dose: 2 Df Dosage<br>Form Every Day | Not Reported |
| Hydrochlorothiazide | S | Oral | Daily Dose: 1 Df Dosage<br>Form Every Day | Not Reported |
| Cipralelex          | S | Oral |                                           | Alphapharm   |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Jul-2009                            | 7049235        | DIRECT           | N                  |                 |                      |                      | 29 YR           | Male       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Throat Tightness;<br>Unevaluable Event | Lexapro        |                  |                    | S               |                      | Once Daily           |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 07-Jul-2009              | 7051890                       | EXPEDITED (15-DAY) | Y                  | OT              | 2009S1011285         |                         | 48 YR           | Male         | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Purpura                  | Lamotrigine                   |                    |                    | S               | Oral                 | Oral                    |                 | Not Reported |                |
|                          | Enalapril                     |                    |                    | S               | Oral                 | 1df;Twice A Day; Oral   |                 | Not Reported |                |
|                          | Oxcarbazepine (Oxcarbazepine) |                    |                    | S               | Oral                 | 2.5 Df;Daily; Oral      |                 | Not Reported |                |
|                          | Metoprolol Succinate          |                    |                    | S               | Oral                 | 1 Df;Twice A Day; Oral  |                 | Not Reported |                |
|                          | Ferrous Sulfate               |                    |                    | S               | Oral                 | 1 Df;Daily; Ora         |                 | Not Reported |                |
|                          | Simvastatin                   |                    |                    | S               | Oral                 | 1 Df; Oral; Daily; Oral |                 | Not Reported |                |
|                          | Baclofen                      |                    |                    | S               | Oral                 | 1 Df; Twice A Day; Oral |                 | Not Reported |                |
|                          | Hydrochlorothiazide           |                    |                    | S               | Oral                 | 1 Df;Daily; Oral        |                 | Not Reported |                |
|                          | Cipralelex                    |                    |                    | S               | Oral                 | 1.5 Df;Daily; Oral      |                 | Not Reported |                |
|                          | Tavor (Lorazepam)             |                    |                    | C               |                      |                         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2009              | 7052906       | EXPEDITED (15-DAY) | Y                  | DE              | 1000007155           |                      | 30 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
|------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|-----------------|----------------|
| Completed Suicide                                                                                                | Escitalopram Oxalate     |                    |                    | S               |                      | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D) |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jul-2009                                                                                                      | 6959078                  | EXPEDITED (15-DAY) | N                  | HO              | B0568235A            |                                           |                 | Male            | NOR            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Abdomen; Condition Aggravated; Drug Interaction; Fat Tissue Increased; Lipoatrophy; Lipodystrophy Acquired | Epivir                   |                    |                    | S               | Unknown              |                                           |                 | Glaxosmithkline |                |
|                                                                                                                  | Videx                    |                    |                    | S               | Unknown              |                                           |                 | Not Reported    |                |
|                                                                                                                  | Kaletra                  |                    |                    | S               | Oral                 |                                           |                 | Not Reported    |                |
|                                                                                                                  | Ciprallex                |                    |                    | S               | Unknown              |                                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jul-2009                                                                                                      | 7056512                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000007258           |                                           | 84 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Disorientation; Hallucination, Auditory; Hallucination, Visual                                        | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral             |                 | Not Reported    |                |
|                                                                                                                  | Topalgic (France)        |                    |                    | S               |                      | 200 Mg (100 Mg, 2 In 1 D)                 |                 | Not Reported    |                |
|                                                                                                                  | Previscan (Fluindione)   |                    |                    | C               |                      |                                           |                 | Not Reported    |                |
|                                                                                                                  | Paracetamol              |                    |                    | C               |                      |                                           |                 | Not Reported    |                |
|                                                                                                                  | Prozac                   |                    |                    | C               |                      |                                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Jul-2009                                                                                                      | 7071116                  | NON-EXPEDITED      | N                  | OT              | IMP_04346_2009       |                                           |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Depression; Hallucination; Somnolence                                                                   | Bupropion Hydrochloride  |                    |                    | S               |                      | (300 Mg)                                  | 6 YR            | Not Reported    |                |
|                                                                                                                  | Lamotrigine              |                    |                    | S               | Oral                 | (400 Mg Oral)                             | 6 YR            | Not Reported    |                |
|                                                                                                                  | Paroxetine Hydrochloride |                    |                    | S               | Oral                 | (Df Oral)                                 |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |      |              |
|---------------------------|---|------|--------------|
| Clonazepam                | S | (Df) | Not Reported |
| Lexapro                   | S | (Df) | Not Reported |
| Insulin Human             | C |      | Not Reported |
| Tiotropium                | C |      | Not Reported |
| Clopidogrel Bisulfate     | C |      | Not Reported |
| Simvastatin               | C |      | Not Reported |
| Blood Pressure Medication | C |      | Not Reported |
| Apo-Hydroxyzine /0058401/ | C |      | Not Reported |
| Metoprolol                | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2009              | 7045331       | EXPEDITED (15-DAY) | Y                  | HO              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T200901305 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Silicon Granuloma     | Hydromorphone Hydrochloride |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Prednisone                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Esomeprazole                |              |            | S           |              |                    |                 | Not Reported |
|                       | Alprazolam                  |              |            | S           |              |                    |                 | Not Reported |
|                       | Warfarin Sodium             |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2009              | 7054385       | DIRECT           | N                  | LT, OT          |                      |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Delirium; Hypertension;<br>Mental Disorder; Nervous<br>System Disorder;<br>Palpitations; Thinking<br>Abnormal; Unevaluable<br>Event | Lexapro        |              |            | S           | Oral         | 10mg One Per Day Po |                 | Forest       |
|                                                                                                                                     | Hctz           |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                     | Antenolol      |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                     | Effexor        |              |            | C           |              |                     |                 | Not Reported |
|                                                                                                                                     | Avinza         |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2009              | 7054450       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Alopecia; Emotional Distress                | Lexapro                 |                           |                             | S                        |                               | 5mg 1 Per Day                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Jul-2009                                 | 7055776                 | EXPEDITED (15-DAY)        | N                           | HO                       | 1000007199                    |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Thinking Abnormal; Withdrawal Syndrome      | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2009                                 | 7039129                 | EXPEDITED (15-DAY)        | Y                           |                          | 1000006914                    |                               | 74 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Osteoarthritis; Rheumatoid Factor Increased | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                             | Mirtazapine             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                             | Deanxit (Tablets)       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                             | Melitracen (Tablets)    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2009                                 | 7043415                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000006931                    |                               | 71 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>              | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Generalised Tonic-Clonic Seizure            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1in 1 D), Oral  |                          | Not Reported        |                         |
|                                             | Risperdal               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                             | Metformin Hydrochloride |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                             | Nifedipine              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                             | Xiaoke Wan              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>           | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jul-2009                                 | 7054411                 | DIRECT                    | N                           |                          |                               |                               | 27 YR                    | Female              | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>       |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------------|-----------------------------------------------------|-----------------|------------------|----------------|
| Bladder Pain; Dysuria; Micturition Urgency                                                                                                                                                                         | Lexapro                  |                    |                    | S               | Oral                                        | 10 Mg 1 Daily Po                                    |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 10-Jul-2009                                                                                                                                                                                                        | 7055109                  | DIRECT             | N                  |                 |                                             |                                                     | 46 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>       |                |
| Abnormal Behaviour; Dizziness; Somnolence; Vision Blurred                                                                                                                                                          | Lexapro                  |                    |                    | S               | Oral                                        | 10mg 1 Time A Day Po                                |                 | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Jul-2009                                                                                                                                                                                                        | 7020917                  | EXPEDITED (15-DAY) | Y                  | HO              | SE-ELI_LILLY_AND_COMP<br>ANY-SE200906000405 |                                                     | 62 YR           | Male             | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>       |                |
| Kidney Infection; Urinary Retention                                                                                                                                                                                | Duloxetine Hydrochloride |                    |                    | S               |                                             | Unk, Unk                                            | 50 DAY          | Eli Lilly And Co |                |
|                                                                                                                                                                                                                    | Duloxetine Hydrochloride |                    |                    | S               |                                             | Unk, Unk                                            | 5 DAY           | Eli Lilly And Co |                |
|                                                                                                                                                                                                                    | Escitalopram Oxalate     |                    |                    | S               |                                             |                                                     | 84 DAY          | Not Reported     |                |
| <u>FDA Received Date</u>                                                                                                                                                                                           | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>       | <u>Country</u> |
| 13-Jul-2009                                                                                                                                                                                                        | 7055616                  | DIRECT             | Y                  |                 |                                             |                                                     | 21 YR           | Female           | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                              | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>       |                |
| Abnormal Sensation In Eye; Agitation; Blepharospasm; Dry Mouth; Ear Discomfort; Epigastric Discomfort; Headache; Heart Rate Increased; Hot Flush; Hyperhidrosis; Nasal Discomfort; Nausea; Paraesthesia; Sedation; | Lexapro                  |                    |                    | S               | Oral                                        | 10 Mg Once Before Sleep Po (This Was My First Dose) |                 | Not Reported     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tremor; Vomiting

| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Jul-2009                                              | 7055703        | DIRECT           | Y                  |                 |                      |                      | 20 YR           | Male       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Frustration Tolerance<br>Decreased; Suicidal<br>Ideation | Lexapro        |                  |                    | S               |                      | Normal 1 Dose        |                 |            | Not Reported   |
|                                                          | Ativan         |                  |                    | C               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------|----------------|
| 13-Jul-2009                                                                                                                                             | 7077857              | EXPEDITED (15-DAY) | Y                  | HO              | 1000007313           |                                  | 48 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Balance Disorder;<br>Cerebellar Syndrome;<br>Dizziness; Eye Pain;<br>Radiculopathy; Vision<br>Blurred; Visual Acuity<br>Reduced; Visual Field<br>Defect | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                             |                 |            | Not Reported   |
|                                                                                                                                                         | Femara               |                    |                    | S               | Oral                 | (2.5 Mg), Oral                   |                 |            | Not Reported   |
|                                                                                                                                                         | Femara               |                    |                    | S               | Oral                 | Oral                             |                 |            | Not Reported   |
|                                                                                                                                                         | Cyamemazine          |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D),<br>Oral |                 |            | Not Reported   |
|                                                                                                                                                         | Cyamemazine          |                    |                    | S               | Oral                 | 25 Mg (25 Mg, 1 In 1 D),<br>Oral |                 |            | Not Reported   |
|                                                                                                                                                         | Prazepam             |                    |                    | S               | Oral                 | Oral                             |                 |            | Not Reported   |
|                                                                                                                                                         | Sectral              |                    |                    | S               | Oral                 | Oral                             |                 |            | Not Reported   |
|                                                                                                                                                         | Solu-Medrol          |                    |                    | C               |                      |                                  |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 14-Jul-2009                                                               | 7049340                      | EXPEDITED (15-DAY) | Y                  | HO              | AU-ROCHE-642670      |                      | 48 YR           | Female     | AUS            |
| <u>Preferred Term</u>                                                     | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Sleep-Related<br>Event; Flushing;<br>Mydriasis;<br>Somnambulism; | Valium                       |                    |                    | S               | Oral                 |                      |                 |            | Roche          |
|                                                                           | Codeine Phosphate\Doxylamine |                    |                    | S               | Unknown              |                      |                 |            | Not Reported   |
|                                                                           | Seroquel                     |                    |                    | S               | Unknown              |                      |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |          |   |         |  |                                   |              |
|------------|----------|---|---------|--|-----------------------------------|--------------|
| Somnolence | Stilnox  | S | Oral    |  |                                   | Not Reported |
|            | Lexapro  | S | Oral    |  |                                   | Not Reported |
|            | Alcohol  | S | Unknown |  |                                   | Not Reported |
|            | Caltrate | C |         |  | Drug Reported As:<br>Caltrate 600 | Not Reported |
|            | Fish Oil | C |         |  | Drug: Fish Oil (Nos)              | Not Reported |

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jul-2009                                                 | 7055989        | DIRECT           | N                  | HO, LT, OT      |                      |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Migraine;<br>Suicidal Ideation; Suicide Attempt | Cymbalta       |                  |                    | S               | Oral                 | 60mg Daily Po        |                 | Not Reported |                |
|                                                             | Lexapro        |                  |                    | S               | Oral                 | 20mg Daily Po        |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Jul-2009                                 | 7060320              | EXPEDITED (15-DAY) | Y                  | OT              | 1000007292           |                      | 19 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematochezia; Large Intestinal Haemorrhage | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 15-Jul-2009                                                                         | 6974025              | EXPEDITED (15-DAY) | Y                  | HO              | 1000005568           |                                 | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Confusional State;<br>Disorientation; Mania;<br>Weight Decreased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |                |
|                                                                                     | Lexomil              |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                     | Theralene            |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                     | Pariet               |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                     | Spasfon Lyoc         |                    |                    | C               |                      |                                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 15-Jul-2009                                | 7002795                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000006207                |                                                                                             | 41 YR           | Male         | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Escitalopram Oxalate     |                    |                    | S               | Oral                      | 1120 Mg (1120 Mg, Once)<br>Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                            |                          |                    |                    |                 | Oral                      | 1120 Mg (1120 Mg, Once)<br>Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                            |                          |                    |                    |                 | Oral                      | 1120 Mg (1120 Mg, Once)<br>Oral 10 Mg (10 Mg, 1 In 1 D), Oral 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                            | Amisulpride              |                    |                    | S               | Oral                      | 4 Boxes (Once), Oral                                                                        |                 | Not Reported |                |
|                                            | Atorvastatin             |                    |                    | S               | Oral                      | 4 Boxes (Once), Oral                                                                        |                 | Not Reported |                |
|                                            | Piportil (Solution)      |                    |                    | C               |                           | 2 Boxes (Once), Oral                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2009                                | 7040688                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000006924                |                                                                                             | 48 YR           | Male         | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Respiratory Tract<br>Infection; Seizure    | Lexapro                  |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                            |                 | Not Reported |                |
|                                            | Mianserin (10 Milligram) |                    |                    | C               |                           |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2009                                | 7050491                  | EXPEDITED (15-DAY) | N                  | OT              | ZA-JNJFOC-<br>20090702305 |                                                                                             |                 | Male         | ZAF            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Mouth; Influenza;                      | Risperdal                |                    |                    | S               | Unknown                   |                                                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |           |   |         |              |
|--------------------------|-----------|---|---------|--------------|
| Salivary Gland Calculus; | Risperdal | S | Unknown | Not Reported |
| Salivary Gland Disorder  | Ciprallex | S | Unknown | Not Reported |
|                          | Effexor   | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2009              | 7062235       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007370           |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Confusional State;     | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |
| Contusion; Fall; Wrist |                |              |            |             |              | Oral                     |                 |              |
| Fracture               | Benadryl       |              |            | S           | Oral         | Oral                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jul-2009              | 7065205       | DIRECT           |                    | HO, OT          |                      |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Aggression; Mania;    | Lexapro        |              |            | S           | Oral         | 10 Mg 1 - Daily Oral |                 | Not Reported |
| Personality Change    |                |              |            |             | Oral         | 10 Mg 1 - Daily Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2009              | 6945638       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005046           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Epistaxis; Metrorrhagia | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), |                 | Not Reported |
|                         |                      |              |            |             |              | Oral                     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Jul-2009              | 7014481       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-PFIZER INC-<br>2009202061 |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Acute Psychosis; Drug   | Alprazolam     |              |            | S           | Oral         | Unk                |                 | Pfizer     |
| Dependence; Dysarthria; |                |              |            |             |              |                    |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                           |   |                  |              |
|------------------------------------------------------------------|---------------------------|---|------------------|--------------|
| Fatigue; Indifference;<br>Medication Error; Memory<br>Impairment | Ziprasidone Hydrochloride | S | 80 Mg+ 40 Mg/Day | Pfizer       |
|                                                                  | Ciprallex                 | S | 20 Mg, 1x/Day    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jul-2009              | 7064730       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007490           |                      | 46 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyspnoea; Urticaria   | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Clotiazepam          |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Stilnox              |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2009              | 6788997       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001119           |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Agitation; Confusional<br>State; Delusion; Drug<br>Interaction; Hallucination,<br>Visual | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                          | Escitalopram Oxalate |              |            | S           | Oral         | Oral                           |                 | Not Reported |
|                                                                                          | Rasagiline Mesylate  |              |            | S           | Oral         | 1 Mg (1 Mg,1 In 1 D),Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2009              | 7063598       | DIRECT           | Y                  |                 |                      |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Feeling<br>Abnormal; Loss Of Libido;<br>Menorrhagia;<br>Menstruation Irregular;<br>Nausea; Palpitations;<br>Sedation; Sexual<br>Dysfunction; Somnolence | Lexapro        |              |            | S           | Oral         | 10mg Once A Day Po |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| 20-Jul-2009                                                                | 7064761                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000007519                     |                                  |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Impaired Driving Ability;<br>Legal Problem                                 | Lexapro                 |                           |                             | S                        | Oral                           | Oral                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jul-2009                                                                | 7064822                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000005620                     |                                  | 23 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Chest Pain;<br>Pleuritic Pain                                     | Lexapro                 |                           |                             | S                        | Oral                           | 5 Mg (5 Mg,1 In 1 D),Oral        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jul-2009                                                                | 7065380                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000007488                     |                                  | 24 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abscess Jaw; Oedema<br>Mouth; Swollen Tongue;<br>Tooth Abscess             | Escitalopram Oxalate    |                           |                             | S                        | Oral                           | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                            | Escitalopram Oxalate    |                           |                             | S                        | Oral                           | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                            | Seroquel                |                           |                             | C                        |                                |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Jul-2009                                                                | 7055978                 | EXPEDITED (15-DAY)        | Y                           | HO                       | AU-ASTRAZENECA-<br>2009SE04637 |                                  |                          | Female              | AUS                     |
| <a href="#">Preferred Term</a>                                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>          | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Delusional Disorder,<br>Unspecified Type; Fall;<br>Orthostatic Hypotension | Seroquel                |                           |                             | S                        | Oral                           |                                  | 92 DAY                   | Not Reported        |                         |
|                                                                            | Aricept                 |                           |                             | S                        | Oral                           |                                  |                          | Not Reported        |                         |
|                                                                            | Escitalopram Oxalate    |                           |                             | S                        | Oral                           |                                  |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 21-Jul-2009                                                                 | 7066013                            | EXPEDITED (15-DAY) | Y                  | DS              | 1000007464           |                                    | 60 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia;<br>Musculoskeletal Pain;<br>Pain In Extremity;<br>Periarthritis | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                             | Prazepam                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Solian                             |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2009                                                                 | 7066022                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000007504           |                                    | 89 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Haemorrhagic Stroke;<br>Head Injury                                   | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                             | Aspirin Cardio                     |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                             | Enatec                             |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2009                                                                 | 7059583                            | NON-EXPEDITED      | Y                  |                 | US-AMGEN-KDL293623   |                                    | 87 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Fatigue;<br>Feeling Abnormal;<br>Haemoglobin Decreased;<br>Rash   | Procrit                            |                    |                    | S               | Subcutaneous         |                                    |                 | Not Reported |                |
|                                                                             | Lexapro                            |                    |                    | S               |                      |                                    |                 | Not Reported |                |
|                                                                             | Lipitor                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Lasix                              |                    |                    | C               | Oral                 |                                    |                 | Not Reported |                |
|                                                                             | Unspecified Antihypertensive Agent |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Agrylin                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Aspirin                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Catapres-Tts                       |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Plavix                             |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                             | Antivert                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                      |                    |                    |                 |                                  |                                  |                 |              |                |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------------------|-----------------|--------------|----------------|
| Nitroglycerin<br>Clonidine                                                                            |                      |                    | C<br>C             | Oral            |                                  | Not Reported<br>Not Reported     |                 |              |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2009                                                                                           | 7008539              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000006266                       |                                  | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Dizziness;<br>Fatigue; Feeling<br>Abnormal; Syncope                                   | Escitalopram Oxalate |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                       | Nuvaring             |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2009                                                                                           | 7064831              | EXPEDITED (15-DAY) | Y                  | OT              | 1000007529                       |                                  | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Breast Pain; Breast<br>Swelling; Galactorrhoea;<br>Menstruation Delayed | Escitalopram Oxalate |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                       | Bromazepam (Tablets) |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jul-2009                                                                                           | 7068887              | EXPEDITED (15-DAY) | N                  | DE              | 1000007672                       |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                     | Lexapro              |                    |                    | S               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jul-2009                                                                                           | 7064333              | NON-EXPEDITED      | N                  |                 | US-ABBOTT-08P-163-<br>0488056-00 |                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen False                                                                                     | Norvir               |                    |                    | S               |                                  |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                    |   |              |
|----------|--------------------|---|--------------|
| Positive | Lexapro            | S | Not Reported |
|          | Atazanavir Sulfate | S | Not Reported |
|          | Truvada            | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 27-Jul-2009              | 7064343       | NON-EXPEDITED    | N                  |                 | US-ABBOTT-08P-163-0489481-00 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Screen False     | Norvir               |              |            | S           |              |                    |                 | Not Reported |
| Positive              | Atazanavir Sulfate   |              |            | S           |              |                    |                 | Not Reported |
|                       | Truvada              |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2009              | 7069544       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007653           |                      | 45 YR      | Unknown    | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Poisoning;                                          | Escitalopram Oxalate |              |            | S           | Oral         | 200 Mg, Once, Oral |                 | Not Reported |
| Fatigue; Intentional Overdose; Suicide Attempt; Tachycardia | Alcohol              |              |            | S           | Oral         | Once, Oral         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2009              | 7071329       | DIRECT           | N                  | OT              |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Impulse-Control Disorder; Libido Increased; Mania | Lexapro        |              |            | S           |              | 30 Mg. Once A Day  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2009              | 7076763       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007683           |                      | 45 YR      | Male       | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Intentional Self-Injury; | Escitalopram Oxalate |              |            | S           | Oral         | 200 Mg, Once, Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |                         |   |      |                      |              |
|----------------------------------------------|-------------------------|---|------|----------------------|--------------|
| Somnolence; Suicide Attempt; Vascular Injury | Sodium Selenite         | S | Oral | 200 Mg, Once, Oral   | Not Reported |
|                                              | Opipramol Hydrochloride | S | Oral | 250 Mg, Once, Oral   | Not Reported |
|                                              | Levothyroxine           | S | Oral | 1500 Mcg, Once, Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2009              | 7073233       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007543           |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Kidney Infection; Urinary Retention | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                                     | Duloxetine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2009              | 6706342       | EXPEDITED (15-DAY) | Y                  | CA, OT          | S08-FRA-00223-02     |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Abortion Induced; Maternal Drugs Affecting Foetus; Trisomy 21 | Escitalopram Oxalate                        |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |
|                                                               | Xanax (Alprazolam) - (Tablets) (Alprazolam) |              |            | C           |                |                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Jul-2009              | 7050124       | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-ABBOTT-09P-056-0584513-00 |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Hepatitis; Hepatitis  | Tarka                |              |            | S           | Oral         |                                          |                 | Not Reported |
|                       | Tarka                |              |            | S           | Oral         |                                          |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                                          |                 | Not Reported |
|                       | Bromazepam           |              |            | C           | Oral         | 1/4 Tablet, 1/4 Tablet, 1/2 Tablet Daily |                 | Not Reported |
|                       | Zopiclone            |              |            | C           |              |                                          |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|---------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------------------|-----------------|------------------------------|----------------|
| 30-Jul-2009                                                   | 7073454                                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007695                       |                                  | 70 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Seizure                                                       | Lexapro<br>Blood Pressure Medication<br>(Nos) |                    |                    | S<br>C          |                                  |                                  |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Jul-2009                                                   | 7073513                                       | EXPEDITED (15-DAY) | N                  | HO              | 1000007775                       |                                  | 20 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aphasia; Headache;<br>Movement Disorder;<br>Muscular Weakness | Lexapro                                       |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1d),<br>Oral  |                 | Not Reported                 |                |
|                                                               | Lexapro                                       |                    |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported                 |                |
|                                                               | Spironolactone                                |                    |                    | C               |                                  |                                  |                 | Not Reported                 |                |
|                                                               | Synthroid                                     |                    |                    | C               |                                  |                                  |                 | Not Reported                 |                |
|                                                               | Mircette                                      |                    |                    | C               |                                  |                                  |                 | Not Reported                 |                |
|                                                               | Albuterol (Inhalant)                          |                    |                    | C               |                                  |                                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 30-Jul-2009                                                   | 7075415                                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007727                       |                                  | 39 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Epilepsy                                                      | Escitalopram Oxalate                          |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |                |
|                                                               | Noiafren                                      |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 31-Jul-2009                                                   | 7069415                                       | EXPEDITED (15-DAY) | Y                  | CA, DE          | US-ABBOTT-09P-163-<br>0587271-00 |                                  | < 1 DAY         | Female                       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |                      |   |                |              |
|--------------------|----------------------|---|----------------|--------------|
| Neural Tube Defect | Escitalopram Oxalate | S | Transplacental | Not Reported |
|                    | Prenatal Vitamins    | S | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jul-2009              | 7076588       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007794           |                      | 35 YR      | Male       | DNK            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Decreased Appetite;<br>Weight Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2009              | 6691894       | EXPEDITED (15-DAY) | Y                  | OT              | US-ASTRAZENECA-<br>2008UW13210 |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Anger; Anxiety;    | Seroquel                |              |            | S           | Oral         |                    | 4 YR            | Not Reported |
| Aphasia; Asbestosis;        | Seroquel                |              |            | S           | Oral         |                    | 4 YR            | Not Reported |
| Attention                   | Xanax                   |              |            | S           |              |                    | 4 YR            | Not Reported |
| Deficit/Hyperactivity       | Xanax                   |              |            | S           |              |                    | 4 YR            | Not Reported |
| Disorder; Blood             | Xanax                   |              |            | S           |              |                    | 4 YR            | Not Reported |
| Cholesterol Abnormal;       | Xanax                   |              |            | S           |              |                    | 4 YR            | Not Reported |
| Blood Cholesterol           | Xanax                   |              |            | S           |              |                    | 4 YR            | Not Reported |
| Increased; Blood            | Wellbutrin              |              |            | S           |              |                    | 4 YR            | Not Reported |
| Triglycerides Abnormal;     | Wellbutrin              |              |            | S           |              |                    | 4 YR            | Not Reported |
| Bruxism; Constipation;      | Wellbutrin              |              |            | S           |              |                    | 4 YR            | Not Reported |
| Decreased Appetite;         | Lexapro                 |              |            | S           |              |                    | 3 YR            | Not Reported |
| Depression;                 | Lexapro                 |              |            | S           |              |                    | 3 YR            | Not Reported |
| Disorientation;             | Restoril                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Dissociative Disorder;      | Restoril                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Emotional Distress;         | Restoril                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Feeling Abnormal; Gait      | Cymbalta                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Disturbance; Hallucination; | Cymbalta                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Headache; Hostility;        | Cymbalta                |              |            | S           |              |                    | 4 YR            | Not Reported |
| Hyperhidrosis;              | Zoloft                  |              |            | S           |              |                    |                 | Not Reported |
| Hypertension;               | Neurontin               |              |            | S           |              |                    |                 | Not Reported |
| Hypothyroidism; Insomnia;   | Neurontin               |              |            | S           |              |                    |                 | Not Reported |
| Lethargy; Loss Of           | Neurontin               |              |            | S           |              |                    |                 | Not Reported |
| Personal Independence In    | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                  |                                           |                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Daily Activities; Mental Disorder; Muscle Spasms; Muscle Twitching; Nightmare; Overdose; Pain; Pallor; Pancreatitis; Panic Disorder; Paranoia; Pyrexia; Regurgitation; Renal Failure; Restless Legs Syndrome; Road Traffic Accident; Screaming; Seizure; Sleep Apnoea Syndrome; Stress; Suicidal Ideation; Suicide Attempt; Tachycardia; Tardive Dyskinesia; Thyroid Disorder; Treatment Noncompliance; Urinary Incontinence; Vomiting; Weight Decreased; Withdrawal Syndrome | Effexor<br>Lisinopril<br>Fenofibrate<br>Fenofibrate<br>Levothyroxine<br>Ambien<br>Hydrochlorothiazide<br>Acetaminophen\Hydrocodone<br>Bitartrate<br>Carisoprodol | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2009              | 7071083       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-SYNTHELABO-A02200901908 |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block Second Degree; Electrocardiogram Qt Prolonged; Malaise | Stilnox              |              |            | S           | Oral         |                    | 8 DAY           | Not Reported |
|                                                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    | 8 DAY           | Not Reported |
|                                                                               | Acetaminophen        |              |            | S           | Oral         | 6 Df               | 8 DAY           | Not Reported |
|                                                                               | Cyamemazine          |              |            | S           | Oral         |                    | 8 DAY           | Not Reported |
|                                                                               | Duphalac             |              |            | S           | Oral         | 6 Df               | 8 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2009              | 7078987       | DIRECT           | N                  | OT              |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|-------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Menorrhagia; Weight Increased                         |                         | Lexapro                   | S                           | Oral                     | 1 Tab Daily Po                |                               | Forest                   |                     |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Aug-2009                                           | 6986675                 | EXPEDITED (15-DAY)        | Y                           | HO                       | IE-ABBOTT-09P-229-0571118-00  |                               |                          | Male                | IRL                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gastrointestinal Haemorrhage                          | Lexapro                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                       | Nu-Seals Aspirin        |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                       | Perindopril             |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                       | Glucophage              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                       | Levothyroxine Sodium    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                       | Lansoprazole            |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                       | Lactulose               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Aug-2009                                           | 7129951                 | DIRECT                    | N                           | CA, DS, HO               |                               |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cleft Lip And Palate; Maternal Drugs Affecting Foetus | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Aug-2009                                           | 7081741                 | DIRECT                    | N                           | DE                       |                               |                               | 41 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide; Gun Shot Wound                     | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Aug-2009                                           | 7085763                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | 100007653                     |                               | 45 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                      |   |      |                    |              |
|------------------------------------------------------------------------|----------------------|---|------|--------------------|--------------|
| Alcohol Poisoning;                                                     | Escitalopram Oxalate | S | Oral | 200 Mg, Once, Oral | Not Reported |
| Fatigue; Hyperhidrosis;                                                | Alcohol              | S | Oral | Once, Oral         | Not Reported |
| Hypertension; Intentional<br>Overdose; Suicide<br>Attempt; Tachycardia |                      |   |      |                    |              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Aug-2009                       | 7074178                 | EXPEDITED (15-DAY)        | N                           | HO                       | A0800751A                     |                               | 55 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatitis                         | Lamictal                |                           |                             | S                        | Unknown                       |                               |                          | Glaxosmithkline     |                         |
|                                   | Lexapro                 |                           |                             | S                        | Unknown                       |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Aug-2009                       | 7081059                 | EXPEDITED (15-DAY)        | N                           | HO                       | 1000007936                    |                               | 45 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cholelithiasis; Sepsis            | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg,1 In 1 D),Oral   |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Aug-2009                       | 7081530                 | DIRECT                    | N                           | HO                       |                               |                               | 21 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aphasia; Clonus                   | Lexapro                 |                           |                             | S                        | Oral                          | 10mg Daily Mouth              |                          | Not Reported        |                         |
|                                   | Mircette                |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Spironolactone          |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                   | Synthroid               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 06-Aug-2009                       | 7082703                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000007825                    |                               | 59 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                      |                                                        |                  |              |                                            |                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|------------------|--------------|--------------------------------------------|--------------------------------------------------------------|
| Confusional State;<br>Generalised Tonic-Clonic<br>Seizure; Loss Of<br>Consciousness; Malaise;<br>Oedema Peripheral;<br>Tongue Biting | Escitalopram Oxalate<br>Disulfiram<br>Glucor<br>Seglor | S<br>S<br>C<br>C | Oral<br>Oral | Oral<br>500 Mg (500 Mg, 1 In 1 D),<br>Oral | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|------------------|--------------|--------------------------------------------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2009              | 7082810       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000007857           |                      | 37 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                               | <u>Product</u>                                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                                                   |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|----------------------------------|-----------------|----------------------------------------------------------------------------------------------|
| Diarrhoea; Myalgia;<br>Nausea; Saliva<br>Discolouration; Salivary<br>Hypersecretion | Escitalopram Oxalate<br>Plavix<br>Exetrol<br>Niaspan<br>Alby-E<br>Lipitor<br>Ramipril |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2009              | 7082813       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007882           |                      | 56 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>                                                                                                                                                                                                           | <u>Duration</u> | <u>Mfr</u>                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------|------------|-----------------------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------|
| Confusional State;<br>Delusion; Encephalopathy;<br>Generalised Tonic-Clonic<br>Seizure; Hyponatraemia;<br>Postictal State; Renal<br>Tubular Disorder; Urine<br>Sodium Increased;<br>Vomiting Projectile | Escitalopram Oxalate<br>Etifoxine<br>Cranberry<br>Herbal Nos<br>Ginseng |              |            | S<br>S<br>S<br>S<br>C | Oral<br>Oral<br>Oral<br>Oral | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral<br>2 Dosage Firns (2 Dosage<br>Forms, 1 In 1 D), Oral<br>4 Dosage Forms (4<br>Dosage Forms, 1 In 1 D),<br>Oral<br>1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D)<br>Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |              |
|----------------|---|--------------|
| Elisor         | C | Not Reported |
| Esberiven Fort | C | Not Reported |
| Exomuc         | C | Not Reported |
| Rhinofluimucil | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2009              | 7082817       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007858           |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Atrioventricular Block<br>Second Degree;<br>Electrocardiogram Qt<br>Prolonged; Loss Of<br>Consciousness; Malaise | Escitalopram Oxalate                            |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |
|                                                                                                                  | Cyamemazine                                     |              |            | S           | Oral         | 50 Mg (25 Mg, 2 In 1 D),<br>Oral                      |                 | Not Reported |
|                                                                                                                  | Zolpidem                                        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                           |                 | Not Reported |
|                                                                                                                  | Propoxyphene Hydrochloride<br>And Acetaminophen |              |            | S           | Oral         | 6 Dosage Forms (6<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                  | Duphalac                                        |              |            | S           | Oral         | 6 Dosage Forms (6<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2009              | 7081946       | EXPEDITED (15-DAY) | Y                  | DS              | 1000007969           |                      | 58 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Agitation; Anhedonia;<br>Apathy; Crying;<br>Depressed Mood; Feeling<br>Guilty; Insomnia;<br>Obsessive Rumination;<br>Obsessive Thoughts | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                         | Zolpidem             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                         | Lexomil (Tablets)    |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Aug-2009              | 7087748       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005396           |                      | 52 YR      | Male       | DNK            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|-----------------|----------------|
| Bruxism; Drug Ineffective;<br>Dysphemia; Tremor                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg, (10 Mg,1 In 1 D),Oral |                 | Not Reported    |                |
|                                                                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2009                                                                               | 6919577                 | NON-EXPEDITED      | N                  |                 | A0759303A            |                              | 71 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;<br>Rash; Skin Discolouration;<br>Therapeutic Response<br>Unexpected | Paxil                   |                    |                    | S               | Unknown              |                              | 7 YR            | Glaxosmithkline |                |
|                                                                                           | Valtrex                 |                    |                    | S               | Oral                 | 1g Three Times Per Day       | 1 WEEK          | Glaxosmithkline |                |
|                                                                                           | Lexapro                 |                    |                    | S               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Cozaar                  |                    |                    | C               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Antidepressant          |                    |                    | C               |                      |                              |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2009                                                                               | 7076621                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000007808           |                              | 75 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>      |                |
| Diabetic Coma                                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported    |                |
|                                                                                           | Loftyl(Tablets)         |                    |                    | C               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Omeprazole              |                    |                    | C               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Omeprazole              |                    |                    | C               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Metformin Hydrochloride |                    |                    | C               |                      |                              |                 | Not Reported    |                |
|                                                                                           | Glucophage              |                    |                    | C               |                      |                              |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Aug-2009                                                                               | 7083202                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000007978           |                              | 85 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>      |                |
| Infection; Serotonin                                                                      | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral  |                 | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                    |   |              |
|----------|--------------------|---|--------------|
| Syndrome | Midon              | C | Not Reported |
|          | Lipitor            | C | Not Reported |
|          | Aspirin            | C | Not Reported |
|          | Calcichew D3 Forte | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 11-Aug-2009              | 7066907       | EXPEDITED (15-DAY) | Y                  | DE              | US-SANOFI-SYNTHELABO-A03200903164 |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound | Ambien Cr      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                   | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Aug-2009              | 7077896       | EXPEDITED (15-DAY) | Y                  | HO              | AU-ASTRAZENECA-2009SE06774 |                      | 49 YR      | Female     | AUS            |

| <u>Preferred Term</u>                         | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Flushing; Mydriasis; Somnambulism; Somnolence | Seroquel                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Stilnox                                |              |            | S           | Oral         |                    | 8 DAY           | Not Reported |
|                                               | Valium                                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Alcohol                                |              |            | S           |              |                    |                 | Not Reported |
|                                               | Lexapro                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Codeine Phosphate\Doxylamine Succinate |              |            | S           |              |                    |                 | Not Reported |
|                                               | Caltrate                               |              |            | C           |              |                    |                 | Not Reported |
|                                               | Fish Oil                               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2009              | 7084609       | EXPEDITED (15-DAY) | Y                  | HO              | 1000008012           |                      | 42 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Blood Alkaline Phosphatase Increased; Drug Interaction; Drug | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral 10 Mg (10 Mg, 1 In 1 D) Oral |                 | Not Reported |

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|                                                      |   |      |                                                               |              |
|------------------------------------------------------|---|------|---------------------------------------------------------------|--------------|
| Level Increased; Gamma-Glutamyltransferase Increased |   | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral 10 Mg (10 Mg, 1 In 1 D) Oral |              |
| Omeprazole                                           | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2009              | 7097488       | DIRECT           | Y                  | DE              |                      |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Completed Suicide; Intentional Overdose; Self-Medication; Toxicity To Various Agents | Celexa         |              |            | S           |              | Not Prescribed For The Client |                 | Not Reported |
|                                                                                      | Lexapro        |              |            | S           | Oral         | 20 Mg At Bedtime Po           |                 | Not Reported |
|                                                                                      | Lamictal       |              |            | S           |              |                               |                 | Not Reported |
|                                                                                      | Xanax          |              |            | S           |              |                               |                 | Not Reported |
|                                                                                      | Gabapentin     |              |            | S           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 6906823       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2009CG00321 |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder; Fall; Haematoma; Head Injury; Hypotension; Orthostatic Hypotension; Wound | Atacand                     |              |            | S           | Oral         |                    | 1 YR            | Not Reported |
|                                                                                                    | Rivotril                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Levomepromazine             |              |            | S           | Oral         |                    | 30 YR           | Not Reported |
|                                                                                                    | Amitriptyline Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Bromazepam                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Efferalgan Codeine          |              |            | S           | Oral         |                    | 1 YR            | Not Reported |
|                                                                                                    | Vastarel                    |              |            | S           |              |                    | 1 YR            | Not Reported |
|                                                                                                    | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                    | Symbicort                   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                       |   |      |  |  |  |        |  |              |
|-----------------------|---|------|--|--|--|--------|--|--------------|
| Omeprazole            | C |      |  |  |  |        |  | Not Reported |
| Sinemet               | C | Oral |  |  |  | 12 DAY |  | Not Reported |
| Sinemet               | C | Oral |  |  |  |        |  | Not Reported |
| Actonel               | C |      |  |  |  |        |  | Not Reported |
| Calcium Carbonate     | C |      |  |  |  |        |  | Not Reported |
| Prevican (Fluindione) | C |      |  |  |  |        |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7058190       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007243           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Lipase Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                 | Nordette             |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7085596       | DIRECT           | N                  | DS              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Feeling Abnormal; Imprisonment; Suicidal Ideation; Thinking Abnormal; Violence-Related Symptom | Clonazepam     |              |            | S           |              | 1 Once Daily       |                 | Barr         |
|                                                                                                | Lexapro        |              |            | S           |              | 1 Once Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7085854       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007984           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Intracranial Pressure Increased; Visual Acuity | Escitalopram Oxalate |              |            | S           |              | 0.3333 Dosage Forms (1 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                  |   |      |                        |              |
|----------------------------|----------------------------------|---|------|------------------------|--------------|
| Reduced; Vitreous Floaters | Ethinyl Estradiol\Levonorgestrel | S | Oral | Dosage Forms,1 In 3 D) | Not Reported |
|                            | Prazepam                         | S |      | Oral<br>(As Required)  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7085858       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007986           |                      | 54 YR      | Male       | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Amnesia; Epilepsy; Malaise | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                            | Zyprexa              |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                            | Stilnox              |              |            | C           |              |                             |                 | Not Reported |
|                            | Lercan               |              |            | C           |              |                             |                 | Not Reported |
|                            | Pariet               |              |            | C           |              |                             |                 | Not Reported |
|                            | Flonase              |              |            | C           |              |                             |                 | Not Reported |
|                            | Furosemide           |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7085971       | DIRECT           | N                  | DE              |                      |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zoloft         |              |            | S           |              | 200mg              |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | 10mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2009              | 7086337       | DIRECT           | N                  | RI              |                      |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Imprisonment; Suicidal Ideation; Violence-Related Symptom | Clonazepam     |              |            | S           | Oral         | 1 Once Daily Po    |                 | Not Reported |
|                                                           | Lexapro        |              |            | S           | Oral         | 1 Once Daily Po    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Aug-2009                                                                                                                                                | 7096721                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000006645           |                                                                                                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Congenital<br>Pyelocaliectasis;<br>Hydronephrosis; Maternal<br>Drugs Affecting Foetus;<br>Maternal Exposure During<br>Breast Feeding | Lexapro                                |                    |                    | S               | Transplacental       | 5 Mg (5 Mg, 1 In 1 D),<br>Transplacental, 5 Mg (5<br>Mg, 1 In 1 D),<br>Transammary                   |                 | Not Reported |                |
|                                                                                                                                                            |                                        |                    |                    |                 | Transplacental       | 5 Mg (5 Mg, 1 In 1 D),<br>Transplacental, 5 Mg (5<br>Mg, 1 In 1 D),<br>Transammary                   |                 |              |                |
|                                                                                                                                                            | Levothyroxine                          |                    |                    | C               |                      |                                                                                                      |                 | Not Reported |                |
|                                                                                                                                                            | Prenatal Vitamins                      |                    |                    | C               |                      |                                                                                                      |                 | Not Reported |                |
|                                                                                                                                                            | Pulmicort Respules                     |                    |                    | C               |                      |                                                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2009                                                                                                                                                | 7007282                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000006211           |                                                                                                      | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Cancer; Breast<br>Cancer In Situ; Hot Flush;<br>Overdose                                                                                            | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 25 Mg (25 Mg, 1<br>In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                            |                                        |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 25 Mg (25 Mg, 1<br>In 1 D), Oral |                 |              |                |
|                                                                                                                                                            |                                        |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral, 25 Mg (25 Mg, 1<br>In 1 D), Oral |                 |              |                |
|                                                                                                                                                            | Tamoxifen Citrate                      |                    |                    | S               |                      |                                                                                                      |                 | Not Reported |                |
|                                                                                                                                                            | Ambien                                 |                    |                    | C               |                      |                                                                                                      |                 | Not Reported |                |
|                                                                                                                                                            | Oral Contraceptives (Nos)<br>(Tablets) |                    |                    | C               |                      |                                                                                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------|-----------------|-----------------|----------------|
| 13-Aug-2009                                                   | 7080655              | EXPEDITED (15-DAY) | N                  | HO              | B0588059A            |                                                               | 32 YR           | Female          | NOR            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Neuroleptic Malignant Syndrome; Pruritus; Rash Maculo-Papular | Lamictal             |                    |                    | S               | Unknown              |                                                               |                 | Glaxosmithkline |                |
|                                                               | Ciprallex            |                    |                    | S               | Unknown              | 10mg Per Day                                                  |                 | Not Reported    |                |
|                                                               | Buspar               |                    |                    | S               | Unknown              | 40mg Per Day                                                  |                 | Not Reported    |                |
|                                                               | Ritalin              |                    |                    | S               | Unknown              | 60mg Per Day                                                  |                 | Glaxosmithkline |                |
|                                                               | Zyprexa              |                    |                    | S               | Unknown              | 15mg Per Day                                                  |                 | Not Reported    |                |
|                                                               | Chlorprothixene      |                    |                    | S               | Unknown              | 30mg Per Day                                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Aug-2009                                                   | 7079660              | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000007763           |                                                               | 66 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Loss Of Consciousness; Somnolence           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>5 Mg (5 Mg,1 In 1 D),Oral      |                 | Not Reported    |                |
|                                                               |                      |                    |                    |                 | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral ; 1 YR<br>5 Mg (5 Mg,1 In 1 D),Oral |                 |                 |                |
|                                                               | Clonidine            |                    |                    | S               | Oral                 | Oral                                                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 14-Aug-2009                                                   | 7094796              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008145           |                                                               | 43 YR           | Female          | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>      |                |
| Homicidal Ideation; Loss Of Consciousness; Suicidal Ideation  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                              |                 | Not Reported    |                |
|                                                               | Klonopin             |                    |                    | S               | Oral                 | 0.25 Mg (0.25 Mg, 1 In 1 D), Oral                             |                 | Not Reported    |                |
|                                                               | Alcohol              |                    |                    | S               |                      |                                                               |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Aug-2009                                                                                                                                                                                               | 7094902              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008126           |                                                              | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                                                                                                                                   | Lexapro              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                  |                 | Not Reported |                |
|                                                                                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral                                 |                 | Not Reported |                |
|                                                                                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                  |                 | Not Reported |                |
|                                                                                                                                                                                                           | Tegretol             |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                           | Zonegran             |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                           | Albuterol            |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                           | Advair Hfa           |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                           | Elavil               |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                                                                           | Claritin             |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Aug-2009                                                                                                                                                                                               | 7095232              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008034           |                                                              | 28 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Bile Duct Necrosis                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D)                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Aug-2009                                                                                                                                                                                               | 7014522              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006365           |                                                              | 35 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Anxiety;<br>Cognitive Disorder;<br>Depressed Mood;<br>Gastrointestinal<br>Haemorrhage;<br>Haematemesis;<br>Hypertension; Irritability;<br>Suicidal Ideation; Suicide<br>Attempt; Suspiciousness; | Escitalopram Oxalate |                    |                    | S               | Oral                 | Built Up To 20 Milligram<br>Daily (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thalassaemia Minor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2009              | 7095219       | DIRECT           | Y                  | OT              |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|------------|
| Anxiety; Diarrhoea;<br>Dizziness; Dry Mouth; Eye<br>Disorder; Formication;<br>Hyperhidrosis; Insomnia;<br>Mydriasis; Tachycardia;<br>Tremor | Lexapro        |              |            | S           | Oral         | 10 Mg At Bedtime Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2009              | 7095544       | DIRECT           | Y                  | HO              |                      |                      | 33 YR      | Male       | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Chest Pain; Delusion;<br>Panic Reaction; Suicidal<br>Ideation | Lexapro<br>Buspar<br>Trazodone Hydrochloride |              |            | S<br>C<br>C | Oral         | 10mg Qday Po       |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Aug-2009              | 7056403       | EXPEDITED (15-DAY) | Y                  | HO              | ES-PFIZER INC-<br>2009237098 |                      | 40 YR      | Unknown    | ESP            |

| <u>Preferred Term</u>                                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u>  | <u>Mfr</u>             |
|-------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|------------------|------------------------|
| Abdominal Distension;<br>Abdominal Pain; Ascites;<br>Oedema Peripheral;<br>Oliguria | Champix<br>Cipralex |              |            | S<br>S      | Oral<br>Oral | Unk<br>Unk         | 20 DAY<br>20 DAY | Pfizer<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 18-Aug-2009              | 7084714       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14407712 |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                         |                  |                                                                |
|----------------------------|-----------------------------------------|------------------|----------------------------------------------------------------|
| Drug Screen False Positive | Reyataz<br>Norvir<br>Truvada<br>Lexapro | S<br>S<br>S<br>S | Bristol Myers Squibb<br>Abbott<br>Not Reported<br>Not Reported |
|----------------------------|-----------------------------------------|------------------|----------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2009              | 7097677       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 001460               |                      | 12 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Chorea; Clonus;<br>Dyskinesia; Dysphemia;<br>Dystonia; Extensor Plantar<br>Response; Extrapyrimal<br>Disorder; Hyperreflexia;<br>Hypertonia; Muscle<br>Rigidity; Posture<br>Abnormal; Tremor | Alprazolam (Alprazolam) |              |            | S           |              | (One Time Dose Of<br>0.25mg) 1 Day Until Not<br>Continuing;     |                 | Not Reported |
|                                                                                                                                                                                              | Escitalopram Oxalate    |              |            | S           |              | (10 Mg, One Time Doe Of<br>10 Mg) 1 Day Until Not<br>Continuing |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2009              | 7097697       | EXPEDITED (15-DAY) | Y                  | HO              | 1000008187           |                      | 47 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Gastrointestinal Disorder;<br>Generalised Tonic-Clonic<br>Seizure;<br>Hypomagnesaemia;<br>Overdose | Escitalopram Oxalate                                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |
|                                                                                                    | Bactrim Forte                                        |              |            | S           | Oral         | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                    | Bactrim Forte                                        |              |            | S           | Oral         | Oral                                                  |                 | Not Reported |
|                                                                                                    | Imovane                                              |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Levothyrox                                           |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Dedrogyl                                             |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Epoetin Beta                                         |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Racecadotril                                         |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Xyzall                                               |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                                    | Calcidose                                            |              |            | C           |              |                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------------------------------------------------------------|-----------------|-----------------|----------------|
| 19-Aug-2009                                                                          | 6966967                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000005521                               |                                                                            | 79 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>      |                |
| Haemophagocytic<br>Lymphohistiocytosis;<br>Pancytopenia                              | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                           |                 | Not Reported    |                |
|                                                                                      | Depakene                |                    |                    | S               | Oral                                     | 1000 Mg (500 Mg, 2 In 1<br>D), Oral                                        |                 | Not Reported    |                |
|                                                                                      | Fotemustine             |                    |                    | S               | Intravenous (not<br>otherwise specified) | 25.7143 Mg (180 Mg, 1 In<br>1 Wk) Intravenous (Not<br>Otherwise Specified) |                 | Not Reported    |                |
|                                                                                      | Lanzor (Capsules)       |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
|                                                                                      | Furosemide (Tablets)    |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
|                                                                                      | Aprovel (Tablets)       |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
|                                                                                      | Tahor (Tablets)         |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Aug-2009                                                                          | 7085368                 | EXPEDITED (15-DAY) | N                  | OT              | A0802683A                                |                                                                            | 60 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>      |                |
| Anosmia                                                                              | Wellbutrin              |                    |                    | S               |                                          |                                                                            |                 | Glaxosmithkline |                |
|                                                                                      | Lexapro                 |                    |                    | S               | Oral                                     | 20mg Per Day                                                               |                 | Not Reported    |                |
|                                                                                      | Verapamil Hydrochloride |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
|                                                                                      | Hydrochlorothiazide     |                    |                    | C               |                                          |                                                                            |                 | Not Reported    |                |
|                                                                                      | Prilosec                |                    |                    | C               |                                          |                                                                            |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Aug-2009                                                                          | 7085417                 | EXPEDITED (15-DAY) | Y                  | HO              | D0062649A                                |                                                                            | 24 YR           | Female          | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>      |                |
| Altered State Of<br>Consciousness;<br>Intentional Overdose;<br>Intentional Overdose; | Lamotrigine             |                    |                    | S               | Oral                                     | 7900mg Per Day                                                             | 1 DAY           | Glaxosmithkline |                |
|                                                                                      | Citalopram Hydrobromide |                    |                    | S               | Oral                                     |                                                                            | 1 DAY           | Not Reported    |                |
|                                                                                      | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 500mg Per Day                                                              | 1 DAY           | Not Reported    |                |

# FDA Adverse Event Reporting System

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|                            |                         |   |      |                |       |              |
|----------------------------|-------------------------|---|------|----------------|-------|--------------|
| Nystagmus; Suicide Attempt | Zolpidem                | S | Oral | 200mg Per Day  | 1 DAY | Not Reported |
|                            | Melperone Hydrochloride | S | Oral | 2200mg Per Day | 1 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2009              | 6936796       | EXPEDITED (15-DAY) | Y                  | OT              | 1000004953           |                      | 58 YR      | Male       | DNK            |

| <u>Preferred Term</u>                               | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Dysuria; Urinary Retention | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                     |                               |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |
|                                                     | Escitalopram Oxalate          |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                              |                 | Not Reported |
|                                                     | Trihexyphenidyl Hydrochloride |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                              |                 | Not Reported |
|                                                     | Trihexyphenidyl Hydrochloride |              |            | S           | Oral         | Oral                                                          |                 | Not Reported |
|                                                     | Mirtazapine                   |              |            | S           | Oral         | 45 Mg (45 Mg, 1 In 1 D),<br>Oral                              |                 | Not Reported |
|                                                     | Risperdal                     |              |            | S           | Oral         | 4 Mg (4 Mg, 1 In 1 D), Oral                                   |                 | Not Reported |
|                                                     | Alprazolam                    |              |            | C           |              |                                                               |                 | Not Reported |
|                                                     | Valpromide                    |              |            | C           |              |                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Aug-2009              | 7100202       | EXPEDITED (15-DAY) | N                  | CA, OT          | 1000008263           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Congenital Anomaly;<br>Craniosynostosis;<br>Developmental Delay;<br>Injury; Maternal Drugs<br>Affecting Foetus; Talipes | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |
|                                                                                                                                                  | Paxil          |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|------------------------------|----------------|
| 21-Aug-2009                                                                                                                                                                | 6903906                            | EXPEDITED (15-DAY) | Y                  | DE              | 1000003571           |                          | 21 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide;<br>Intentional Overdose                                                                                                                                 | Escitalopram Oxalate<br>Quetiapine |                    |                    | S<br>S          |                      |                          |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Aug-2009                                                                                                                                                                | 7097833                            | DIRECT             | N                  | OT              |                      |                          | 17 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Behaviour;<br>Agitation; Alopecia;<br>Amnesia; Anger; Impulse-<br>Control Disorder;<br>Trichotillomania                                                           | Lexapro                            |                    |                    | S               | Oral                 | One Tablet Daily Po      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Aug-2009                                                                                                                                                                | 7098536                            | DIRECT             | N                  | OT              |                      |                          | 34 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                   |                |
| Cognitive Disorder;<br>Contusion; Discomfort;<br>Fall; Fatigue; Hypotension;<br>Impaired Work Ability;<br>Musculoskeletal Stiffness;<br>Pruritus; Somnolence;<br>Urticaria | Lexapro                            |                    |                    | S               | Oral                 | 2.5 Mg Once Daily, Am Po |                 | Forest                       |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 21-Aug-2009                                                                                                                                                                | 7102384                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000008217           |                          | 27 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>                   |                |
| Loss Of Consciousness                                                                                                                                                      | Escitalopram Oxalate               |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D), |                 | Not Reported                 |                |

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|                                                                                                                                                                                                                                           |                                       | Pulmicort (Solution)<br>Cypretyl (Tablets) |                    | C<br>C          |                                  | Oral                                                             |                 |              | Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------------|--------------------|-----------------|----------------------------------|------------------------------------------------------------------|-----------------|--------------|------------------------------|
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                         | <u>Case Type</u>                           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 24-Aug-2009                                                                                                                                                                                                                               | 7084009                               | EXPEDITED (15-DAY)                         | N                  | OT              | 1000007893                       |                                                                  | 47 YR           | Female       | USA                          |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                        | <u>Comp.</u>                               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                              |
| Angle Closure Glaucoma;<br>Asthenia; Disease<br>Recurrence; Dizziness;<br>Dry Mouth; Eye Movement<br>Disorder; Fatigue; Feeling<br>Hot; Headache;<br>Nystagmus; Pallor;<br>Peripheral Coldness;<br>Restless Legs Syndrome;<br>Tachycardia | Lexapro                               |                                            |                    | S               | Oral                             | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                 |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Lamictal                              |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Abilify                               |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Albuterol (Aerosol For<br>Inhalation) |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Allegra                               |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                         | <u>Case Type</u>                           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 24-Aug-2009                                                                                                                                                                                                                               | 7103396                               | EXPEDITED (15-DAY)                         | N                  | OT              | 1000008333                       |                                                                  |                 | Male         | DNK                          |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>                        | <u>Comp.</u>                               | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                              |
| International Normalised<br>Ratio Decreased                                                                                                                                                                                               | Escitalopram Oxalate                  |                                            |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           |                                       |                                            |                    |                 | Oral                             | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |                              |
|                                                                                                                                                                                                                                           | Warfarin Sodium                       |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Paracetamol                           |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Concor                                |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
|                                                                                                                                                                                                                                           | Sanval                                |                                            |                    | C               |                                  |                                                                  |                 | Not Reported |                              |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>                         | <u>Case Type</u>                           | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u>               |
| 25-Aug-2009                                                                                                                                                                                                                               | 7096260                               | NON-EXPEDITED                              | N                  |                 | US-ABBOTT-08P-163-<br>0484585-00 |                                                                  | 66 YR           | Female       | USA                          |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Alopecia                                                                                                                                                                                             | Synthroid               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Synthroid               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Lexapro                 |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Lexapro                 |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Rosuvastatin Calcium    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2009                                                                                                                                                                                          | 7068211                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000007541            |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Failure;<br>Drug Interaction                                                                                                                                                             | Escitalopram Oxalate    |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Lamotrigine             |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Phenytoin               |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2009                                                                                                                                                                                          | 7097274                 | EXPEDITED (15-DAY) | N                  | HO              | AU-JNJFOC-20090805657 |                      |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Cogwheel Rigidity;<br>Hyperglycaemia;<br>Hypophagia; Hypotension;<br>Mobility Decreased;<br>Neuroleptic Malignant<br>Syndrome; Pyrexia;<br>Tachycardia | Risperidone             |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Amisulpride             |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Donepezil Hydrochloride |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Quetiapine              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Simvastatin             |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Caltrate                |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Aspirin                 |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Cholecalciferol         |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
|                                                                                                                                                                                                      | Metformin Hydrochloride |                    |                    | C               | Unknown               |                      |                 | Not Reported |                |
| Novomix 30                                                                                                                                                                                           |                         |                    | C                  | Subcutaneous    | 16 Unit Daily         |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2009              | 7108377       | EXPEDITED (15-DAY) | Y                  | DE, LT          | 1000008358           |                      | 56 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <u>Product</u>                                                                                                                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                              | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------------------------------|--------------|-------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------|
| Abnormal Behaviour;<br>Alveolitis; Aspiration;<br>Blood Calcium Decreased;<br>Blood Chloride<br>Decreased; Cardiogenic<br>Shock; Cholestasis;<br>Coma; Disorientation;<br>Disturbance In Attention;<br>Fall; Haemoglobin<br>Decreased;<br>Haemophagocytic<br>Lymphohistiocytosis;<br>Hepatic Steatosis;<br>Hyponatraemia; Interstitial<br>Lung Disease; Lung<br>Disorder; Pancytopenia;<br>Pleural Neoplasm;<br>Proteinuria; Seizure; Sinus<br>Tachycardia; Urinary<br>Incontinence | Escitalopram Oxalate<br><br>Pneumorel<br>Biocalyptol (Pholcodine)<br>Antarene<br>Rhinofluimucil<br>Noctran<br>Temesta (Lorazepam)<br>Celestene (France)<br>Thiovalone |              |            | S<br><br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral         | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2009              | 7108761       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008427           |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>          | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                       |
|-----------------------|--------------------------------------------------|--------------|------------|----------------------|--------------|----------------------------------|-----------------|------------------------------------------------------------------|
| Cataract              | Lexapro<br><br>Singulair<br>Flonase<br>Synthroid |              |            | S<br><br>C<br>C<br>C | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------------------------------------------------|-----------------|--------------|----------------|
| 28-Aug-2009                                                         | 6954279              | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-09P-056-0563236-00          |                                                                | 79 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Leukopenia; Pancytopenia; Thrombocytopenia                 | Depakene             |                    |                    | S               | Oral                                  |                                                                |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                                  |                                                                |                 | Not Reported |                |
|                                                                     | Fotemustine          |                    |                    | S               | Intravenous (not otherwise specified) |                                                                |                 | Not Reported |                |
|                                                                     | Aprovel              |                    |                    | C               | Oral                                  |                                                                |                 | Not Reported |                |
|                                                                     | Tahor                |                    |                    | C               | Oral                                  |                                                                |                 | Not Reported |                |
|                                                                     | Lansoprazole         |                    |                    | C               | Oral                                  |                                                                |                 | Not Reported |                |
|                                                                     | Furosemide           |                    |                    | C               | Oral                                  |                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2009                                                         | 7052880              | EXPEDITED (15-DAY) | Y                  | HO              | 1000007187                            |                                                                | 40 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Ascites; Muscle Strain; Oedema Peripheral; Oliguria | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 10 Mg (10 Mg, 1 In 1 D), Oral                                  |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 15 Mg (15 Mg, 1 In 1 D), Oral                                  |                 | Not Reported |                |
|                                                                     | Varenicline Tartrate |                    |                    | S               | Oral                                  | 0.5 Mg (0.5 Mg, 1 In 1 D), Oral; 1 Mg (0.5 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                     |                      |                    |                    |                 | Oral                                  | 0.5 Mg (0.5 Mg, 1 In 1 D), Oral; 1 Mg (0.5 Mg, 2 In 1 D), Oral |                 |              |                |
|                                                                     | Varenicline Tartrate |                    |                    | S               | Oral                                  | 2 Mg (1 Mg, 2 In 1 D), Oral                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2009                                                         | 7099103              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-26584               |                                                                |                 | Unknown      | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------|---------------------------|-----------------|--------------|----------------|
| Completed Suicide                                            | Zolpidem                |                    |                    | S               | Unknown                 | Unk, Unk                  |                 | Ranbaxy      |                |
|                                                              | Alprazolam              |                    |                    | S               | Unknown                 |                           |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate    |                    |                    | S               | Unknown                 |                           |                 | Not Reported |                |
|                                                              | Carbon Monoxide         |                    |                    | S               | Unknown                 |                           |                 | Not Reported |                |
|                                                              | Estrogens               |                    |                    | S               | Unknown                 |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Aug-2009                                                  | 7099491                 | EXPEDITED (15-DAY) | Y                  | OT              | US-ROCHE-652008         |                           | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicidal Ideation; Loss Of Consciousness; Suicidal Ideation | Klonopin                |                    |                    | S               | Oral                    |                           |                 | Roche        |                |
|                                                              | Lexapro                 |                    |                    | S               | Oral                    | Other Indication: Anxiety |                 | Not Reported |                |
|                                                              | Alcohol                 |                    |                    | S               | Unknown                 |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2009                                                  | 7100234                 | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-26713 |                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose                                         | Acetaminophen           |                    |                    | S               | Oral                    | Unk, Unk                  |                 | Ranbaxy      |                |
|                                                              | Oxcarbazepine           |                    |                    | S               | Oral                    |                           |                 | Ranbaxy      |                |
|                                                              | Zyprexa                 |                    |                    | S               | Oral                    |                           |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate    |                    |                    | S               | Oral                    |                           |                 | Not Reported |                |
|                                                              | Trazodone Hydrochloride |                    |                    | S               | Oral                    |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2009                                                  | 7100245                 | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009US-26728 |                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                      |   |      |          |              |
|-------------------|----------------------|---|------|----------|--------------|
| Completed Suicide | Acetaminophen        | S | Oral | Unk, Unk | Ranbaxy      |
|                   | Clonazepam           | S | Oral |          | Not Reported |
|                   | Lisinopril           | S | Oral |          | Ranbaxy      |
|                   | Hydrocodone          | S | Oral |          | Not Reported |
|                   | Escitalopram Oxalate | S | Oral |          | Not Reported |
|                   | Cocaine              | S | Oral |          | Not Reported |

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 31-Aug-2009                                                                                        | 7101724        | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-2009SE09380 |                      | 83 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Cardiac Failure; Dyspnoea; Electrocardiogram Qt Interval Abnormal; Torsade De Pointes | Nexium         |                    |                    | S               | Oral                       |                      | 5 DAY           | Not Reported |                |
|                                                                                                    | Cipralext      |                    |                    | S               | Oral                       |                      | 53 DAY          | Not Reported |                |
|                                                                                                    | Actos          |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                    | Simvastatin    |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                    | Torom          |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                    | Lisinopril     |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                    | Aspirin        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                    | Fosamax        |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 31-Aug-2009                                                                                | 7118191              | NON-EXPEDITED    | N                  | HO              | 175700USA            |                                                              | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Drug Ineffective; Dyspnoea; Therapeutic Product Effect Decreased | Lisinopril           |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
|                                                                                            | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                            |                      |                  |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2009              | 7102962       | EXPEDITED (15-DAY) | Y                  | OT              | NO-JNJFOC-20090808186 |                      |            | Female     | NOR            |

| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Blood Bilirubin Increased | Durogesic              |              |            | S           | Transdermal  | Over A Period Of 3 Years |                 | Not Reported |
|                           | Iron\Vitamins Nos      |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Eszopiclone            |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Levothyroxine Sodium   |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Unspecified Ingredient |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Tpn                    |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Arixtra                |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Cipralex               |              |            | S           | Unknown      |                          |                 | Not Reported |
|                           | Lovaza                 |              |            | S           | Unknown      |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2009              | 7109398       | DIRECT           | N                  | RI              |                      |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Amnesia; Anxiety; Body Temperature Fluctuation; Chills; Dry Eye; Dry Mouth; Dyspepsia; Fatigue; Fear; Feeling Abnormal; Formication; Hallucination; Heart Rate Increased; Hypoaesthesia; Influenza Like Illness; Insomnia; Loss Of Consciousness; Migraine; Muscle Contractions Involuntary; Mydriasis; Nausea; Oropharyngeal Pain; Pyrexia; Rash Generalised; Suicidal | Lexapro        |              |            | S           | Oral         | 10 Mg Per Day Po   | 1 DAY           | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ideation; Vision Blurred

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2009              | 7110656       | DIRECT           | N                  | HO              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Crying;<br>Dizziness; Fall | Lexapro        |              |            | S           |              | 10 Mg Once A Day   | 3 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Sep-2009              | 7116048       | EXPEDITED (15-DAY) | Y                  | HO              | TPG2009A00856        |                      | 83 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Bradycardia; Cardiac Failure; Dyspnoea; Electrocardiogram Qt Interval Abnormal; Pulmonary Embolism; Pulmonary Hypertension; Torsade De Pointes | Actos                                       |              |            | S           | Oral         | 45 Mg (45 Mg, 1 In 1 D), Per Oral |                 | Not Reported |
|                                                                                                                                                | Ciprallex                                   |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Per Oral | 52 DAY          | Not Reported |
|                                                                                                                                                | Nexium (Esomeprazole Magnesium)             |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D), Per Oral | 4 DAY           | Not Reported |
|                                                                                                                                                | Simcora (Simvastatin)                       |              |            | C           |              |                                   |                 | Not Reported |
|                                                                                                                                                | Torseamide                                  |              |            | C           |              |                                   |                 | Not Reported |
|                                                                                                                                                | Lisinopril (Lisinopril)                     |              |            | C           |              |                                   |                 | Not Reported |
|                                                                                                                                                | Acetylsalicylic Acid (Acetylsalicylic Acid) |              |            | C           |              |                                   |                 | Not Reported |
|                                                                                                                                                | Fosamax                                     |              |            | C           |              |                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2009              | 7082706       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007826           |                      | 38 YR      | Female     | MYS            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Supraventricular Tachycardia | Lexapro        |              |            | S           | Oral         | 30 Mg (10 Mg, 3 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                              |                |              |            |             | Oral         | 30 Mg (10 Mg, 3 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D),Oral |                 |              |

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|            |   |      |                                             |              |
|------------|---|------|---------------------------------------------|--------------|
| Lexapro    | S | Oral | D),Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
| Clonazepam | C |      |                                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Sep-2009              | 7107406       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2009264524 |                      | 69 YR      | Unknown    | FRA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Hydroxyzine Hydrochloride   |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                       | Escitalopram Oxalate        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Amitriptyline Hydrochloride |              |            | S           | Oral         | Unk                | 9 DAY           | Not Reported |
|                       | Ramipril                    |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                       | Zolpidem                    |              |            | C           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Sep-2009              | 7116254       | DIRECT           | N                  | OT              |                      |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Fatigue; Incorrect Dose Administered; Off Label Use | Lexapro        |              |            | S           | Oral         | 20mg 2.5 Times Po  |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2009              | 7043335       | EXPEDITED (15-DAY) | Y                  | OT              | 1000006949           |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Altered State Of Consciousness; Fall; Head Injury; Malaise; Orthostatic Hypotension; Syncope | Nebivolol Hydrochloride |              |            | S           | Oral         | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                              | Escitalopram Oxalate    |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral        |                 | Not Reported |
|                                                                                              | Brotizolam              |              |            | S           | Oral         | Oral                               |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2009              | 7108133       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-26971 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zolpidem Tartrate             |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Lamotrigine                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Phenazopyridine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ramelteon                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alprazolam                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ibuprofen                     |              |            | S           | Oral         |                    |                 | Ranbaxy      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2009              | 7108184       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-27327 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Acyclovir               |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                            | Risperidone             |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                            | Haloperidol             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Vancomycin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Lamotrigine             |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Metaxalone              |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Heparin                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Oxycodone               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Bupropion               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Clonidine               |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Methadone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Albuterol               |              |            | S           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2009              | 7108323       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-27296 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Zolpidem Tartrate    |              |            | S           |              |                    |                 | Ranbaxy      |
|                       | Chloral Hydrate      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Carisoprodol         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydrocodone          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Marijuana            |              |            | S           |              |                    |                 | Not Reported |
|                       | Cocaine              |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Carbamazepine        |              |            | S           |              |                    |                 | Not Reported |
|                       | Diazepam             |              |            | S           |              |                    |                 | Not Reported |
|                       | Nordazepam           |              |            | S           |              |                    |                 | Not Reported |
|                       | Morphine             |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 09-Sep-2009              | 7108326       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2009RR-27306 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen                         |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Aspirin                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Quetiapine                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ibuprofen                             |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Escitalopram Oxalate                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Caffeine Citrate                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Naproxen                              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Fexofenadine                          |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Butalbital Acetaminophen And Caffeine |              |            | S           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 09-Sep-2009                                                                         | 7109105                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2009FR36661      |                                  | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Hyponatraemia; Hypoxia;<br>Joint Injury; Skeletal Injury       | Hydrochlorothiazide/Valsartan |                    |                    | S               |                      | Unk                              |                 | Novartis     |                |
|                                                                                     | Ivabradine                    |                    |                    | S               |                      | Unk                              |                 | Not Reported |                |
|                                                                                     | Escitalopram Oxalate          |                    |                    | S               |                      | 1 Df, Qd                         |                 | Not Reported |                |
|                                                                                     | Nicardipine Hydrochloride     |                    |                    | C               |                      | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2009                                                                         | 6906497                       | EXPEDITED (15-DAY) | Y                  | CA              | 1000003668           |                                  |                 | Male         | IRL            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Cleft<br>Lip; Cleft Palate; Maternal<br>Condition Affecting Foetus | Lexapro                       |                    |                    | S               | Transplacental       | See Image                        |                 | Not Reported |                |
|                                                                                     | Levonelle (Tablets)           |                    |                    | C               | Transplacental       | See Image                        |                 | Not Reported |                |
|                                                                                     | Folic Acid                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2009                                                                         | 7125346                       | EXPEDITED (15-DAY) | N                  | OT              | 1000008691           |                                  | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alcohol Increased;<br>Legal Problem                                           | Lexapro                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                     | Alcohol                       |                    |                    | S               |                      | 2 Beers (Once)                   |                 | Not Reported |                |
|                                                                                     | Lorazepam                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Sep-2009                                                                         | 7096693                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007945           |                                  | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                                                                                                                                                                                                                     |                          |   |      |                                      |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---|------|--------------------------------------|--------------|
| Colitis Ulcerative; Fall;<br>Feeling Abnormal;<br>Hyperhidrosis; Malaise;<br>Musculoskeletal Stiffness;<br>Nausea; Nuclear Magnetic<br>Resonance Imaging Brain<br>Abnormal; Partial<br>Seizures; Tremor;<br>Unresponsive To Stimuli | Lexapro                  | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Per Oral | Not Reported |
|                                                                                                                                                                                                                                     | Yasmin                   | C |      |                                      | Not Reported |
|                                                                                                                                                                                                                                     | Allergy Injections (Nos) | C |      |                                      | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 11-Sep-2009                                          | 7117093        | DIRECT           | N                  |                 |                      |                      | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anorgasmia; Ejaculation<br>Failure; Genital Disorder | Lexapro        |                  |                    | S               |                      | 10mg Daily           | 6 DAY           | Forest     |                |
| Male; Male Orgasmic<br>Disorder                      | Lexapro        |                  |                    | S               |                      | 20mg Daily           | 2 DAY           | Forest     |                |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 11-Sep-2009                                                                                | 7125371              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008666           |                                                                 | 42 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Dizziness; Paraesthesia;<br>Visual Impairment;<br>Withdrawal Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |                |
|                                                                                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5mg (5 Mg, 1 In 1 D),<br>Oral | 1 MTH           | Not Reported |                |
|                                                                                            |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5mg (5 Mg, 1 In 1 D),<br>Oral |                 |              |                |
|                                                                                            | Depakote             |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Sep-2009              | 7126005       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008715           |                      | 38 YR      | Male       | DNK            |

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| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a>      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>                                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------|------------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|---------------------------------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| Agranulocytosis;<br>Pancytopenia                                   | Escitalopram Oxalate         |                           |                             | S                        | Oral                                     | Oral                                                                                  |                          | Not Reported        |                         |
|                                                                    | Rituxan                      |                           |                             | S                        | Intravenous (not<br>otherwise specified) | 17.8571 Mg/M2 (375 M<br>G/M2, 1 In 21 D),<br>Intravenous (Not<br>Otherwise Specified) |                          | Not Reported        |                         |
|                                                                    | Doxorubicin (Injection)      |                           |                             | C                        |                                          |                                                                                       |                          | Not Reported        |                         |
|                                                                    | Cyclophosphamide (Injection) |                           |                             | C                        |                                          |                                                                                       |                          | Not Reported        |                         |
|                                                                    | Vincristine Sulfate          |                           |                             | C                        |                                          |                                                                                       |                          | Not Reported        |                         |
|                                                                    | Prednisone                   |                           |                             | C                        |                                          |                                                                                       |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a>                                                         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Sep-2009                                                        | 7117198                      | DIRECT                    | N                           | DE                       |                                          |                                                                                       | 40 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a>      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>                                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                  | Lexapro                      |                           |                             | S                        |                                          |                                                                                       | 12 DAY                   | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a>                                                         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Sep-2009                                                        | 7130263                      | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000008727                               |                                                                                       | 44 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a>      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>                                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated;<br>Erectile Dysfunction;<br>Libido Decreased | Escitalopram Oxalate         |                           |                             | S                        | Oral                                     | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                  | <a href="#">Case #</a>       | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a>                                                         | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Sep-2009                                                        | 7133622                      | DIRECT                    | N                           |                          |                                          |                                                                                       | 69 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                     | <a href="#">Product</a>      | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>                                                           | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyskinesia                                                         | Pristiq Extended Release     |                           |                             | S                        | Oral                                     | I Daily Po                                                                            | 1 DAY                    | Not Reported        |                         |
|                                                                    | Lexapro                      |                           |                             | S                        |                                          |                                                                                       |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------|-----------------|--------------|----------------|
| 14-Sep-2009                                                                                                                                                                             | 7133771                          | EXPEDITED (15-DAY) | Y                  | DS              | S07-FRA-03414*01           |                                    | 66 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Drug Interaction; Mydriasis; Serotonin Syndrome; Visual Impairment; Weight Decreased                                                                                    | Escitalopram Oxalate             |                    |                    | S               | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral        |                 | Not Reported |                |
|                                                                                                                                                                                         | Oxycontin                        |                    |                    | S               | Oral                       | 120 Mg (60 Mg, 2 In 1 D), Oral     |                 | Not Reported |                |
|                                                                                                                                                                                         | Fentanyl                         |                    |                    | S               | Nasal                      | 800 Mcg (200 Mcg, 4 In 1 D), Nasal |                 | Not Reported |                |
|                                                                                                                                                                                         | Morphine Sulfate                 |                    |                    | S               | Oral                       | 60 To 120 Mg Daily (30 Mg), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                         | Taxotere (Docetaxel) (Docetaxel) |                    |                    | C               |                            |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Acetaminophen                    |                    |                    | C               |                            |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Prednisone                       |                    |                    | C               |                            |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Rythmol                          |                    |                    | C               |                            |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Tareg                            |                    |                    | C               |                            |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2009                                                                                                                                                                             | 6259219                          | EXPEDITED (15-DAY) | N                  | HO, OT          | US-ASTRAZENECA-2006UW21906 |                                    | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Blood Triglycerides Increased; Diabetes Mellitus; Diabetic Nephropathy; Diabetic Neuropathy; Hyperlipidaemia; Neuroleptic Malignant Syndrome; Ovarian Cyst | Seroquel                         |                    |                    | S               | Oral                       | 100-200 Mg                         | 2 MTH           | Not Reported |                |
|                                                                                                                                                                                         | Seroquel                         |                    |                    | S               | Oral                       | 100-200 Mg                         | 2 MTH           | Not Reported |                |
|                                                                                                                                                                                         | Seroquel                         |                    |                    | S               | Oral                       |                                    | 1 MTH           | Not Reported |                |
|                                                                                                                                                                                         | Seroquel                         |                    |                    | S               | Oral                       |                                    | 1 MTH           | Not Reported |                |
|                                                                                                                                                                                         | Seroquel                         |                    |                    | S               | Oral                       | 100 Mg-200 Mg                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Seroquel                         |                    |                    | S               | Oral                       | 100 Mg-200 Mg                      |                 | Not Reported |                |
|                                                                                                                                                                                         | Abilify                          |                    |                    | S               |                            |                                    | 1 YR            | Not Reported |                |
|                                                                                                                                                                                         | Abilify                          |                    |                    | S               | Oral                       |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Geodon                           |                    |                    | S               |                            |                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Geodon                           |                    |                    | S               |                            | 80 Mg                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |   |      |                                                           |        |              |
|----------------------------|---|------|-----------------------------------------------------------|--------|--------------|
| Risperdal                  | S |      |                                                           | 17 MTH | Not Reported |
| Risperdal                  | S | Oral |                                                           |        | Not Reported |
| Thorazine                  | S |      |                                                           | 1 YR   | Not Reported |
| Thorazine                  | S |      |                                                           |        | Not Reported |
| Perphenazine               | S |      |                                                           | 1 YR   | Not Reported |
| Lexapro                    | S |      |                                                           |        | Not Reported |
| Trazodone Hydrochloride    | S | Oral | 100 Mg-150 Mg                                             | 4 MTH  | Not Reported |
| Trazodone Hydrochloride    | S | Oral | 100 Mg-150 Mg                                             | 4 MTH  | Not Reported |
| Trazodone Hydrochloride    | S | Oral | 100 Mg-150 Mg                                             |        | Not Reported |
| Trazodone Hydrochloride    | S | Oral | 100 Mg-150 Mg                                             |        | Not Reported |
| Effexor                    | S | Oral |                                                           |        | Not Reported |
| Paxil                      | S |      |                                                           |        | Not Reported |
| Ativan                     | S |      |                                                           |        | Not Reported |
| Buspar                     | S |      |                                                           |        | Not Reported |
| Amitriptyline              | S |      |                                                           |        | Not Reported |
| Hydrochloride\Perphenazine |   |      |                                                           |        |              |
| Remeron                    | S | Oral |                                                           |        | Not Reported |
| Remeron                    | S | Oral |                                                           |        | Not Reported |
| Lamictal                   | C | Oral | 25 Mg-200 Mg                                              |        | Not Reported |
| Lisinopril                 | C |      | 10 Mg-20 Mg                                               |        | Not Reported |
| Detrol La                  | C |      |                                                           |        | Not Reported |
| Codeine                    | C |      | 300-30 Mg, 1-2 Tablets<br>Every 4 To 6 Hours As<br>Needed |        | Not Reported |
| Metronidazole              | C |      |                                                           |        | Not Reported |
| Nabumetone                 | C |      |                                                           |        | Not Reported |
| Prozac                     | C |      |                                                           |        | Not Reported |
| Wellbutrin                 | C |      |                                                           |        | Not Reported |
| Zoloft                     | C |      |                                                           |        | Not Reported |
| Xanax                      | C |      |                                                           |        | Not Reported |
| Glucophage                 | C | Oral | 500 Mg-2000 Mg                                            |        | Not Reported |
| Avandaryl                  | C | Oral | 4/2 Mg                                                    |        | Not Reported |
| Motrin                     | C |      |                                                           |        | Not Reported |
| Albuterol                  | C |      | 90 Mcg Inhaler                                            |        | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------------------------------------------------------------------|-----------------|----------------------|----------------|
| 15-Sep-2009                                                                                                            | 7132162              | EXPEDITED (15-DAY) | Y                  | DS              | 1000008749                               |                                                                                           |                 | Male                 | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Pruritus Generalised; Skin Haemorrhage; Somnolence                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 5 Mg (5 Mg, 1 In 1 D), Oral                                                               |                 | Not Reported         |                |
|                                                                                                                        | Alprazolam           |                    |                    | S               | Oral                                     | 3 Mg (0,5 Mg, 6 In 1 D), Oral                                                             |                 | Not Reported         |                |
|                                                                                                                        | Lexomil              |                    |                    | C               |                                          |                                                                                           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 16-Sep-2009                                                                                                            | 6805702              | EXPEDITED (15-DAY) | Y                  | DS              | 1000000410                               |                                                                                           | 32 YR           | Female               | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Dizziness; Gestational Diabetes; Maternal Exposure During Pregnancy; Pregnancy; Visual Impairment; Withdrawal Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported         |                |
|                                                                                                                        |                      |                    |                    |                 | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |                      |                |
|                                                                                                                        |                      |                    |                    |                 | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |                      |                |
|                                                                                                                        | L-Throx              |                    |                    | C               |                                          |                                                                                           |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Sep-2009                                                                                                            | 7117550              | NON-EXPEDITED      | N                  |                 | US-BRISTOL-MYERS SQUIBB COMPANY-14559165 |                                                                                           | 61 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Dreams; Dyspepsia; Hyperhidrosis                                                                              | Megace               |                    |                    | S               | Oral                                     | 1 Df = 1 Tab.2008-Jan09:1df; Jan09:2 Df.                                                  |                 | Bristol Myers Squibb |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                        | Lexapro              |                    | S                  | Oral            | Nov08-<br>Jan09:10mg;Jan09-<br>24feb09:20mg;25feb-<br>10mar:10mg;11mar:20mg. |                      | Not Reported    |              |                |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                        | Lexapro              |                    | S                  | Oral            | Nov08-<br>Jan09:10mg;Jan09-<br>24feb09:20mg;25feb-<br>10mar:10mg;11mar:20mg. |                      | Not Reported    |              |                |
|                                                                                                        | Xanax                |                    | C                  |                 |                                                                              |                      | Not Reported    |              |                |
|                                                                                                        | Metoprolol           |                    | C                  |                 |                                                                              |                      | Not Reported    |              |                |
|                                                                                                        | Percocet             |                    | C                  |                 |                                                                              |                      | Not Reported    |              |                |
|                                                                                                        | Crestor              |                    | C                  |                 |                                                                              |                      | Not Reported    |              |                |
|                                                                                                        | Nexium               |                    | C                  |                 |                                                                              |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2009                                                                                            | 7117874              | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2009264035                                                 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Reaction                                                                                       | Xanax                |                    |                    | S               |                                                                              |                      |                 | Pfizer       |                |
|                                                                                                        | Lexapro              |                    |                    | S               |                                                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2009                                                                                            | 7136021              | DIRECT             | Y                  | DS              |                                                                              |                      | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Heart Rate<br>Decreased; Hyperhidrosis;<br>Pallor; Presyncope;<br>Unresponsive To Stimuli | Lexapro              |                    |                    | S               |                                                                              |                      |                 | Not Reported |                |
|                                                                                                        | Xopenex Hfa          |                    |                    | S               |                                                                              |                      |                 | Not Reported |                |
|                                                                                                        | Singulair            |                    |                    | S               |                                                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2009                                                                                            | 7136045              | EXPEDITED (15-DAY) | N                  | OT              | 1000008833                                                                   |                      | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dizziness; Dry<br>Mouth; Dry Throat;                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                                                                         | 5-10 Mg Daily, Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                              |                                                                |             |      |                     |                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-------------|------|---------------------|----------------------------------------------|
| Dysphonia; Fatigue;<br>Nausea; Palpitations;<br>Panic Attack;<br>Restlessness; Sensation<br>Of Foreign Body; Sleep<br>Disorder; Suicidal<br>Ideation; Tremor | Escitalopram Oxalate<br>Eltroxin (Tablets)<br>Centyl (Tablets) | S<br>C<br>C | Oral | 5-10 Mg Daily, Oral | Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-------------|------|---------------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2009              | 7127713       | DIRECT           | Y                  |                 |                      |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                   | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>             |
|-------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|------------------------|
| Disturbance In Attention;<br>Feeling Abnormal;<br>Mydriasis; Somnolence | Escitalopram Oxalate<br>Ramelteon |              |            | S<br>C      | Oral         | Escitalopram 5mg 1 Tab<br>Daily Po |                 | Pfizer<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2009              | 6957153       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005282           |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Generalised Tonic-Clonic<br>Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2009              | 7063515       | EXPEDITED (15-DAY) | Y                  | DE              | 1000007363           |                      | 45 YR      | Male       | FRA            |

| <u>Preferred Term</u>          | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------|--------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------------------------|
| Asphyxia; Completed<br>Suicide | Escitalopram Oxalate<br>Athyml |              |            | S<br>C      | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2009              | 7124849       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14372254 |                      | 36 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|----------------------|
| Agitation; Drug Interaction;<br>Irritability | Buspar         |              |            | S           | Oral         | Dose Reduced To 10mg<br>From Oct2008 |                 | Bristol Myers Squibb |
|                                              | Klonopin       |              |            | C           |              |                                      |                 | Not Reported         |
|                                              | Buspar         |              |            | S           | Oral         | Dose Reduced To 10mg<br>From Oct2008 |                 | Bristol Myers Squibb |
|                                              | Lexapro        |              |            | S           | Oral         |                                      |                 | Not Reported         |
|                                              | Lexapro        |              |            | S           | Oral         |                                      |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2009              | 7124982       | EXPEDITED (15-DAY) | Y                  | OT              | IN-ROXANE<br>LABORATORIES, INC.-<br>2009-RO-00959RO |                      | 12 YR      | Male       | IND            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyskinesia;<br>Extrapyramidal Disorder | Alprazolam           |              |            | S           |              |                    |                 | Roxane       |
|                                        | Alprazolam           |              |            | S           |              |                    |                 | Roxane       |
|                                        | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                        | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                        | Rabeprazole          |              |            | S           |              |                    | 5 DAY           | Not Reported |
|                                        | Rabeprazole          |              |            | S           |              |                    | 5 DAY           | Not Reported |
|                                        | Diphenhydramine      |              |            | C           | Oral         |                    |                 | Not Reported |
|                                        | Diphenhydramine      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2009              | 7077639       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DSA_34038_2009       |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Acidosis; Aphasia;<br>Arrhythmia;<br>Arteriosclerosis Coronary<br>Artery; Blood Potassium<br>Decreased; Dry Eye;<br>Essential Hypertension;<br>Fall; Gait Inability;<br>Generalised Tonic-Clonic | Cardizem La      |              |            | S           | Oral         | 180 Mg Oral           |                 | Not Reported |
|                                                                                                                                                                                                  | Lexapro          |              |            | S           | Oral         | Df; Frequency Qd Oral |                 | Not Reported |
|                                                                                                                                                                                                  | Remeron          |              |            | S           | Oral         | Df Oral               |                 | Not Reported |
|                                                                                                                                                                                                  | Valium           |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                  | Benicar          |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                  | Tylenol          |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                  | Artificial Tears |              |            | C           |              |                       |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seizure; Hypersensitivity;  
Hypokalaemia;  
Hyponatraemia; Iron  
Deficiency Anaemia; Left  
Ventricular Hypertrophy;  
Loss Of Consciousness;  
Mitral Valve  
Incompetence; Po2  
Decreased; Renal Artery  
Arteriosclerosis; Sinus  
Tachycardia; Swelling;  
Syncope; Tricuspid Valve  
Incompetence; Vision  
Blurred

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2009              | 7143253       | EXPEDITED (15-DAY) | Y                  | DS              | 1000008970           |                      | 48 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Anxiety;<br>Apathy; Confusional State;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Diarrhoea; Dysgeusia;<br>Dyspnoea; Headache;<br>Hyperhidrosis; Intraocular<br>Pressure Increased;<br>Muscle Spasms; Pruritus;<br>Psychiatric Symptom;<br>Restlessness; Sleep<br>Disorder; Suicidal<br>Ideation; Tinnitus; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                      | Alprazolam           |              |            | S           | Oral         | 9 Mg (9 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                      | Sobril               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                      | Sarotex              |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                      | Nozinan              |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2009              | 7145121       | EXPEDITED (15-DAY) | Y                  | HO              | 1000008968           |                      | 93 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |                      |   |      |                             |              |
|---------------------------------------------------------------------------------|----------------------|---|------|-----------------------------|--------------|
| Hyperkalaemia;<br>Hyponatraemia;<br>International Normalised<br>Ratio Increased | Escitalopram Oxalate | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                 | Perindopril          | S | Oral | 8 Mg (8 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                 | Sintrom              | S | Oral | 1 Mg, As Required, Oral     | Not Reported |
|                                                                                 | Plavix               | C |      |                             | Not Reported |
|                                                                                 | Levothyroxine        | C |      |                             | Not Reported |
|                                                                                 | Diltiazem            | C |      |                             | Not Reported |
|                                                                                 | Torem (Tablets)      | C |      |                             | Not Reported |
|                                                                                 | Rasilez (Tablets)    | C |      |                             | Not Reported |
|                                                                                 | Neurontin            | C |      |                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2009              | 6546132       | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | A0680992A            |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                      |
|---------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|---------------------------------|
| Atrial Septal Defect;<br>Congenital Anomaly;<br>Craniosynostosis;<br>Developmental Delay;<br>Maternal Exposure During<br>Pregnancy; Talipes | Paxil<br>Lexapro |              |            | S<br>S      |              |                    |                 | Glaxosmithkline<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2009              | 7126106       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008717           |                      | 28 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Maternal Drugs Affecting<br>Foetus; Metrorrhagia;<br>Pregnancy | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 24-Sep-2009              | 7128826       | NON-EXPEDITED    | Y                  | OT              | US-ASTRAZENECA-<br>2009UW17939 |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Glucose Increased | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                        | Lamictal                    |                    |                    | S               |                          |                       |                 |              | Not Reported   |
|------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------|-----------------|--------------|----------------|
|                                                                        | Lexapro                     |                    |                    | S               |                          |                       |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2009                                                            | 7129767                     | EXPEDITED (15-DAY) | Y                  | DS, OT          | NO-PFIZER INC-2009266558 |                       | 48 YR           | Unknown      | NOR            |
| <u>Preferred Term</u>                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension;                                                  | Alprazolam                  |                    |                    | S               | Oral                     | (2+2+2+3 Mg)          |                 | Pfizer       |                |
| Abdominal Pain; Anxiety;                                               | Ciprallex                   |                    |                    | S               | Oral                     |                       |                 | Not Reported |                |
| Apathy; Confusional State;                                             | Oxazepam                    |                    |                    | C               |                          |                       |                 | Not Reported |                |
| Depersonalisation/Derealisation Disorder;                              | Levomepromazine             |                    |                    | C               |                          | When Needed           |                 | Not Reported |                |
| Diarrhoea; Dysgeusia;                                                  | Amitriptyline Hydrochloride |                    |                    | C               | Oral                     | When Needed           |                 | Not Reported |                |
| Dyspnoea; Headache;                                                    |                             |                    |                    |                 |                          |                       |                 |              |                |
| Hyperhidrosis; Intraocular Pressure Increased;                         |                             |                    |                    |                 |                          |                       |                 |              |                |
| Muscle Spasms; Pruritus;                                               |                             |                    |                    |                 |                          |                       |                 |              |                |
| Psychiatric Symptom;                                                   |                             |                    |                    |                 |                          |                       |                 |              |                |
| Restlessness; Sleep Disorder; Suicidal Ideation; Tinnitus; Tremor      |                             |                    |                    |                 |                          |                       |                 |              |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2009                                                            | 7138874                     | DIRECT             | N                  | OT              |                          |                       | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Diabetic Neuropathy; Irritability; Pain; Treatment Failure | Lexapro                     |                    |                    | S               |                          | 10 Mg Once A Day Tab  |                 | Not Reported |                |
|                                                                        | Cymbalta                    |                    |                    | C               |                          |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2009                                                            | 7146279                     | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2009IN10235          |                       | 12 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Clonus;                                      | Alprazolam                  |                    |                    | S               |                          | 0.25 Mg, Once/Single, |                 | Not Reported |                |
| Dysarthria; Dyskinesia;                                                | Escitalopram Oxalate        |                    |                    | S               |                          | 10 Mg, Once/Single,   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysphemia; Dystonia;  
Extensor Plantar  
Response; Extrapramidal  
Disorder; Hypertonia;  
Movement Disorder;  
Muscle Rigidity; Posture  
Abnormal; Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2009              | 7131505       | EXPEDITED (15-DAY) |                    | OT              | PHEH2009US11016      |                      |            | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Dysphagia;      | Tekturna Hct        |              |            | S           |              | 150/12.5 Mg        |                 | Novartis     |
| Feeling Hot; Head          | Metoprolol Tartrate |              |            | S           |              | 50 Mg, Unk         |                 | Not Reported |
| Titubation; Hyperhidrosis; | Lexapro             |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |
| Hypoaesthesia; Muscle      |                     |              |            |             |              |                    |                 |              |
| Spasms; Seizure; Vision    |                     |              |            |             |              |                    |                 |              |
| Blurred                    |                     |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Sep-2009              | 7144089       | EXPEDITED (15-DAY) | Y                  | DE              | 1000009056           |                      |            | Male       | IRL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------------|----------------------|----------------------|------------|------------|----------------|
| 28-Sep-2009              | 7138850       | DIRECT           | N                  | DS, HO, LT, RI,<br>OT |                      |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Akathisia; Alcohol Use; | Lexapro        |              |            | S           | Oral         | 10 Mg 1 X Day Po   |                 | Forest     |
| Anxiety; Blood Pressure | Campral        |              |            | S           | Oral         | 333 Mg 3 X Day Po  |                 | Forest     |
| Increased; Delusion;    |                |              |            |             |              |                    |                 |            |
| Suicide Attempt         |                |              |            |             |              |                    |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------|-----------------|--------------|----------------|
| 28-Sep-2009                                                                                                                                                    | 7138854                        | DIRECT             | Y                  | HO, LT, RI, OT  |                          |                                 | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Arthritis; Chest Pain;<br>Divorced; Dyspnoea<br>Exertional; Family Stress;<br>Gastrointestinal Disorder;<br>Insomnia; Suicide Attempt | Lexapro                        |                    |                    | S               | Oral                     | ? Once A Day Po                 | 13 DAY          | Not Reported |                |
|                                                                                                                                                                | Celebrex                       |                    |                    | S               | Oral                     | 200mgs Once A Day Po            | 8 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2009                                                                                                                                                    | 7141181                        | DIRECT             | N                  | DS, RI          |                          |                                 | 35 YR           | Male         | SGP            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction; Loss<br>Of Libido; Male Sexual<br>Dysfunction; Organic<br>Erectile Dysfunction                                                           | Lexapro                        |                    |                    | S               |                          | 10mg Daily                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2009                                                                                                                                                    | 7147763                        | EXPEDITED (15-DAY) | Y                  | OT              | 1000009040               |                                 | 39 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt; Systolic<br>Hypertension; Tachycardia                                                                                | Escitalopram Oxalate           |                    |                    | S               | Oral                     | (300 Mg, Once), Oral            |                 | Not Reported |                |
|                                                                                                                                                                | Acetaminophen\Aspirin\Caffeine |                    |                    | S               | Oral                     | (3 Dosage Forms, Once),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                | Alcohol                        |                    |                    | S               | Oral                     | 2 Bottles Of Beer, Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                       | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2009                                                                                                                                                    | 7133650                        | EXPEDITED (15-DAY) | N                  | OT              | CA-BAYER-<br>200933522NA |                                 | 42 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |           |   |               |  |        |  |  |              |
|-----------------------------------------------|-----------|---|---------------|--|--------|--|--|--------------|
| Haemoglobin Decreased;<br>Vaginal Haemorrhage | Mirena    | S | Intra-uterine |  |        |  |  | Bayer        |
|                                               | Ciprallex | S | Oral          |  | 1 WEEK |  |  | Not Reported |
|                                               | Ciprallex | S | Oral          |  | 3 WEEK |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2009              | 7149193       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009104           |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome; Suicidal<br>Behaviour | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                    |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |
|                                                    | Ibuprofen            |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                    | Ferrous Gluconate    |              |            | C           |              |                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 30-Sep-2009              | 6258620       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ASTRAZENECA-<br>2006UW25940 |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Bipolar Disorder; | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
| Bipolar I Disorder;         | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
| Depression; Diabetes        | Seroquel       |              |            | S           | Oral         | 20-425 Mg          |                 | Not Reported |
| Mellitus; Diabetes Mellitus | Seroquel       |              |            | S           | Oral         | 20-425 Mg          |                 | Not Reported |
| Inadequate Control;         | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
| Hallucination, Auditory;    | Abilify        |              |            | S           | Oral         |                    |                 | Not Reported |
| Homicidal Ideation;         | Haldol         |              |            | S           |              |                    |                 | Not Reported |
| Hyperglycaemia; Major       | Navane         |              |            | S           |              |                    |                 | Not Reported |
| Depression; Mood Swings;    | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
| Psychotic Disorder;         | Thorazine      |              |            | S           |              |                    |                 | Not Reported |
| Schizoaffective Disorder;   | Zyprexa        |              |            | S           | Oral         | 10-20 Mg           |                 | Not Reported |
| Schizoaffective Disorder    | Zyprexa        |              |            | S           | Oral         | 10-20 Mg           |                 | Not Reported |
| Bipolar Type;               | Lithium        |              |            | S           |              |                    |                 | Not Reported |
| Schizophrenia;              |                |              |            |             |              |                    |                 | Not Reported |
| Schizophrenia; Suicidal     |                |              |            |             |              |                    |                 | Not Reported |
| Ideation; Suicide Attempt;  |                |              |            |             |              |                    |                 | Not Reported |

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|              |                      |   |              |                                                         |              |
|--------------|----------------------|---|--------------|---------------------------------------------------------|--------------|
| Tachyphrenia | Paxil                | S |              |                                                         | Not Reported |
|              | Lexapro              | S | Oral         | 10-20 Mg                                                | Not Reported |
|              | Cogentin             | S |              |                                                         | Not Reported |
|              | Depakote             | C | Oral         |                                                         | Not Reported |
|              | Nph Insulin          | C |              | 50 Units/44 Units, 30 Units/15 Units                    | Not Reported |
|              | Insulin 70/30        | C | Subcutaneous | 40 Units Every Morning/30 Units Every Evening, 70 Units | Not Reported |
|              | Glucotrol            | C | Oral         |                                                         | Not Reported |
|              | Avandia              | C | Oral         |                                                         | Not Reported |
|              | Trileptal            | C | Oral         |                                                         | Not Reported |
|              | Tylenol With Codeine | C |              | Every 6 Hrs                                             | Not Reported |
|              | Tylenol              | C | Oral         | 650 Mg Every 4 Hrs                                      | Not Reported |
|              | Dilantin             | C | Oral         |                                                         | Not Reported |
|              | Lopresor             | C | Oral         | 50-200 Mg                                               | Not Reported |
|              | Albuterol            | C |              | 2 Puffs Every 4-6 Hrs                                   | Not Reported |
|              | Albuterol            | C |              | 2 Puffs Every 4-6 Hrs                                   | Not Reported |
|              | Mavik                | C | Oral         |                                                         | Not Reported |
|              | Lasix                | C | Oral         | 20-40 Mg                                                | Not Reported |
|              | Singulair            | C | Oral         |                                                         | Not Reported |
|              | Desyrel              | C |              |                                                         | Not Reported |
|              | Capoten              | C |              |                                                         | Not Reported |
|              | Benazepril           | C | Oral         |                                                         | Not Reported |
|              | Wellbutrin           | C | Oral         |                                                         | Not Reported |
|              | Buspar               | C | Oral         |                                                         | Not Reported |
|              | Aspirin              | C | Oral         | 81-325 Mg                                               | Not Reported |
|              | Ativan               | C |              |                                                         | Not Reported |
|              | Restoril             | C |              |                                                         | Not Reported |
|              | Klonopin             | C | Oral         | 1-6 Mg                                                  | Not Reported |
|              | Glucophage           | C |              | 500-1500 Mg                                             | Not Reported |
|              | Nitroglycerin        | C |              |                                                         | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|               |   |          |              |
|---------------|---|----------|--------------|
| Fluticasone   | C | 1250 Mcg | Not Reported |
| Advair Diskus | C |          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Sep-2009              | 7013039       | EXPEDITED (15-DAY) | Y                  | OT              | ES-PFIZER INC-2009220762 |                      | 51 YR      | Unknown    | ESP            |

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Fatigue;<br>Sedation; Urinary<br>Incontinence | Celecoxib            |              |            | S           | Oral         | 200 Mg, 1x/Day     | 4 DAY           | Pfizer       |
|                                                         | Diazepam             |              |            | S           | Oral         | 5 Mg, 1x/Day       | 4 DAY           | Not Reported |
|                                                         | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg, 1x/Day      | 4 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2009              | 7126172       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008719           |                      | 38 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Metrorrhagia          | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D) |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D) |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 30-Sep-2009              | 7134848       | EXPEDITED (15-DAY) | N                  | HO              | US-ASTRAZENECA-2009SE14269 |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose;<br>Delirium; Gastric Bypass;<br>Migraine; Pyrexia;<br>Serotonin Syndrome;<br>Thyroid Disorder; Tremor | Zomig          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                            | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                            | Amitriptyline  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                            | Imitrex        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Suboxone       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Potassium      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Testosterone   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Progesterone   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Estrogen Patch |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                            | Lorazepam      |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                       |                      | Gabapentin         |                    | C               |                                          |                               |                 |              | Not Reported   |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|--------------|----------------|
|                                                       |                      | Hydrocortisone     |                    | C               |                                          |                               |                 |              | Not Reported   |
|                                                       |                      | Cyanocobalamin     |                    | C               |                                          |                               |                 |              | Not Reported   |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2009                                           | 7045254              | EXPEDITED (15-DAY) | Y                  | OT              | 1000007024                               |                               | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Coagulopathy; Vaginal Haemorrhage                     | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 15 Mg (15 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 7.5 Mg (7.5 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2009                                           | 7071818              | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20090709765                    |                               | 36 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Meniscus Injury; Oedema Peripheral           | Risperdal            |                    |                    | S               | Oral                                     |                               |                 | Not Reported |                |
|                                                       | Lexapro              |                    |                    | S               | Unknown                                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2009                                           | 7087368              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008032                               |                               | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Generalised Tonic-Clonic Seizure; Tinnitus | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 10 Mg (10 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 5 Mg (5 Mg,1 In 1 D),Oral     |                 | Not Reported |                |
|                                                       | Olanzapine           |                    |                    | C               |                                          |                               |                 | Not Reported |                |
|                                                       | Depo-Provera         |                    |                    | C               |                                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Oct-2009                                           | 7132504              | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-14791669 |                               | 44 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Fatigue; Gait Disturbance; Hepatic Pain; Hepatomegaly; Mood Swings; Muscle Atrophy; Restlessness | Abilify        |              |            | S           | Oral         | Initial Dose:2mg T Am And Tt Hs) Increased To 5mg(04aug09)Bid |                 | Not Reported |
|                                                                                                  | Abilify        |              |            | S           | Oral         | Initial Dose:2mg T Am And Tt Hs) Increased To 5mg(04aug09)Bid |                 | Not Reported |
|                                                                                                  | Lexapro        |              |            | S           |              |                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2009              | 7150296       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009124           |                      | 80 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Cyanosis; Dysarthria; Hypertonia; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Malaise; Postictal State; Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                         | Parkinane            |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                                         | Sinemet              |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                                         | Stilnox              |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2009              | 7150983       | EXPEDITED (15-DAY) | N                  | OT              | 1000009135           |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Aura; Back Pain; Disorientation; Headache; Loss Of Consciousness; Postictal Headache; Postictal State; Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,Once), Oral |                 | Not Reported |
|                                                                                                                | Flonase        |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                | Allegra        |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                | Singulair      |              |            | C           |              |                          |                 | Not Reported |
|                                                                                                                | Alprazolan     |              |            | C           |              |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2009              | 7079840       | EXPEDITED (15-DAY) | Y                  | DE              | 1000007891           |                      | 61 YR      | Male       | USA            |

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| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Completed Suicide; Gun Shot Wound | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                   | Ambien Cr      |              |            | S           | Oral         | 12.5 Mg, As Required, Oral    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2009              | 7085342       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007970           |                      | 83 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Atrioventricular Block Complete; Blood Creatinine Increased; Blood Urea Increased; C-Reactive Protein Increased; Refusal Of Treatment By Patient; Supraventricular Extrasystoles; Syncope; Vertigo | Escitalopram Oxalate |              |            | S           |              | 5 Mg (5 Mg, 1 In 1 D) |                 | Not Reported |
|                                                                                                                                                                                                    | Proscar              |              |            | C           |              |                       |                 | Not Reported |
|                                                                                                                                                                                                    | Folierite            |              |            | C           |              |                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2009              | 7130517       | EXPEDITED (15-DAY) | Y                  | DE              | 1000008781           |                      | 64 YR      | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Abdominal Distension; Completed Suicide; Diarrhoea; Nausea; Stress | Lexapro        |              |            | S           | Oral         | 5 Mg (5mg, 1 In 1 D), Oral    |                 | Not Reported |
|                                                                    | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                    | Cymbalta       |              |            | S           | Oral         | 20 Mg, Oral                   |                 | Not Reported |
|                                                                    | Klonopin       |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2009              | 7148165       | DIRECT           | Y                  | HO              |                      |                      | 21 YR      | Female     | USA            |

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| <a href="#">Preferred Term</a>                                                                                           | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Chills; Muscle Spasms; Restlessness; Serotonin Syndrome; Vomiting; Yawning                                               | Lexapro                  |                           |                             | S                        | Oral                          | 10 Mg Daily Po                |                          | Forest              |                         |
| <a href="#">FDA Received Date</a>                                                                                        | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Oct-2009                                                                                                              | 7153161                  | EXPEDITED (15-DAY)        | N                           | OT                       | 1000009178                    |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>                                                                                           | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depression; Flank Pain; Kidney Infection; Suicidal Ideation                                                              | Escitalopram Oxalate     |                           |                             | S                        | Oral                          | Oral                          |                          | Not Reported        |                         |
|                                                                                                                          | Aspirin\Caffeine\Codeine |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                        | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Oct-2009                                                                                                              | 7153868                  | EXPEDITED (15-DAY)        | N                           | CA                       | 1000009164                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                           | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Congenital Pulmonary Valve Atresia; Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Pyloric Stenosis | Lexapro                  |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                        | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Oct-2009                                                                                                              | 6866204                  | EXPEDITED (15-DAY)        | Y                           | DE                       | US-PFIZER INC-2008153740      |                               | 61 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                                                           | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                                                                        | Estradiol                |                           |                             | S                        |                               |                               |                          | Pfizer              |                         |
|                                                                                                                          | Paracetamol+Codeine      |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                          | Diphenhydramine          |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                          | Escitalopram Oxalate     |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                                                                          | Levothyroxine            |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |      |              |
|------------------------|---|------|--------------|
| Oxycodone              | S | Oral | Not Reported |
| Unspecified Ingredient | S | Oral | Not Reported |
| Progesterone           | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 07-Oct-2009                                                            | 7155303              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009198           |                        | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pregnancy | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg,L In 1 D) |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 08-Oct-2009              | 7143541        | EXPEDITED (15-DAY) | Y                  | HO              | CH-JNJFOC-<br>20090908578 |                      | 77 YR           | Female       | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium                 | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Haldol         |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Phenytoin      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Phenytoin      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Phenytoin      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Phenytoin      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Phenytoin      |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Axura          |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Axura          |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |
|                          | Axura          |                    |                    | S               | Oral                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                             | Ciprallex                 |                    | S                  | Oral            |                      |                             |                 | Not Reported |                |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
|                                                                                                                             | Ciprallex                 |                    | S                  | Oral            |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2009                                                                                                                 | 7151549                   | DIRECT             | N                  | RI, OT          |                      |                             | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Antisocial Behaviour;<br>Disturbance In Attention;<br>Feeling Abnormal;<br>Hyperhidrosis; Insomnia;<br>Irritability; Phobia | Effexor                   |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                             | Lexapro                   |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                             | Zoloft                    |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                             |                           |                    |                    |                 |                      |                             |                 |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Oct-2009                                                                                                                 | 7163357                   | EXPEDITED (15-DAY) | Y                  | DE              | B0596120A            |                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiotoxicity; Sepsis                                                                                                      | Escitalopram Oxalate      |                    |                    | S               |                      | 1000 Mg / Per Day /         |                 | Not Reported |                |
|                                                                                                                             | Paclitaxel                |                    |                    | S               |                      | 80 Mg/M2 / Weekly /         |                 | Not Reported |                |
|                                                                                                                             | Cyclophosphamide          |                    |                    | S               |                      | 60 Mg/M2 /                  |                 | Not Reported |                |
|                                                                                                                             | Doxorubicin Hydrochloride |                    |                    | S               |                      | 600 Mg/M2 /                 |                 | Not Reported |                |
|                                                                                                                             | Trastuzumab               |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Oct-2009                                                                                                                 | 6901549                   | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000003593           |                             | 59 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness;<br>Meningorrhagia                                                                                    | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5 Or 10 Mg (1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                             | Seresta                   |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                             | Benerva                   |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                             | Nicobion                  |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2009              | 7085345       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000007973           |                      | 83 YR      | Female     | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Blood Sodium Decreased;   | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Bradycardia; Bundle       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),    |                 | Not Reported |
| Branch Block Right; Drug  |                      |              |            |             |              | Oral                        |                 |              |
| Level Increased;          |                      |              |            |             |              |                             |                 |              |
| Electrocardiogram         | Zestril              |              |            | C           |              |                             |                 | Not Reported |
| Repolarisation            | Aspirin Cardio       |              |            | C           |              |                             |                 | Not Reported |
| Abnormality; Myocardial   | Acidum Folicum       |              |            | C           |              |                             |                 | Not Reported |
| Infarction; Pneumonia;    | Perenterol           |              |            | C           |              |                             |                 | Not Reported |
| Pulmonary Embolism;       | Dipiperon            |              |            | C           |              |                             |                 | Not Reported |
| Ventricular Extrasystoles |                      |              |            |             |              |                             |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2009              | 7144669       | EXPEDITED (15-DAY) | Y                  | DE, LT          | CH-JNJFOC-20091001021 |                      | 22 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;    | Risperidone     |              |            | S           | Oral         |                    |                 | Not Reported |
| Respiratory Arrest    | Cipralext       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trileptal       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Chlorprothixene |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 09-Oct-2009              | 7145104       | EXPEDITED (15-DAY) | Y                  | DE, LT          | CH-JNJFOC-20091001797 |                      | 35 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;    | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
| Depression            | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |              |
|-------------|---|------|--------------|
| Risperdal   | S | Oral | Not Reported |
| Haldol      | S | Oral | Not Reported |
| Haldol      | S | Oral | Not Reported |
| Haldol      | S | Oral | Not Reported |
| Haldol      | S | Oral | Not Reported |
| Seroquel Xr | S | Oral | Not Reported |
| Seroquel Xr | S | Oral | Not Reported |
| Ciprallex   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2009              | 7146981       | EXPEDITED (15-DAY) | Y                  | HO              | ES-MYLANLABS-2009S1016921 |                      | 66 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Hallucination, Visual | Escitalopram Oxalate |              |            | S           |              | 10 Mg/Day          | 2 YR            | Alphapharm   |
|                                                            | Rasagiline Mesylate  |              |            | S           |              | 1 Mg/Day           | 3 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 6890107       | NON-EXPEDITED    | N                  | OT              | 1000003170           |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Vitamin D Deficiency  | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 6974767       | NON-EXPEDITED    | N                  | OT              | 1000005699           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Abdominal Pain; Chest Pain; Clumsiness; Constipation; Dizziness; Dyspnoea; Fatigue; Nausea; Seizure; Speech | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Disorder; Transient  
Ischaemic Attack; Weight  
Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7010348       | NON-EXPEDITED    | Y                  | OT              | 1000005861           |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Lymphocytosis; Pleural Effusion | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                 | Diovan         |              |            | C           |              |                               |                 | Not Reported |
|                                 | Norvasc        |              |            | C           |              |                               |                 | Not Reported |
|                                 | Meloxicam      |              |            | C           |              |                               |                 | Not Reported |
|                                 | Lovastatin     |              |            | C           |              |                               |                 | Not Reported |
|                                 | Nexium         |              |            | C           |              |                               |                 | Not Reported |
|                                 | Vitamin D Nos  |              |            | C           |              |                               |                 | Not Reported |
|                                 | Flomax         |              |            | C           |              |                               |                 | Not Reported |
|                                 | Xanax          |              |            | C           |              |                               |                 | Not Reported |
|                                 | Albuterol      |              |            | C           |              |                               |                 | Not Reported |
|                                 | Flonase        |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7042673       | EXPEDITED (15-DAY) | Y                  | HO, OT          | NO-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14685168 |                      |            | Male       | NOR            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------|-----------------|----------------------|
| Acute Abdomen; Drug Interaction; Lipoatrophy; Lipodystrophy Acquired | Videx          |              |            | S           |              |                       |                 | Bristol Myers Squibb |
|                                                                      | Ciprallex      |              |            | S           |              | Film Coated Tablets   |                 | Not Reported         |
|                                                                      | Kaletra        |              |            | S           | Oral         | Soft Gelatin Capsules |                 | Not Reported         |
|                                                                      | Epivir         |              |            | S           |              |                       |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7157201       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009302           |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                        |            |   |      |         |  |              |
|--------------------------------------------------------|------------|---|------|---------|--|--------------|
| Anxiety; Blood Pressure Increased; Depression; Seizure | Lexapro    | S | Oral | Oral    |  | Not Reported |
|                                                        | Symbyax    | S |      | 6/25 Mg |  | Not Reported |
|                                                        | Wellbutrin | S | Oral | Oral    |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7158608       | EXPEDITED (15-DAY) | Y                  | DE              | 1000009306           |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Asphyxia; Completed Suicide | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                             | Trileptal            |              |            | C           |              |                             |                 | Not Reported |
|                             | Atarax               |              |            | C           |              |                             |                 | Not Reported |
|                             | Zyprexa              |              |            | C           |              |                             |                 | Not Reported |
|                             | Theralen             |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7158620       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009330           |                      | 51 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Epilepsy; Weight Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10mg, 1 In 1 D), Oral |                 | Not Reported |
|                            | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D)(Oral)  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7169611       | NON-EXPEDITED    | Y                  | HO              | 1000005454           |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------------|-----------------|--------------|
| Blood Sodium Decreased; Urinary Tract Infection | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D), 20 Mg (20 Mg, 1 In 1 D), 10 Mg (10 Mg, 1 In 1 D), 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                                                                                                                     | 7169649        | NON-EXPEDITED    | N                  | HO              | 1000005925           |                                                                    | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Anxiety; Depression;<br>Diarrhoea; Drug<br>Ineffective; Eating<br>Disorder; Fatigue                                                                                                    | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                 |                |                  |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                                                                                                                                                                 | Prozac         |                  |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                                                                                                     | 7169665        | NON-EXPEDITED    | N                  | HO              | 1000006110           |                                                                    | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Anxiety; Decreased<br>Appetite; Depression;<br>Diarrhoea; Dizziness;<br>Fatigue; Heart Rate<br>Increased; Nausea;<br>Nervousness; Panic<br>Attack; Restlessness;<br>Somnolence; Tremor | Lexapro        |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                        |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Xanax          |                  |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                 | Nortriptyline  |                  |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                                                                                                     | 7169743        | NON-EXPEDITED    | N                  | OT              | 1000006486           |                                                                    | 23 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                                                                                                                                               | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                 |                |                  |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1<br>D), Oral   |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                |                  |                    |                 |                      |                               | D), Oral        |              |                |
|--------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                      |                | Toprol XL        |                    | C               |                      |                               |                 |              | Not Reported   |
|                                      |                | Flonase          |                    | C               |                      |                               |                 |              | Not Reported   |
|                                      |                | Vitamin          |                    | C               |                      |                               |                 |              | Not Reported   |
|                                      |                | Pepcid           |                    | C               |                      |                               |                 |              | Not Reported   |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                          | 7169754        | NON-EXPEDITED    | N                  | OT              | 1000006581           |                               | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Delusion; Irritability; Mania | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                      | Toprol XL      |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                      | Lipitor        |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                          | 7169775        | NON-EXPEDITED    | Y                  | OT              | 1000007130           |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                         | Lexapro        |                  |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                          | 7169777        | NON-EXPEDITED    | Y                  | OT              | 1000007144           |                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                        | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                          | 7170029        | NON-EXPEDITED    | N                  | HO              | 1000007337           |                               | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure              | Lexapro        |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |

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|                                                                                     |                         |        |      |                                    |                              |
|-------------------------------------------------------------------------------------|-------------------------|--------|------|------------------------------------|------------------------------|
| Increased; Disorientation;<br>Dyspnoea; Feeling Jittery;<br>Heart Rate Increased;   | Lexapro                 | S      | Oral | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral | Not Reported                 |
| Hypoaesthesia;<br>Nervousness; Panic<br>Attack; Paraesthesia;<br>Somnolence; Tremor | Alprazolam<br>Combivent | C<br>C |      |                                    | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 13-Oct-2009              | 7170031             | NON-EXPEDITED    | Y                  | HO              | 1000007702           |                      | 55 YR           | Female                       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hepatitis                | Lexapro<br>Lamictal |                  |                    | S<br>S          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2009              | 7170039        | NON-EXPEDITED    | Y                  | OT              | 1000008086           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                | 7170049        | NON-EXPEDITED    | N                  | OT              | 1000007480           |                                    | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                            | Kadian         |                  |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                            | Lisinopril     |                  |                    | C               |                      |                                    |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7170052       | NON-EXPEDITED    | N                  | OT              | S07-USA-06169-01     |                      | 26 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Akathisia; Anxiety; Depression; Overdose; Paraesthesia; Sleep Disorder; Suicidal Ideation; Tremor | Lexapro        |                  |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                   | Wellbutrin     |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                       | 7170119        | NON-EXPEDITED    | Y                  | DE, OT          | 1000007560           |                               | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                             | Lexapro        |                  |                    | S               | Oral                 |                               |                 | Not Reported |                |
|                                                                                                   | Zyprexa        |                  |                    | S               |                      | 30 Mg, Oral                   |                 | Not Reported |                |
|                                                                                                   | Symbyax        |                  |                    | S               |                      | 12/25mg (1 In 1 D)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                       | 7170123        | NON-EXPEDITED    | N                  | HO              | 1000007706           |                               | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Depression; Headache; Insomnia; Nausea                                                 | Lexapro        |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                   | Lamictal       |                  |                    | C               |                      |                               | Not Reported    |              |                |
|                                                                                                   | Clonazepam     |                  |                    | C               |                      |                               | Not Reported    |              |                |
|                                                                                                   | Pravachol      |                  |                    | C               |                      |                               | Not Reported    |              |                |
|                                                                                                   | Zetia          |                  |                    | C               |                      |                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                       | 7170124        | NON-EXPEDITED    | Y                  | OT              | 1000005617           |                               |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Priapism                                                                                          | Lexapro        |                  |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                   | Seroquel       |                  |                    | C               |                      |                               | Not Reported    |              |                |
|                                                                                                   | Viagra         |                  |                    | C               |                      |                               | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                                      | 7172700                | NON-EXPEDITED    | Y                  | HO, LT, OT      | S08-USA-02237-01     |                                                        | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction;<br>Drug Hypersensitivity;<br>Gastroesophageal Reflux<br>Disease; Overdose;<br>Respiratory Tract Infection | Lexapro                |                  |                    | S               | Oral                 | 20 Mg (1 In 1 D), Oral : 30<br>Mg (30 Mg, Daily), Oral |                 | Not Reported |                |
|                                                                                                                                  | Unspecified Ingredient |                  |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                  | Clonazepam             |                  |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                  | Inhaler                |                  |                    | C               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                      | 7174028                | NON-EXPEDITED    | Y                  | OT              | 1000000518           |                                                        |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                                                                                                     | Lexapro                |                  |                    | S               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                      | 7174049                | NON-EXPEDITED    | N                  | OT              | 1000000839           |                                                        | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Depression;<br>Feelings Of<br>Worthlessness;<br>Headache; Insomnia;<br>Pain; Suicidal Ideation                       | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                       |                 | Not Reported |                |
|                                                                                                                                  | Wellbutrin             |                  |                    | C               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                      | 7174052                | NON-EXPEDITED    | Y                  | HO              | 1000000888           |                                                        | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                                                                                              | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                              | 7174069        | NON-EXPEDITED    | Y                  | OT              | 1000001035           |                                       | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Pressure Increased; Dizziness; Dry Mouth; Dyskinesia; Fatigue; Hot Flush; Hyperhidrosis; Insomnia; Tremor | Lexapro        |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral           |                 | Not Reported |                |
|                                                                                                                          | Lantus         |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Insulin Nos    |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Nph Insulin    |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Synthroid      |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Lorazepam      |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Darvocet       |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Meclizine      |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Multi-Vitamin  |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Senokot        |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          | Avapro         |                  |                    | C               |                      |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                              | 7174077        | NON-EXPEDITED    | Y                  | HO              | 1000001048           |                                       | 63 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Hypoglycaemia; Syncope                                                                                      | Lexapro        |                  |                    | S               |                      | 20 Mg (20 Mg, Qd)                     |                 | Not Reported |                |
|                                                                                                                          | Sunitinib      |                  |                    | S               |                      | 50 Mg (Qd)                            |                 | Not Reported |                |
|                                                                                                                          | Sorafenib      |                  |                    | S               |                      | 800 Mg (400 Mg, Bid)                  |                 | Not Reported |                |
|                                                                                                                          | Accupril       |                  |                    | S               |                      | 40 Mg (40 Mg, Qd)                     |                 | Not Reported |                |
|                                                                                                                          | Omacor         |                  |                    | S               |                      | 4000 Mg (1000 Mg, Qid)                |                 | Not Reported |                |
|                                                                                                                          | Coreg          |                  |                    | S               |                      | 12.5 Mg (12.5 Mg, Qd)                 |                 | Not Reported |                |
|                                                                                                                          | Humalog        |                  |                    | S               |                      | 50 Units (25 Units Qam, 25 Units Qpm) |                 | Not Reported |                |
|                                                                                                                          | Hydralazine    |                  |                    | S               | Subcutaneous         | 25 Mg, Tid                            |                 | Not Reported |                |
|                                                                                                                          | Novolog        |                  |                    | S               |                      | (100 Units/MI Tid), Subcutaneous      |                 | Not Reported |                |
|                                                                                                                          | Pravachol      |                  |                    | S               |                      | 40 Mg (40 Mg, Qd)                     |                 | Not Reported |                |
|                                                                                                                          | Aspirin        |                  |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                          |                |                  |                    |                 |                      |                                       |                 |              |                |



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| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------------------|--------------------------|---------------------|-------------------------|
| 13-Oct-2009                                                                                                                     | 7174115                 | NON-EXPEDITED             | N                           | OT                       | 1000001143                    |                                           | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Triglycerides Increased; Dizziness; Headache; Hyperhidrosis; Muscle Spasms; Nausea; Overdose; Suicidal Ideation; Vomiting | Lexapro                 |                           |                             | S                        | Oral                          | See Image                                 |                          | Not Reported        |                         |
|                                                                                                                                 |                         |                           |                             |                          | Oral                          | See Image                                 |                          |                     |                         |
|                                                                                                                                 |                         |                           |                             |                          | Oral                          | See Image                                 |                          |                     |                         |
|                                                                                                                                 |                         |                           |                             |                          | Oral                          | See Image                                 |                          |                     |                         |
|                                                                                                                                 |                         |                           |                             |                          | Oral                          | See Image                                 |                          |                     |                         |
|                                                                                                                                 |                         |                           |                             |                          | Oral                          | See Image                                 |                          |                     |                         |
|                                                                                                                                 | Xanax                   |                           |                             | C                        |                               |                                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Oct-2009                                                                                                                     | 7174121                 | NON-EXPEDITED             | Y                           | OT                       | 1000001199                    |                                           |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicidal Ideation                                                                                                               | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (Daily), Oral : 20 Mg (Daily), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Oct-2009                                                                                                                     | 7174122                 | NON-EXPEDITED             | Y                           | OT                       | 1000001206                    |                                           |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Serotonin Syndrome                                                                                                              | Lexapro                 |                           |                             | S                        |                               |                                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Oct-2009                                                                                                                     | 7174123                 | NON-EXPEDITED             | Y                           | HO                       | 1000001222                    |                                           | 66 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Leukopenia                                                                                                                      | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral             |                          | Not Reported        |                         |
|                                                                                                                                 | Albuterol               |                           |                             | C                        |                               |                                           |                          | Not Reported        |                         |

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| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                        | 7175299        | NON-EXPEDITED    | Y                  | OT              | 1000001454           |                                  | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal<br>Haemorrhage                                                                    | Lexapro        |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                    | Aciphex        |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                    | Synthroid      |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                    | Zantac         |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                    | Tums           |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                        | 7175321        | NON-EXPEDITED    | N                  | OT              | 1000001288           |                                  | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Depression;<br>Dizziness; Feelings Of<br>Worthlessness; Irritability;<br>Suicidal Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                    | Chantix        |                  |                    | S               |                      | Daily                            |                 | Not Reported |                |
|                                                                                                    | Levoxyl        |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                    | Lisinopril     |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                    | Singulair      |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                        | 7175329        | NON-EXPEDITED    | Y                  | OT              | 1000001321           |                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                 | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                        | 7175367        | NON-EXPEDITED    | Y                  | OT              | 1000001502           |                                  | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

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|                   |                         |   |      |                                  |              |
|-------------------|-------------------------|---|------|----------------------------------|--------------|
| Suicidal Ideation | Lexapro                 | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                   | Darvocet-N 100          | C |      |                                  | Not Reported |
|                   | Trazodone Hydrochloride | C |      |                                  | Not Reported |
|                   | Flonase                 | C |      |                                  | Not Reported |
|                   | Astelin                 | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7176979       | NON-EXPEDITED    | Y                  | OT              | 1000001591           |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7177048       | NON-EXPEDITED    | Y                  | OT              | 1000001674           |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Decreased Appetite; Drug Interaction; Eye Movement Disorder; Food Craving; Headache; Nausea; Pruritus Generalised; Suicidal Ideation; Tremor; Visual Impairment; Vomiting; Weight Increased | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                             | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 Qod),<br>Oral    |                 | Not Reported |
|                                                                                                                                                                                             | Amitriptyline           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                             | Tramadol Hydrochloride  |              |            | S           | Oral         | 50 Mg (50 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                             | Flexeril                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                             | Phenergan               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                             | Darvocet                |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                             | Propranolol             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                             | Metformin Hydrochloride |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                             | Xanax                   |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                             | Synthroid               |              |            | C           |              |                                  |                 | Not Reported |

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|  |                     |   |              |
|--|---------------------|---|--------------|
|  | Tri-Sprintec        | C | Not Reported |
|  | Hydrochlorothiazide | C | Not Reported |
|  | Wellbutrin XL       | C | Not Reported |
|  | Centrum             | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009              | 7177057        | NON-EXPEDITED    | Y                  | OT              | 1000001737           |                                  | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                          | Wellbutrin     |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                          | Synthroid      |                  |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>          | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|---------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Oct-2009                       | 7177066             | NON-EXPEDITED    | N                  | HO              | 1000003058           |                      | 86 YR           | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Vomiting | Lexapro             |                  |                    | S               | Oral                 | 1 In 1 D, Oral       |                 | Not Reported |                |
|                                   | Hydroxyurea         |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Atenolol            |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                   | Amlodipine Besylate |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                                                                                                         | 7177087        | NON-EXPEDITED    | N                  | OT              | 1000003119           |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood;<br>Depression; Feeling Of<br>Body Temperature<br>Change; Hyperhidrosis;<br>Influenza Like Illness;<br>Overdose; Pain;<br>Paraesthesia; Suicidal<br>Ideation; Withdrawal<br>Syndrome | Lexapro        |                  |                    | S               | Oral<br>Oral         | See Image<br>See Image |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                   | 7177090                | NON-EXPEDITED    | Y                  | HO              | 1000003177           |                                  | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Confusional State                                                                                    | Lexapro                |                  |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                               | Unspecified Ingredient |                  |                    | S               | Oral                 | 2400 Mg (400 Mg, 6 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                               | Lamotrigine            |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                               | Levetiracetam          |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                               | Phenytoin              |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                               | Quetiapine             |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                   | 7179025                | NON-EXPEDITED    | N                  | OT              | 1000003223           |                                  | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Confusional State; Eating Disorder; Pain; Stress; Suicidal Ideation; Tachyphrenia; Tinnitus | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                               | Lexapro                |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                               | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                               | Lexapro                |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                   | 7179031                | NON-EXPEDITED    | Y                  | HO              | 1000003458           |                                  | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                                                                           | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                               | Toprol XL              |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                               | Caduet                 |                  |                    | C               |                      |                                  |                 | Not Reported |                |

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| Neurontin                                          |                        | C                |                    | Not Reported    |                      |                                                                               |                 |              |                |
|----------------------------------------------------|------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Protonix                                           |                        | C                |                    | Not Reported    |                      |                                                                               |                 |              |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                        | 7179038                | NON-EXPEDITED    | Y                  | OT              | 1000003667           |                                                                               | 30 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                 | Lexapro                |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
|                                                    |                        |                  |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral                 |                 |              |                |
|                                                    | Hydroxychloroquine     |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                    | Prednisone             |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                    | Azathioprine           |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                    | Tramadol Hydrochloride |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                    | Lantus                 |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |
| Calcium With Vitamin D (Tablets)                   |                        |                  | C                  |                 |                      |                                                                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                        | 7179054                | NON-EXPEDITED    | Y                  | HO              | 1000004973           |                                                                               | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory; Overdose; Suicide Attempt | Lexapro                |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                    |                        |                  |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                    |                        |                  |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 1 Once, Oral, 30 Mg (30 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                    | Unspecified Ingredient |                  |                    | S               |                      | Once, High Dose<br>Once, High Dose                                            |                 | Not Reported |                |
|                                                    | Tylenol                |                  |                    | C               |                      |                                                                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |                |                  |                    |                              |                      |                                                                    |                 |              |                |
|------------------------------------------------------------|----------------|------------------|--------------------|------------------------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| Aleve<br>Risperdal                                         |                | C<br>C           |                    | Not Reported<br>Not Reported |                      |                                                                    |                 |              |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                | 7179059        | NON-EXPEDITED    | Y                  | HO                           | 1000004977           |                                                                    |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased                                     | Lexapro        |                  |                    | S                            | Oral                 | 10 Mg (1 In 1 D), Oral                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                | 7179061        | NON-EXPEDITED    | Y                  | HO                           | 1000004993           |                                                                    | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Hypertension; Insomnia              | Lexapro        |                  |                    | S                            | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                | 7179070        | NON-EXPEDITED    | Y                  | HO                           | 1000005024           |                                                                    | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose                                       | Lexapro        |                  |                    | S                            | Oral                 | 20 Dosage Forms, Once,<br>Oral                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                | 7179082        | NON-EXPEDITED    | Y                  | HO                           | 1000005208           |                                                                    | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia;<br>Electrocardiogram Qt<br>Prolonged; Syncope | Lexapro        |                  |                    | S                            | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 40 Mg (40 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                            |                |                  |                    |                              | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 40 Mg (40 Mg, 1 In 1<br>D), Oral |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |   |              |
|-----------------------------------------------|---|--------------|
| Linaclotide (Capsules)                        | C | Not Reported |
| Prempro                                       | C | Not Reported |
| Lunesta                                       | C | Not Reported |
| Aleve                                         | C | Not Reported |
| Dulcolax Tablets                              | C | Not Reported |
| Zithromax                                     | C | Not Reported |
| Omnaris (Nasal Drops (Including Nasal Spray)) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7179092       | NON-EXPEDITED    | Y                  | HO              | 1000005233           |                      | 70 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastrointestinal Haemorrhage | Lexapro                          |              |            | S           |              |                    |                 | Not Reported |
|                              | Aspirin                          |              |            | S           |              |                    |                 | Not Reported |
|                              | Numerous Other Medications (Nos) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2009              | 7179147       | NON-EXPEDITED    | Y                  | OT              | 1000005381           |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Lexapro                 |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                              | Trileptal               |              |            | S           | Oral         | 600 Mg (600 Mg), Oral         |                 | Not Reported |
|                                              | Geodon                  |              |            | C           |              |                               |                 | Not Reported |
|                                              | Neurontin               |              |            | C           |              |                               |                 | Not Reported |
|                                              | Trazodone Hydrochloride |              |            | C           |              |                               |                 | Not Reported |
|                                              | Valium                  |              |            | C           |              |                               |                 | Not Reported |
|                                              | Aciphex                 |              |            | C           |              |                               |                 | Not Reported |
|                                              | Marinol                 |              |            | C           |              |                               |                 | Not Reported |
|                                              | Miralax                 |              |            | C           |              |                               |                 | Not Reported |
|                                              | Boniva                  |              |            | C           |              |                               |                 | Not Reported |
|                                              | Enablex                 |              |            | C           |              |                               |                 | Not Reported |
|                                              | Copaxone                |              |            | C           |              |                               |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 13-Oct-2009                                                                                                                                                      | 7212251                     | NON-EXPEDITED      | Y                  | HO              | 1000006570                 |                               | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased                                                                                                                                         | Lexapro                     |                    |                    | S               | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2009                                                                                                                                                      | 7212300                     | NON-EXPEDITED      | Y                  | OT              | 1000000791                 |                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Fulminant                                                                                                                                              | Escitalopram Oxalate        |                    |                    | S               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2009                                                                                                                                                      | 7139125                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000008871                 |                               | 48 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Electrocardiogram Qrs Complex Prolonged; Intentional Overdose; Respiratory Depression; Seizure; Suicide Attempt; Tachyarrhythmia; Ventricular Fibrillation | Escitalopram Oxalate        |                    |                    | S               | Oral                       | (800 Mg, Once), Oral          |                 | Not Reported |                |
|                                                                                                                                                                  | Amitriptyline Hydrochloride |                    |                    | S               | Oral                       | (1000 Mg, Once) , Oral        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2009                                                                                                                                                      | 7148409                     | EXPEDITED (15-DAY) | Y                  | DE              | CH-ASTRAZENECA-2009SE19259 |                               | 35 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                | Seroquel Xr                 |                    |                    | S               | Oral                       |                               | 5 DAY           | Zeneca       |                |
|                                                                                                                                                                  | Seroquel Xr                 |                    |                    | S               | Oral                       |                               | 4 DAY           | Zeneca       |                |
|                                                                                                                                                                  | Risperdal                   |                    |                    | S               | Oral                       |                               | 3 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |           |   |      |        |              |
|--|-----------|---|------|--------|--------------|
|  | Risperdal | S | Oral | 18 DAY | Not Reported |
|  | Risperdal | S | Oral | 5 DAY  | Not Reported |
|  | Risperdal | S | Oral | 4 DAY  | Not Reported |
|  | Risperdal | S | Oral | 32 DAY | Not Reported |
|  | Haldol    | S | Oral | 6 DAY  | Not Reported |
|  | Haldol    | S | Oral | 5 DAY  | Not Reported |
|  | Haldol    | S | Oral | 2 DAY  | Not Reported |
|  | Haldol    | S | Oral | 1 DAY  | Not Reported |
|  | Ciprallex | S | Oral | 1 DAY  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Oct-2009              | 7150174       | EXPEDITED (15-DAY) | N                  | DE              | US-ABBOTT-09P-163-0601310-00 |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Subdural Haemorrhage | Vicodin        |              |            | S           |              | 5/500 Mg           |                 | Not Reported |
|                                | Lexapro        |              |            | S           |              | 10 Mg Or 20 Mg     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2009              | 7154973       | DIRECT           | Y                  | HO              |                      |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Maternal Drugs Affecting Foetus; Tremor Neonatal | Wellbutrin     |              |            | S           | Oral         | 300mg Daily Po During The Pregnancy | 9 MTH           | Not Reported |
|                                                  | Lexapro        |              |            | S           | Oral         | 20 Mg Daily Po                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2009              | 7160859       | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2009TR10832      |                      | 32 YR      | Female     | TUR            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Migraine; Oculogyric Crisis; | Escitalopram Oxalate |              |            | S           |              | 10 Mg/Day          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |                                           |   |                                          |  |                    |  |              |  |  |
|----------------------------------------------|-------------------------------------------|---|------------------------------------------|--|--------------------|--|--------------|--|--|
| Serotonin Syndrome;<br>Therapy Non-Responder | Metoclopramide                            | S | Intravenous (not<br>otherwise specified) |  | 10 Mg, Intravenous |  | Not Reported |  |  |
|                                              | Analgesics (No<br>Ingredients/Substances) | C |                                          |  |                    |  | Not Reported |  |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2009              | 7156387       | DIRECT           |                    | HO, LT, OT      |                      |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Blood<br>Phosphorus Abnormal;<br>Blood Potassium<br>Abnormal; Cerebral<br>Haemorrhage;<br>Confusional State;<br>Decreased Activity; Fall;<br>Gait Disturbance;<br>Hallucination;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Lexapro        |              |            | S           | Oral         | 1 Bedtime Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Oct-2009              | 7162552       | EXPEDITED (15-DAY) | N                  | OT              | 1000009365           |                      | 51 YR      | Male       | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Inflammation; Mucosal<br>Disorder; Nasal Polyps;<br>Sinus Disorder | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                    | Ramipril       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                    | Uroxatral      |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2009              | 7151969       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2009279348 |                      | 85 YR      | Unknown    | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Fall; Hyponatraemia;<br>Hypotension | Aldactone      |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |      |                |       |              |
|--|----------------------|---|------|----------------|-------|--------------|
|  | Escitalopram Oxalate | S | Oral | 10 Mg, 1x/Day  | 2 DAY | Not Reported |
|  | Levothyrox           | C |      | 100 Ug, 1x/Day |       | Not Reported |
|  | Lorazepam            | C |      | 1 Mg, 1x/Day   |       | Not Reported |
|  | Caffeine             | C |      |                |       | Not Reported |
|  | Glucophage           | C |      |                |       | Not Reported |
|  | Diosmine             | C |      |                |       | Not Reported |
|  | Arixtra              | C |      | 1 Df, 1x/Day   | 1 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2009              | 7152651              | EXPEDITED (15-DAY) | Y                  | OT              | TR-MYLANLABS-2009S1017335             |                      | 32 YR           | Female       | TUR            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;        | Escitalopram Oxalate |                    |                    | S               |                                       | 10 Mg/Day            |                 | Alphapharm   |                |
| Oculogyric Crisis;       | Metoclopramide       |                    |                    | S               | Intravenous (not otherwise specified) | 10mg                 |                 | Not Reported |                |
| Serotonin Syndrome       |                      |                    |                    |                 |                                       |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2009              | 7162581        | EXPEDITED (15-DAY) | N                  | OT              | AUR-APL-2009-00828   |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Pressure  | Lisinopril     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Fluctuation; Blood       | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Pressure Inadequately    | Depakote       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Controlled; Fall;        | Oxybutynin     |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Headache; Seizure;       |                |                    |                    |                 |                      |                      |                 |              |                |
| Tremor                   |                |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2009              | 7162593              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009451           |                      | 69 YR           | Female       | ESP            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fluid Retention          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg, Oral          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|------------------------------------------|-----------------|--------------|----------------|
| 19-Oct-2009                                                | 7162595              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009391                |                                          |                 | Male         | CAN            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Mouth Haemorrhage;<br>Petechiae                            | Escitalopram Oxalate |                    |                    | S               | Oral                      | Oral                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2009                                                | 7162727              | EXPEDITED (15-DAY) | Y                  | CA              | 1000009404                |                                          |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Digeorge'S Syndrome;<br>Maternal Drugs Affecting<br>Foetus | Escitalopram Oxalate |                    |                    | S               | Transplacental            | 5 Mg (5 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2009                                                | 7165124              | EXPEDITED (15-DAY) | Y                  | HO              | 1000009010                |                                          | 29 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder;<br>Condition Aggravated                  | Escitalopram Oxalate |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral         |                 | Not Reported |                |
|                                                            | Xanax                |                    |                    | C               |                           |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Oct-2009                                                | 7153024              | EXPEDITED (15-DAY) | Y                  | OT              | AT-JNJFOC-<br>20090908153 |                                          | 24 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Restless Legs Syndrome                                     | Risperdal            |                    |                    | S               | Oral                      |                                          |                 | Not Reported |                |
|                                                            | Risperdal            |                    |                    | S               | Oral                      | 0-0-0-1                                  |                 | Not Reported |                |
|                                                            | Risperdal            |                    |                    | S               | Oral                      |                                          |                 | Not Reported |                |
|                                                            | Risperdal            |                    |                    | S               | Oral                      |                                          |                 | Not Reported |                |

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|            |   |      |         |  |  |              |
|------------|---|------|---------|--|--|--------------|
| Risperdal  | S | Oral |         |  |  | Not Reported |
| Cipralelex | S | Oral | 2-0-0-0 |  |  | Not Reported |
| Cipralelex | S | Oral |         |  |  | Not Reported |
| Zyprexa    | C | Oral |         |  |  | Not Reported |
| Zyprexa    | C | Oral |         |  |  | Not Reported |
| Zyprexa    | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |
| Lorazepam  | C | Oral |         |  |  | Not Reported |

| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2009                                                  | 7107170        | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000008390           |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Maternal Exposure During<br>Pregnancy | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Oct-2009                            | 7156875                    | EXPEDITED (15-DAY) | Y                  | HO              | FR-EISAI INC.-E3810-03231-SPO-FR |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disorientation; Fall;<br>Hyponatraemia | Pariet (Rabeprazole)       |                    |                    | S               | Oral                             |                      |                 | Not Reported |                |
|                                        | Pariet (Rabeprazole)       |                    |                    | S               | Oral                             |                      |                 | Not Reported |                |
|                                        | Escitalopram Oxalate       |                    |                    | S               | Oral                             |                      |                 | Not Reported |                |
|                                        | Acetylsalicylate Lysine 75 |                    |                    | C               |                                  |                      |                 | Not Reported |                |
|                                        | Acepromazine               |                    |                    | C               |                                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Maleate\Clorazepate  
Dipotassium  
Lorazepam  
Brompheniramine Maleate

C  
C

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Oct-2009              | 7156998       | EXPEDITED (15-DAY) | N                  | HO, LT, OT      | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14827042 |                      | 57 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>           |
|------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|----------------------|
| Acute Kidney Injury;<br>Asthenia; Diarrhoea;<br>Hyperkalaemia; Muscle<br>Spasms; Nausea;<br>Vomiting | Hydrochlorothiazide\Irbesartan        |              |            | S           |              | 1 Df = 1(Units Not Specified)               |                 | Bristol Myers Squibb |
|                                                                                                      | Metformin Hydrochloride               |              |            | S           |              |                                             | 2 MTH           | Bristol Myers Squibb |
|                                                                                                      | Sitagliptin Phosphate                 |              |            | S           |              | Taken For A Month                           | 1 MTH           | Not Reported         |
|                                                                                                      | Escitalopram Oxalate                  |              |            | S           |              |                                             |                 | Not Reported         |
|                                                                                                      | Inexium                               |              |            | C           |              |                                             |                 | Not Reported         |
|                                                                                                      | Rivotril                              |              |            | C           |              |                                             |                 | Not Reported         |
|                                                                                                      | Potassium Chloride                    |              |            | C           |              |                                             |                 | Not Reported         |
|                                                                                                      | Fenofibrate                           |              |            | C           |              | 1 Df = 300(Units Not Specified) Secalip 300 |                 | Not Reported         |
|                                                                                                      | Acepromazine\Aceprometazine\          |              |            | C           |              |                                             |                 | Not Reported         |
|                                                                                                      | Clorazepate Dipotassium<br>Alprazolam |              |            | C           |              |                                             |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2009              | 7168678       | EXPEDITED (15-DAY) | N                  | CA              | 1000009473           |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Anal Atresia; Congenital<br>Cystic Kidney Disease;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Oct-2009              | 7169753       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008494           |                      | 26 YR      | Female     | DNK            |

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| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| Caesarean Section;<br>Complication Of Delivery;<br>Maternal Exposure During<br>Pregnancy; Pregnancy                                         | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>Oral                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Oct-2009                                                                                                                                 | 7169760                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000009488           |                                                                 |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Disturbance In Attention;<br>Hyponatraemia; Incorrect<br>Dose Administered; Major<br>Depression; Urinary<br>Retention | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>Oral 20 Mg (20 Mg, 1 In 1<br>D) Oral | 48 HR           | Not Reported |                |
|                                                                                                                                             | Risperidal                      |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Ixel (Tablets)                  |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2009                                                                                                                                 | 6518322                         | EXPEDITED (15-DAY) | Y                  | OT              | S07-DEN-06335-01     |                                                                 | 62 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Muscle<br>Spasms; Myoclonus; Poor<br>Quality Sleep                                                                        | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                     |                 | Not Reported |                |
|                                                                                                                                             | Primperan                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |                |
|                                                                                                                                             | Dimitone (Carvedilol)           |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Amlodipine                      |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Cardopax (Isosorbide Dinitrate) |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | (Isosorbide Dinitrate)          |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Furix (Furosemide)              |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | (Furosemide)                    |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Hjertemagnyl                    |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Ramipril                        |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Simvastatin                     |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | Spirocort (Budesonide)          |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                             | (Solution) (Budesonide)         |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
| Pantoloc                                                                                                                                    |                                 |                    | C                  |                 |                      |                                                                 | Not Reported    |              |                |



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|                                |   |              |
|--------------------------------|---|--------------|
| Plavix                         | C | Not Reported |
| Fem-Mono Retard                | C | Not Reported |
| Bricanyl (Terbutaline Sulfate) | C | Not Reported |
| (Terbutaline Sulfate)          |   |              |
| Spirix (Spironolactone)        | C | Not Reported |
| (Spironolactone)               |   |              |
| Travatan (Travoprost) (Liquid) | C | Not Reported |
| (Travoprost)                   |   |              |
| Nitroglycerin                  | C | Not Reported |
| Triatec (Tablets)              | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2009              | 7171564       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009562           |                      | 20 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ammonia Increased;       | Escitalopram Oxalate |              |            | S           | Oral         | (Once), Oral; Oral |                 | Not Reported |
| Blood Lactic Acid        |                      |              |            |             | Oral         | (Once), Oral; Oral |                 |              |
| Increased; Brain Oedema; | Depakote             |              |            | S           | Oral         | (Once), Oral; Oral |                 | Not Reported |
| Drug Level Above         |                      |              |            |             | Oral         | (Once), Oral; Oral |                 |              |
| Therapeutic;             | Depakote             |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Extrapyramidal Disorder; | Aripiprazole         |              |            | S           |              | (Once)             |                 | Not Reported |
| Intentional Overdose;    |                      |              |            |             |              |                    |                 |              |
| Nervous System Disorder; |                      |              |            |             |              |                    |                 |              |
| Tachycardia              |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2009              | 7171623       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009597           |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Blood Pressure | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Fluctuation; Fall; Gait | Oxybutynin     |              |            | S           |              |                    |                 | Not Reported |
| Disturbance; Headache;  | Lisinopril     |              |            | S           |              |                    |                 | Not Reported |
| Seizure; Tremor         | Depakote       |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2009              | 7068001       | EXPEDITED (15-DAY) | Y                  | DE, LT          | 1000007531           |                      | 72 YR      | Male       | DNK            |

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| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Cerebral Artery Embolism;<br>Completed Suicide;<br>Delirium; Haematemesis;<br>Hallucination, Visual;<br>Intentional Overdose;<br>Psychomotor<br>Hyperactivity; Pulmonary<br>Embolism; Seizure | Escitalopram Oxalate                  |              |            | S           | Oral         | (60 Mg,Once), Oral; 10 Mg<br>(10 Mg,1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                      |                                       |              |            |             | Oral         | (60 Mg,Once), Oral; 10 Mg<br>(10 Mg,1 In 1 D), Oral |                 |              |
|                                                                                                                                                                                                                      | Plavix                                |              |            | C           |              |                                                     |                 | Not Reported |
|                                                                                                                                                                                                                      | Cordarone                             |              |            | C           |              |                                                     |                 | Not Reported |
|                                                                                                                                                                                                                      | Triatec (Ramipril)                    |              |            | C           |              |                                                     |                 | Not Reported |
|                                                                                                                                                                                                                      | Omnice                                |              |            | C           |              |                                                     |                 | Not Reported |
|                                                                                                                                                                                                                      | Dormicum (Midazolam<br>Hydrochloride) |              |            | C           |              |                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2009              | 7172963       | EXPEDITED (15-DAY) | Y                  | HO              | DSU-2009-02216       |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Atrial<br>Fibrillation; Blood Chloride<br>Increased; Blood Glucose<br>Increased; Blood<br>Potassium Decreased;<br>Electrocardiogram<br>Change;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram T Wave<br>Abnormal; Hypotension;<br>Mood Swings; Overdose;<br>Pco2 Decreased; Shock | Benicar                |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Tarka                  |              |            | S           | Oral         | 4/240 Mg,Per Oral  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Lexapro                |              |            | S           | Oral         | Per Oral           |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                            | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2009              | 7173014       | EXPEDITED (15-DAY) | Y                  | DS              | 1000009659           |                      | 45 YR      | Male       | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Drug Dependence; Pain;<br>Withdrawal Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |                             |              |
|-------------------------|---|------|-----------------------------|--------------|
| Escitalopram Oxalate    | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral | Not Reported |
| Methadone Hydrochloride | C |      |                             | Not Reported |
| Prazepam                | C |      |                             | Not Reported |
| Inexium                 | C |      |                             | Not Reported |
| Mag 2                   | C |      |                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2009              | 7173058       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009684           |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Hypertensive Crisis   | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2009              | 7166231       | DIRECT           |                    | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Anorgasmia; Constipation; Sexual Dysfunction; Urticaria | Bupropion Hydrochloride |              |            | S           |              | 150 Mg One Daily 9/12/10 For 3 1/2 Weeks |                 | Not Reported |
|                                                         | Lexapro                 |              |            | S           |              | 10 Mg One Daily                          | 3 YR            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Oct-2009              | 7166248       | DIRECT           |                    |                 |                      |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Condition Aggravated; Dry Mouth; Fatigue; Heart Rate Decreased; Loss Of Libido; Palpitations; Sexual Dysfunction; Tinnitus | Lexapro        |              |            | S           |              | 10 Mg 1 A Day<br>10 Mg 1 A Day |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 29-Oct-2009               | 7178121              | EXPEDITED (15-DAY) | Y                  | HO              | 1000009631           |                          | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alkaline            | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                     |                 | Not Reported |                |
| Phosphatase Increased;    | Practazin            |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Blood Potassium           | Athymil              |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Increased; Confusional    | Debridat             |                    |                    | C               |                      |                          |                 | Not Reported |                |
| State; Disorientation;    | Noctamide            |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Gamma-                    | Venlafaxine          |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Glutamyltransferase       | Movicol              |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Increased; General        | Zanidip              |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Physical Health           | Kardegic (Powder)    |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Deterioration;            | Captopril            |                    |                    | C               |                      |                          |                 | Not Reported |                |
| Hyponatraemia; Loss Of    |                      |                    |                    |                 |                      |                          |                 | Not Reported |                |
| Consciousness;            |                      |                    |                    |                 |                      |                          |                 | Not Reported |                |
| Psychomotor Retardation   |                      |                    |                    |                 |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2009               | 7048689              | EXPEDITED (15-DAY) | N                  | DS, HO, OT      | 1000006980           |                          | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1      |                 | Not Reported |                |
| Increased; Aspartate      |                      |                    |                    |                 |                      | D),Oral ; 20 Mg (20 Mg,1 |                 |              |                |
| Aminotransferase          |                      |                    |                    |                 | Oral                 | In 1 D),Oral             |                 |              |                |
| Increased; Asphyxia;      |                      |                    |                    |                 |                      | 10 Mg (10 Mg,1 In 1      |                 |              |                |
| Autonomic Nervous         |                      |                    |                    |                 |                      | D),Oral ; 20 Mg (20 Mg,1 |                 |              |                |
| System Imbalance; Blood   |                      |                    |                    |                 |                      | In 1 D),Oral             |                 |              |                |
| Glucose Increased; Blood  |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg,1 In 1      |                 |              |                |
| Ph Decreased; Blood       |                      |                    |                    |                 |                      | D),Oral ; 20 Mg (20 Mg,1 |                 |              |                |
| Pressure Decreased;       |                      |                    |                    |                 |                      | In 1 D),Oral             |                 |              |                |
| Blood Pressure Increased; |                      |                    |                    |                 |                      |                          |                 |              |                |
| Candida Infection;        |                      |                    |                    |                 |                      |                          |                 |              |                |
| Disturbance In Attention; |                      |                    |                    |                 |                      |                          |                 |              |                |
| Feeding Disorder; Heart   |                      |                    |                    |                 |                      |                          |                 |              |                |
| Rate Increased;           |                      |                    |                    |                 |                      |                          |                 |              |                |
| Hyperhidrosis; Hypoxic-   |                      |                    |                    |                 |                      |                          |                 |              |                |
| Ischaemic                 |                      |                    |                    |                 |                      |                          |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Encephalopathy; Hypoxic-Ischaemic  
Encephalopathy; Loss Of Personal Independence In Daily Activities; Muscle Spasticity; Overdose; Pneumonia; Pneumonia Aspiration; Po2 Decreased; Pupil Fixed; Pyrexia; Respiration Abnormal; Respiratory Rate Increased; Speech Disorder; Suicidal Ideation; Suicide Attempt; Treatment Noncompliance; Unresponsive To Stimuli; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2009              | 6975622       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005651           |                      | 32 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Blood Follicle Stimulating Hormone Decreased;                                                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Blood Luteinising Hormone Decreased; Blood Prolactin Increased; Nuclear Magnetic Resonance Imaging Brain Abnormal; Oestradiol Decreased; Somnolence | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2009              | 7155336       | EXPEDITED (15-DAY) | Y                  | DE, LT          | 1000009219           |                      |            | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Completed Suicide;    | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Physical Assault;  
Restlessness

D),Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2009              | 7169337       | EXPEDITED (15-DAY) | Y                  | DE              | 1000009468           |                      | 35 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Completed Suicide;<br>Depression;<br>Schizoaffective Disorder;<br>Self-Injurious Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral                                                         |                 | Not Reported |
|                                                                                                                  | Seroquel Xr          |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D),Oral; 100 Mg (100 Mg, 1 In 1 D),Oral                       |                 | Not Reported |
|                                                                                                                  |                      |              |            |             | Oral         | 300 Mg (300 Mg, 1 In 1 D),Oral; 100 Mg (100 Mg, 1 In 1 D),Oral                       |                 |              |
|                                                                                                                  | Risperdal            |              |            | S           | Oral         | See Image                                                                            |                 | Not Reported |
|                                                                                                                  |                      |              |            |             | Oral         | See Image                                                                            |                 |              |
|                                                                                                                  |                      |              |            |             | Oral         | See Image                                                                            |                 |              |
|                                                                                                                  |                      |              |            |             | Oral         | See Image                                                                            |                 |              |
|                                                                                                                  |                      |              |            |             | Oral         | See Image                                                                            |                 |              |
|                                                                                                                  | Haldol               |              |            | S           | Oral         | 4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                  |                      |              |            |             | Oral         | 4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral |                 |              |
|                                                                                                                  |                      |              |            |             | Oral         | 4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral |                 |              |
|                                                                                                                  |                      |              |            |             | Oral         | 4mg (4 Mg, 1 In 1 D), Oral; 8 Mg (8 Mg, 1 In 1 D),Oral; 10 Mg (10 Mg, 1 In 1 D),Oral |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------|-----------------|--------------|----------------|
| 02-Nov-2009                                                   | 7178755              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009762            |                             |                 | Male         | FRA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Septic Shock; Tremor                                          | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2009                                                   | 7179654              | EXPEDITED (15-DAY) | N                  | DE              | 1000009795            |                             | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                             | Lexapro              |                    |                    | S               |                       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2009                                                   | 7155200              | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20091004679 |                             | 37 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Self-Injury;<br>Vomiting | Risperdal            |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                               | Risperdal            |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
|                                                               | Ciprallex            |                    |                    | S               | Oral                  |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2009                                                   | 7180807              | EXPEDITED (15-DAY) | N                  | DE              | 1000009788            |                             | 33 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence; Non-Cardiogenic Pulmonary Oedema             | Escitalopram Oxalate |                    |                    | S               |                       |                             |                 | Not Reported |                |
|                                                               | Cannabis             |                    |                    | C               |                       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2009                                                   | 7173138              | DIRECT             | Y                  | LT              |                       |                             | 15 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| Aggression; Suicidal Ideation                                                                 | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg Daily Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2009                                                                                   | 7173145                    | DIRECT             | Y                  | HO, OT          |                      |                                | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Emotional Disorder; Flat Affect; Tremor; Vision Blurred                            | Lexapro                    |                    |                    | S               | Oral                 | 10mg Daily Po                  |                 | Not Reported |                |
|                                                                                               | Cymbalta                   |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                               | Paxil                      |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                               | Wellbutrin                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                               | Seroquel                   |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2009                                                                                   | 7177280                    | EXPEDITED (15-DAY) | N                  | OT              | 1000009737           |                                | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Road Traffic Accident; Suicidal Ideation; Thinking Abnormal; Wrist Fracture | Lexapro                    |                    |                    | S               | Oral                 | 20 Mg, (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                               |                            |                    |                    |                 | Oral                 | 20 Mg, (20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                               | Hydrocodone                |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |
|                                                                                               | Valium                     |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2009                                                                                   | 7181656                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000009759           |                                | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                                      | Escitalopram Oxalate       |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |
|                                                                                               | Depakene                   |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                               | Benzodiazepine Derivatives |                    |                    | C               |                      |                                |                 | Not Reported |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|
| 04-Nov-2009                                               | 7181990        | EXPEDITED (15-DAY) | Y                  | OT              | 1000009811           |                                         | 2 YR            | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Autism Spectrum Disorder; Maternal Drugs Affecting Foetus | Lexapro        |                    |                    | S               | Transplacental       | 60 Mg (60 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                           | Acetaminophen  |                    |                    | C               |                      |                                         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 05-Nov-2009                                                                                                                                                                                              | 7169725              | EXPEDITED (15-DAY) | Y                  | HO              | 1000009475           |                               | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Brain Neoplasm; Coma; General Physical Health Deterioration; Hyponatraemia; Hypotension; Inappropriate Antidiuretic Hormone Secretion; Malnutrition; Neoplasm Recurrence | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                          | Dihydroergotamine    |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                          | Temozolomide         |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                          | Antiepileptics       |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                          | Cortisone            |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 05-Nov-2009              | 7174144              | DIRECT           | Y                  |                 |                      |                      | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Irritability             | Escitalopram Oxalate |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 05-Nov-2009              | 7174345        | DIRECT           | Y                  |                 |                      |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                       |                         |                    |                    |                 |                      |                                                           |                 |            |                              |
|-------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|------------|------------------------------|
| Libido Decreased                                      | Escitalopram Oxalate    |                    | S                  | Oral            | 20 Mg Every Day Po   |                                                           | Not Reported    |            |                              |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 05-Nov-2009                                           | 7182088                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000009794           |                                                           | 44 YR           | Female     | DNK                          |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                              |
| Anxiety; Depression; Drug Dependence; Sleep Disorder  | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral                               |                 |            | Not Reported                 |
|                                                       | Bromazepam              |                    |                    | S               | Oral                 | 12 Mg (12 Mg,1 In 1 D),Oral                               |                 |            | Not Reported                 |
|                                                       | Loxapine<br>Meprobamate |                    |                    | C<br>C          |                      |                                                           |                 |            | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 05-Nov-2009                                           | 7182092                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000009781           |                                                           | 41 YR           | Male       | DNK                          |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                              |
| Drug Dependence                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral                               |                 |            | Not Reported                 |
|                                                       | Bromazepam              |                    |                    | S               | Oral                 | 9 Mg (9 Mg,1 In 1 D),Oral                                 |                 |            | Not Reported                 |
|                                                       | Depakote                |                    |                    | C               |                      |                                                           |                 |            | Not Reported                 |
|                                                       | Cyamemazine             |                    |                    | C               |                      |                                                           |                 |            | Not Reported                 |
|                                                       | Ixel                    |                    |                    | C               |                      |                                                           |                 |            | Not Reported                 |
| <u>FDA Received Date</u>                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u>               |
| 05-Nov-2009                                           | 7184139                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000009791           |                                                           | 50 YR           | Female     | CHE                          |
| <u>Preferred Term</u>                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                              |
| Dermatitis Allergic; Pain In Jaw; Rash Pustular; Scab | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral                              |                 |            | Not Reported                 |
|                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 |            | Not Reported                 |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                             |  |  |      |                                                                  |  |  |  |              |
|--|---------------------------------------------|--|--|------|------------------------------------------------------------------|--|--|--|--------------|
|  |                                             |  |  | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral,<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral |  |  |  |              |
|  | Lorazepam (0.5 Milligram,<br>Tablets)       |  |  | C    |                                                                  |  |  |  | Not Reported |
|  | Ibandronic Acid (Injection For<br>Infusion) |  |  | C    |                                                                  |  |  |  | Not Reported |
|  | Calcium Gluconate                           |  |  | C    |                                                                  |  |  |  | Not Reported |
|  | Valeriana Officinalis (Tablets)             |  |  | C    |                                                                  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------|----------------|
| 05-Nov-2009              | 7185139        | EXPEDITED (15-DAY) | Y                  | HO              | 1000009793           |                                  | 52 YR           | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Epilepsy                 | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 |            | Not Reported   |
|                          | Lexapro        |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 |            | Not Reported   |
|                          | Simvastatin    |                    |                    | C               |                      |                                  |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                                                                                                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|------------|----------------|
| 06-Nov-2009                                                                                                                                                                                                          | 7174958        | DIRECT           | Y                  | HO, LT          |                      |                                                  | 83 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Depressed Level<br>Of Consciousness;<br>Disturbance In Attention;<br>Haemorrhage; Intentional<br>Self-Injury; Memory<br>Impairment; Restlessness;<br>Suicide Attempt;<br>Treatment<br>Noncompliance; Tremor | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Daily In Am Po                             |                 |            | Not Reported   |
|                                                                                                                                                                                                                      | Remeron        |                  |                    | S               | Oral                 | 15 Mg And Increased To<br>30mg Daily At Night Po |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2009              | 6753412       | EXPEDITED (15-DAY) | Y                  | DE              | 1000000628           |                      | 42 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Asphyxia; Completed Suicide; Drug Level Increased           | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2009                                                 | 6871403              | EXPEDITED (15-DAY) | Y                  | DE              | 1000003158           |                               | 82 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Disorder; Pleural Effusion                            | Escitalopram Oxalate |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2009                                                 | 7169734              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009620           |                               | 30 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage                                                 | Escitalopram Oxalate |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2009                                                 | 7186408              | EXPEDITED (15-DAY) | N                  | OT              | 1000009868           |                               | 28 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Imprisonment; Sexual Abuse                                  | Celexa               |                    |                    | S               | Oral                 | (20 Mg), Oral                 |                 | Not Reported |                |
|                                                             | Lexapro              |                    |                    | S               | Oral                 | (10 Mg), Oral                 |                 | Not Reported |                |
|                                                             | Restoril             |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2009                                                 | 7188928              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000009817           |                               | 57 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Asthenia; Diarrhoea; Electrocardiogram | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                             | Sitagliptin          |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D),    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  |                                |   |      |      |                                   |              |
|----------------------------------------------------------------------------------|--------------------------------|---|------|------|-----------------------------------|--------------|
| Abnormal; Haemodialysis;<br>Hyperkalaemia; Muscle<br>Spasms; Nausea;<br>Vomiting | Metformin Hydrochloride        | S | Oral | Oral | 3000 Mg (1000 Mg, 3 In 1 D), Oral | Not Reported |
|                                                                                  | Hydrochlorothiazide/Irbesartan | S | Oral |      | 150/12.5 Mg Daily, Oral           | Not Reported |
|                                                                                  | Esomeprazole                   | C |      |      |                                   | Not Reported |
|                                                                                  | Rivotril                       | C |      |      |                                   | Not Reported |
|                                                                                  | Diffu-K                        | C |      |      |                                   | Not Reported |
|                                                                                  | Secalip                        | C |      |      |                                   | Not Reported |
|                                                                                  | Noctran                        | C |      |      |                                   | Not Reported |
|                                                                                  | Alprazolam                     | C |      |      |                                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2009              | 7188936       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009830           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Maternal Drugs Affecting<br>Foetus; Neonatal<br>Aspiration; Postmature<br>Baby | Escitalopram Oxalate |              |            | S           | Transplacental | See Image          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2009              | 7188973       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009827           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Incorrect Dose<br>Administered; Medication<br>Error; Overdose; Pallor;<br>Somnolence; Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (20 Mg, 2 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                |                      |              |            |             | Oral         | 40 Mg (20 Mg, 2 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                | Prazepam             |              |            | S           | Oral         | 40 Mg (20 Mg, 2 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                |                      |              |            |             | Oral         | 40 Mg (20 Mg, 2 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Nov-2009                                                                                                                                   | 7109273              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000008366           |                                                              | 7 DAY           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal; Maternal Drugs Affecting Foetus; Neonatal Seizure                                                          | Lexapro              |                    |                    | S               | Transplacental       | 20 Mg, Transplacental                                        |                 | Not Reported |                |
|                                                                                                                                               | Prenatabs Fa         |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2009                                                                                                                                   | 7126919              | EXPEDITED (15-DAY) | Y                  | DE              | 1000008707           |                                                              | 48 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Intentional Overdose                                                                                                       | Lexapro              |                    |                    | S               | Oral                 | More Than 1o (Once); 20 Mg (20 Mg, 1 In 1 D), Oral           |                 | Not Reported |                |
|                                                                                                                                               |                      |                    |                    |                 | Oral                 | More Than 1o (Once); 20 Mg (20 Mg, 1 In 1 D), Oral           |                 |              |                |
|                                                                                                                                               | Oxycontin            |                    |                    | S               | Oral                 | (800 Mg, Once); 160 Mg (80 Md, 2 In 1 D), Oral               |                 | Not Reported |                |
|                                                                                                                                               |                      |                    |                    |                 | Oral                 | (800 Mg, Once); 160 Mg (80 Md, 2 In 1 D), Oral               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2009                                                                                                                                   | 7147820              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009063           |                                                              | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Blood Triglycerides Increased; Cardiometabolic Syndrome; Delusion; Dyslipidaemia; Hypertension; Weight Increased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                               |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (10 Mg, 2 In 1 D), Oral |                 |              |                |
|                                                                                                                                               | Seroquel             |                    |                    | S               | Oral                 | 600 Mg (600 Mg, 1 In 1 D), Oral, 400 Mg (400 Mg, 1 In        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                   |   |  |      |                                                                                      |              |
|--|-------------------|---|--|------|--------------------------------------------------------------------------------------|--------------|
|  |                   |   |  | Oral | 1 D), Oral<br>600 Mg (600 Mg, 1 In 1 D),<br>Oral, 400 Mg (400 Mg, 1 In<br>1 D), Oral |              |
|  | Seroquel          | S |  | Oral | 400 Mg (400 Mg, 1 In 1 D),<br>Oral                                                   | Not Reported |
|  | Seroquel          | S |  | Oral | 200-300 Mg (1 In 1 D),<br>Oral                                                       | Not Reported |
|  | Zyprexa           | S |  | Oral | 10-15 Mg (1 In 1 D), Oral                                                            | Not Reported |
|  | Zyprexa           | S |  | Oral | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                                     | Not Reported |
|  | Temesta (Tablets) | C |  |      |                                                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2009              | 7162603       | EXPEDITED (15-DAY) | Y                  | DE              | 1000009400           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Asphyxia; Completed<br>Suicide; Hypoxic-<br>Ischaemic<br>Encephalopathy;<br>Respiratory Arrest | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                | Trileptal            |              |            | S           | Oral         | 900 Mg (900 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                | Chlorprothixene      |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                | Risperdal            |              |            | S           | Oral         | 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Nov-2009              | 7189419       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009858           |                      | 34 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Urine Flow Decreased  | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Loperamide           |              |            | C           |              |                                  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Nov-2009                                                   | 7197633                   | NON-EXPEDITED      | N                  |                 | 1000008965           |                                                                                                                                                                                                                                                                                                 | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Hot; Motion Sickness; Palpitations; Visual Impairment | Milnacipran Hydrochloride |                    |                    | S               | Oral                 | 12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral 12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral 12.5 Mg (12.5 Mg, 1 In 1 D), Oral 25 Mg (12.5 Mg, 2 In 1 D), Oral 50 Mg (25 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                               | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                                                                                                                                                                                                                                                                   |                 | Not Reported |                |
|                                                               | Wellbutrin                |                    |                    | C               |                      |                                                                                                                                                                                                                                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2009                                                   | 7179057                   | DIRECT             | Y                  | HO, LT          |                      |                                                                                                                                                                                                                                                                                                 | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Autoimmune Hepatitis; Autoimmune Pancreatitis; Cholelithiasis | Lexapro                   |                    |                    | S               | Oral                 | 10mg 1x Daily Po                                                                                                                                                                                                                                                                                |                 | Forest       |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2009                                                   | 7116188                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000008645           |                                                                                                                                                                                                                                                                                                 | 50 YR           | Male         | NIC            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism; Tremor                                          | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D)<br>Oral                                                                                                                                                                                                                                                                 |                 | Not Reported |                |
|                                                               | Valproic Acid             |                    |                    | C               |                      |                                                                                                                                                                                                                                                                                                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>               | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------|-----------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|---------------------------------------------|--------------------------|---------------------|-------------------------|
| 12-Nov-2009                                                             | 7174078                           | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000009625                    |                                             | 57 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                 | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Parkinsonism                                                            | Escitalopram Oxalate              |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral               |                          | Not Reported        |                         |
|                                                                         | Topalgic (Tramadol Hydrochloride) |                           |                             | C                        |                               |                                             |                          | Not Reported        |                         |
|                                                                         | Vastarel                          |                           |                             | C                        |                               |                                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>               | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Nov-2009                                                             | 7191229                           | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000009433                    |                                             |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                 | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction; Epistaxis; Increased Tendency To Bruise; Metrorrhagia | Escitalopram Oxalate              |                           |                             | S                        | Oral                          | 1 Tablet Daily, Oral, 2 Tablets Daily, Oral |                          | Not Reported        |                         |
|                                                                         |                                   |                           |                             |                          | Oral                          | 1 Tablet Daily, Oral, 2 Tablets Daily, Oral |                          |                     |                         |
|                                                                         | Desogestrel                       |                           |                             | S                        | Oral                          | Oral                                        |                          | Not Reported        |                         |
|                                                                         | Cephaloridine                     |                           |                             | S                        |                               |                                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>               | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Nov-2009                                                             | 7192614                           | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000009996                    |                                             |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                 | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                                                       | Lexapro                           |                           |                             | S                        |                               |                                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                       | <a href="#">Case #</a>            | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>               | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Nov-2009                                                             | 7194850                           | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000009931                    |                                             | 68 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                          | <a href="#">Product</a>           | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                 | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Colitis; Rectal Haemorrhage                                             | Lexapro                           |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In 1 D),                    |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |               |  |  |   |      |  |  |  |              |
|--|---------------|--|--|---|------|--|--|--|--------------|
|  |               |  |  |   | Oral |  |  |  |              |
|  | Xanax         |  |  | C |      |  |  |  | Not Reported |
|  | Singulair     |  |  | C |      |  |  |  | Not Reported |
|  | Simvastatin   |  |  | C |      |  |  |  | Not Reported |
|  | Advair Diskus |  |  | C |      |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2009              | 7053993       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007097           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Muscle Spasms; Nausea; Vomiting | Lexapro                |              |            | S           | Oral         | 0.2 MI (0.2 MI,1 In 1 D),Oral |                 | Not Reported |
|                                 | Oxazepam               |              |            | C           |              |                               |                 | Not Reported |
|                                 | Temazepam              |              |            | C           |              |                               |                 | Not Reported |
|                                 | Paracetamol+Codeine    |              |            | C           |              |                               |                 | Not Reported |
|                                 | Ondansetron (Tablets)  |              |            | C           |              |                               |                 | Not Reported |
|                                 | Esoemprazole (Tablets) |              |            | C           |              |                               |                 | Not Reported |
|                                 | Alprazolam             |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2009              | 7143254       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000008911           |                      | 80 YR      | Female     | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Coma; Generalised Tonic-Clonic Seizure; Somnolence | Lexapro              |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                    | Insulatard           |              |            | C           |              |                           |                 | Not Reported |
|                                                    | Acetylsalicylic Acid |              |            | C           |              |                           |                 | Not Reported |
|                                                    | Emconcor             |              |            | C           |              |                           |                 | Not Reported |
|                                                    | Actrapid             |              |            | C           |              |                           |                 | Not Reported |
|                                                    | Plavix               |              |            | C           |              |                           |                 | Not Reported |
|                                                    | Zocor                |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Nov-2009              | 7155694       | EXPEDITED (15-DAY) | Y                  | OT              | TR-WATSON-2009-08533 |                      | 32 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                              |   |                                          |               |  |  |  |  |              |
|---------------------------------------------------------------|------------------------------|---|------------------------------------------|---------------|--|--|--|--|--------------|
| Drug Interaction;<br>Oculogyric Crisis;<br>Serotonin Syndrome | Metoclopramide Hydrochloride | S | Intravenous (not<br>otherwise specified) | 10 Mg, Single |  |  |  |  | Watson       |
|                                                               | Escitalopram Oxalate         | S |                                          |               |  |  |  |  | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Nov-2009                       | 7171552                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000009563                    |                               | 81 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Parkinsonism                   | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 5 Mg (5 Mg,1 In 1 D),Oral   |                          | Not Reported        |
|                                | Hemigoxine              |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Kardegic                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Previscan (Fluindione)  |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Nov-2009                       | 7193633                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000009903                    |                               | 85 YR               | Female              | BEL                     |

| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>  | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|------------------------------|--------------------------|---------------------|
| Tonic Clonic Movements;<br>Transient Ischaemic<br>Attack | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D),Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2009                       | 7174119                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000009596                    |                               | 32 YR               | Female              | TUR                     |

| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a>                    | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|------------------------------------------|-----------------------------|--------------------------|---------------------|
| Drug Interaction;<br>Oculogyric Crisis;<br>Serotonin Syndrome | Escitalopram Oxalate    |                       |                     | S                    | Oral                                     | 10 Mg (10 Mg), Oral         |                          | Not Reported        |
|                                                               | Metoclopramide          |                       |                     | S                    | Intravenous (not<br>otherwise specified) | 10 Mg, Intravenous          |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Nov-2009                       | 7183093                | DIRECT                    | Y                           |                          |                               |                               | 66 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                       |                          |                           |                             |                          |                               |                               |                          |                     |                         |
|---------------------------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Myalgia; Pyrexia                                                                      | Lexapro                  |                           |                             | S                        | Oral                          | Oral                          |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Nov-2009                                                                           | 7196235                  | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010007                    |                               | 40 YR                    | Female              | IRL                     |
| <a href="#">Preferred Term</a>                                                        | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Level Increased                                                                  | Lexapro                  |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          |                     | Not Reported            |
|                                                                                       | Lexapro                  |                           |                             | S                        | Oral                          | 5 Mg (5 Mg, 1 In 1 D), Oral   |                          |                     | Not Reported            |
|                                                                                       | Clozaril                 |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2009                                                                           | 7179493                  | EXPEDITED (15-DAY)        |                             | OT                       | AU-MYLANLABS-2009S1019216     |                               | 24 YR                    | Female              | AUS                     |
| <a href="#">Preferred Term</a>                                                        | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Bipolar Disorder; Dizziness; Nausea; Somnolence; Vomiting                    | Escitalopram Oxalate     |                           |                             | S                        | Oral                          |                               |                          |                     | Alphapharm              |
|                                                                                       | Isopitin                 |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                                       | Topamax                  |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
|                                                                                       | Prochlorperazine Maleate |                           |                             | C                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2009                                                                           | 7196433                  | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010045                    |                               |                          | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                        | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anger; Anxiety; Haemorrhoid Operation; Incorrect Dose Administered; Memory Impairment | Escitalopram Oxalate     |                           |                             | S                        |                               | 10 Mg                         |                          |                     | Not Reported            |
|                                                                                       | Tramadol Hydrochloride   |                           |                             | S                        |                               | 20 Gtt                        |                          |                     | Not Reported            |
|                                                                                       | Unspecified Ingredient   |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Nov-2009                                                                           | 7197211                  | EXPEDITED (15-DAY)        | Y                           | HO, RI                   | 1000010067                    |                               | 65 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                        | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                  |                        |   |      |                                                       |              |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------|---|------|-------------------------------------------------------|--------------|
| Cell Death; Device<br>Related Infection; Fall;<br>Rhabdomyolysis;<br>Staphylococcal Infection;<br>Surgical Procedure<br>Repeated | Escitalopram Oxalate   | S | Oral | 10 Mg, (10 Mg, 1 In 1 D),<br>Oral                     | Not Reported |
|                                                                                                                                  | Bactrim Forte          | S | Oral | 3 Dosage Forms (1<br>Dosage Forms, 3 In 1 D),<br>Oral | Not Reported |
|                                                                                                                                  | Lescol                 | S | Oral | 80 Mg (80 Mg, 1 In 1 D),<br>Oral                      | Not Reported |
|                                                                                                                                  | Xanax                  | S | Oral | 0.25 Mg (0.25 Mg, 1 In 1<br>D), Oral                  | Not Reported |
|                                                                                                                                  | Fluconazole            | S | Oral | 100 Mg (100 Mg, 1 In 1 D),<br>Oral                    | Not Reported |
|                                                                                                                                  | Fucidine (Tablets)     | C |      |                                                       | Not Reported |
|                                                                                                                                  | Amlor                  | C |      |                                                       | Not Reported |
|                                                                                                                                  | Previscan (Fluindione) | C |      |                                                       | Not Reported |
|                                                                                                                                  | Tenormin               | C |      |                                                       | Not Reported |
|                                                                                                                                  | Inexium                | C |      |                                                       | Not Reported |
|                                                                                                                                  | Imovane                | C |      |                                                       | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 18-Nov-2009                                                          | 6965339              | EXPEDITED (15-DAY) |                    | DS, HO, OT      | GB-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2009-<br>UK-00 |                      | 66 YR           | Female               | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Depressed Level Of<br>Consciousness; Drug<br>Interaction; Somnolence | Catapres-Tts         |                    |                    | S               |                                                               |                      |                 | Boehringer Ingelheim |                |
|                                                                      | Catapres-Tts         |                    |                    | S               |                                                               |                      |                 | Boehringer Ingelheim |                |
|                                                                      | Escitalopram Oxalate |                    |                    | S               |                                                               | 5 Mg                 |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 18-Nov-2009                                                          | 7083074                      | EXPEDITED (15-DAY) |                    | DS, HO, OT      | GB-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2009-<br>UK-00 |                      | 66 YR           | Female               | GBR            |
| <u>Preferred Term</u>                                                | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Depressed Level Of<br>Consciousness; Drug<br>Interaction; Somnolence | Clonidine Transdermal System |                    |                    | S               |                                                               |                      | 2 DAY           | Boehringer Ingelheim |                |
|                                                                      | Clonidine Transdermal System |                    |                    | S               |                                                               |                      | 2 DAY           | Boehringer Ingelheim |                |

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|                                                                                  |                           |                    |                    |                 |                          |                      |                 |              |                |
|----------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                             |                           |                    | S                  |                 | 5 Mg                     |                      | 1 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2009                                                                      | 7180416                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2009293445 |                      | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Rhabdomyolysis                                                                   | Xanax                     |                    |                    | S               | Oral                     | 0.25 Mg, 1x/Day      |                 | Pfizer       |                |
|                                                                                  | Triflucan                 |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       | 4 DAY           | Pfizer       |                |
|                                                                                  | Bactrim Forte             |                    |                    | S               | Oral                     | 1 Df, 3x/Day         | 30 DAY          | Not Reported |                |
|                                                                                  | Lescol                    |                    |                    | S               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                                                                  | Escitalopram Oxalate      |                    |                    | S               | Oral                     | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                                                                  | Amlor                     |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                  | Fucidin (Fusidate Sodium) |                    |                    | C               | Oral                     | 2 Df, 3x/Day         |                 | Not Reported |                |
|                                                                                  | Previscan (Fluindione)    |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                  | Tenormin                  |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                  | Inexium                   |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                  | Zopiclone                 |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2009                                                                      | 7183911                   | DIRECT             | Y                  | HO              |                          |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Myoclonus; Serotonin Syndrome; Unresponsive To Stimuli | Maxalt                    |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                  | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2009                                                                      | 7183977                   | DIRECT             |                    |                 |                          |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                        |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Food Craving; Weight Increased                                                                                                                         |                         | Lexapro                   |                             | S                        |                               | 1 Tablet 1 X Daily            |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Nov-2009                                                                                                                                            | 7198485                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010051                    |                               | 20 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Seizure                                                                                                                                                | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Nov-2009                                                                                                                                            | 7198490                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010103                    |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Meningioma                                                                                                                                             | Lexapro                 |                           |                             | S                        | Oral                          | Oral                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Nov-2009                                                                                                                                            | 7220486                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | 091116-0001172                |                               | 32 YR                    | Male                | AUT                     |
| <a href="#">Preferred Term</a>                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Distension;<br>Chills; Dysuria; Impaired<br>Gastric Emptying; Mood<br>Swings; Panic Attack;<br>Self-Injurious Ideation;<br>Suicidal Ideation | Mephobarbital           |                           |                             | S                        |                               | 800 Mg; Qd;                   |                          | Not Reported        |                         |
|                                                                                                                                                        | Meprobamate             |                           |                             | S                        |                               | 1200 Mg; Qd;                  |                          | Not Reported        |                         |
|                                                                                                                                                        | Trazodone Hydrochloride |                           |                             | S                        |                               | 150 Mg; Qd;                   |                          | Not Reported        |                         |
|                                                                                                                                                        | Escitalopram Oxalate    |                           |                             | S                        |                               | 10 Mg; Qd;                    |                          | Not Reported        |                         |
|                                                                                                                                                        | Quetiapine Fumarate     |                           |                             | S                        |                               | 500 Mg; Qd;                   |                          | Not Reported        |                         |
|                                                                                                                                                        | Alprazolam              |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                                                                                                        | Metazepam               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Nov-2009                                                                                                                                            | 7181818                 | EXPEDITED (15-DAY)        | N                           | OT                       | US-ABBOTT-09P-163-0607783-00  |                               | 28 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|                            |                         |   |      |              |  |  |  |  |  |
|----------------------------|-------------------------|---|------|--------------|--|--|--|--|--|
| Imprisonment; Sexual Abuse | Lexapro                 | S | Oral | Not Reported |  |  |  |  |  |
|                            | Citalopram Hydrobromide | S | Oral | Not Reported |  |  |  |  |  |
|                            | Chlormezanone           | C |      | Not Reported |  |  |  |  |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2009              | 7185322       | DIRECT           |                    |                 |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Sensation In Eye; Balance Disorder; Dizziness; Dyskinesia; Hypersensitivity; Sleep Disorder; Suicidal Ideation | Lexapro        |              |            | S           |              | 10 Milligrams      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2009              | 7201901       | EXPEDITED (15-DAY) | N                  | OT              | 1000010201           |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Head Titubation; Overdose; Restlessness; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | Oral; 30 (30 , 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                 | Atacand              |              |            | C           | Oral         | Oral; 30 (30 , 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Nov-2009              | 7183618       | NON-EXPEDITED    | N                  |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2009-<br>BP-13 |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Ineffective      | Zantac            |              |            | S           | Oral         | 300 Mg             |                 | Boehringer Ingelheim |
|                       | Lexapro           |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |
|                       | Melatonin         |              |            | C           |              |                    |                 | Not Reported         |
|                       | Caltrate          |              |            | C           |              |                    |                 | Not Reported         |
|                       | Calcium Ascorbate |              |            | C           |              |                    |                 | Not Reported         |



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|                                  |                          |                    |                    |                 |                       |                                |                 |              |                |
|----------------------------------|--------------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------------|-----------------|--------------|----------------|
| Centrum Multivitamin             |                          |                    | C                  |                 |                       | Not Reported                   |                 |              |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2009                      | 7186251                  | DIRECT             | N                  | OT              |                       |                                | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Crying                | Lexapro                  |                    |                    | S               | Oral                  | 1 Tablet 1x Daily Po           |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2009                      | 7186368                  | DIRECT             | N                  | OT              |                       |                                | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash Erythematous; Rash Pruritic | Lexapro                  |                    |                    | S               | Oral                  | 5mg One Per Day Po             |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Nov-2009                      | 7203828                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000010158            |                                | 54 YR           | Female       | FRA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence                  | Escitalopram Oxalate     |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1in 1 D),Oral    |                 | Not Reported |                |
|                                  | Lorazepam                |                    |                    | S               | Oral                  | Oral                           |                 | Not Reported |                |
|                                  | Zopiclone                |                    |                    | S               | Oral                  | 7.5 Mg (7.5 Mg, 1in 1 D), Oral |                 | Not Reported |                |
|                                  | Abilify                  |                    |                    | C               |                       |                                |                 | Not Reported |                |
|                                  | Noctamide                |                    |                    | C               |                       |                                |                 | Not Reported |                |
|                                  | Seresta                  |                    |                    | C               |                       |                                |                 | Not Reported |                |
|                                  | Zyprexa                  |                    |                    | C               |                       |                                |                 | Not Reported |                |
|                                  | Sertraline Hydrochloride |                    |                    | C               |                       |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2009                      | 6127508                  | NON-EXPEDITED      | Y                  | DE              | US-JNJFOC-20060901898 |                                | 18 YR           | Unknown      | USA            |
| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                        |   |  |   |      |  |  |              |
|--------------------------------------------|----------------------------------------|---|--|---|------|--|--|--------------|
| Completed Suicide;<br>Intentional Overdose | Amrix                                  |   |  | S |      |  |  | Not Reported |
|                                            | Pseudoephedrine Hydrochloride          |   |  | S |      |  |  | Not Reported |
|                                            | Ibuprofen                              |   |  | S |      |  |  | Not Reported |
|                                            | Aspirin                                | Y |  | S |      |  |  | Not Reported |
|                                            | Acetaminophen And Codeine<br>Phosphate |   |  | S | Oral |  |  | Not Reported |
|                                            | Escitalopram Oxalate                   |   |  | S |      |  |  | Not Reported |
|                                            | Naproxen                               |   |  | S |      |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2009              | 7164872       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009066           |                      | 56 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Atrophy;<br>Intentional Overdose;<br>Labile Blood Pressure;<br>Suicide Attempt | Escitalopram Oxalate |              |            | S           |              | Once               |                 | Not Reported |
|                                                                                         | Zolpidem             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                         | Hydrochlorothiazide  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                         | Losartan             |              |            | C           |              |                    |                 | Not Reported |
|                                                                                         | Atorvastatin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                         | Aliskiren            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 23-Nov-2009              | 7184444       | EXPEDITED (15-DAY) | Y                  | DE              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14849210 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Bacteraemia; Faecaloma;<br>Urinary Bladder Rupture | Aripiprazole         |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Quetiapine           |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                            | Toprol XL            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 23-Nov-2009              | 7184473       | EXPEDITED (15-DAY) | N                  | HO              | US-ASTRAZENECA-<br>2009SE26324 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Akathisia;<br>Confusional State;<br>Dizziness; Hypomania; | Seroquel       |              |            | S           | Oral         |                    | 1 DAY           | Zeneca       |
|                                                                      | Wellbutrin     |              |            | S           | Oral         |                    | 1 DAY           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |           |   |      |        |              |
|--------------------------------------------|-----------|---|------|--------|--------------|
| Overdose; Suicidal Ideation; Swelling Face | Lexapro   | S | Oral | 2 YR   | Not Reported |
|                                            | Lexapro   | S | Oral | 0 YR   | Not Reported |
|                                            | Lexapro   | S | Oral | 7 DAY  | Not Reported |
|                                            | Lexapro   | S | Oral | 25 MTH | Not Reported |
|                                            | Lamictal  | S |      | 0 YR   | Not Reported |
|                                            | Lamictal  | S |      | 0 YR   | Not Reported |
|                                            | Risperdal | S | Oral |        | Not Reported |
|                                            | Zyrtec-D  | C |      |        | Not Reported |

| <u>FDA Received Date</u>                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2009                                                         | 7184985                   | EXPEDITED (15-DAY) |                    | HO, OT          | AU-PFIZER INC-2009282671 |                      | 55 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Creatine Phosphokinase Increased; Serotonin Syndrome | Nardil                    |                    |                    | S               | Oral                     | 60 Mg, 1x/Day        | 20 DAY          | Pfizer       |                |
|                                                                     | Ziprasidone Hydrochloride |                    |                    | S               | Oral                     | 20 Mg, 2x/Day        | 81 DAY          | Pfizer       |                |
|                                                                     | Ziprasidone Hydrochloride |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                     | Lexapro                   |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                     | Olanzapine                |                    |                    | C               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 23-Nov-2009                                                                                         | 7204248              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010291           |                      | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Back Pain; Condition Aggravated; Headache; Neuralgia; Oedema Peripheral; Suicidal Ideation | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 23-Nov-2009              | 7207130        | EXPEDITED (15-DAY) | N                  | OT              | 1000010307           |                      |                 | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                         |                      |                      |                    |                 |                      |                                                                                |                 |                 |                |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------|-----------------|-----------------|----------------|
| Dementia; Suicidal Ideation                                                                                             |                      | Escitalopram Oxalate |                    | S               | Oral                 | (10 Mg), Oral                                                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2009                                                                                                             | 7207132              | EXPEDITED (15-DAY)   | Y                  | HO, LT, OT      | 1000010210           |                                                                                | < 1 DAY         | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>      |                |
| Apgar Score Low; Hypophagia; Insomnia; Irritability; Maternal Drugs Affecting Foetus; Neonatal Anoxia; Weight Decreased | Escitalopram Oxalate |                      |                    | S               | Transplacental       | 5 Mg (5 Mg, 1 In 1 D), Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2009                                                                                                             | 7209004              | EXPEDITED (15-DAY)   | N                  | OT              | 1000010276           |                                                                                | 22 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>      |                |
| Headache; Loss Of Consciousness; Weight Increased                                                                       | Escitalopram Oxalate |                      |                    | S               |                      |                                                                                |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Nov-2009                                                                                                             | 7187259              | EXPEDITED (15-DAY)   | N                  | HO              | A0822180A            |                                                                                |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Akathisia; Confusional State; Dizziness; Hypomania; Suicidal Ideation; Swelling Face                         | Lamictal             |                      |                    | S               | Unknown              | 300mg Per Day                                                                  |                 | Glaxosmithkline |                |
|                                                                                                                         | Wellbutrin           |                      |                    | S               | Oral                 | 150mg Per Day                                                                  | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                         | Lexapro              |                      |                    | S               | Oral                 | 30mg Per Day                                                                   |                 | Not Reported    |                |
|                                                                                                                         | Seroquel             |                      |                    | S               | Oral                 |                                                                                | 1 DAY           | Not Reported    |                |
|                                                                                                                         | Risperdal            |                      |                    | S               | Oral                 | .5mg Twice Per Day                                                             |                 | Not Reported    |                |
|                                                                                                                         | Zyrtec-D             |                      |                    | C               |                      |                                                                                |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------|-----------------|--------------|----------------|
| 24-Nov-2009                                                                                      | 7212244                                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000010232                |                                 |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cortisol Decreased;<br>Diabetes Insipidus;<br>Maternal Exposure During<br>Pregnancy; Pregnancy   | Escitalopram Oxalate                            |                    |                    | S               | Oral                      | Oral                            |                 | Not Reported |                |
|                                                                                                  | Opipramol Hydrochloride                         |                    |                    | S               | Oral                      | Oral                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2009                                                                                      | 6053413                                         | EXPEDITED (15-DAY) | Y                  | OT              | S06-IRL-01778-01          |                                 | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrolyte Imbalance;<br>Seizure                                                                | Lexapro                                         |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2009                                                                                      | 7188899                                         | EXPEDITED (15-DAY) | Y                  | LT              | FR-JNJFOC-<br>20091106677 |                                 | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Drug Interaction;<br>International Normalised<br>Ratio Increased; Muscle<br>Haemorrhage | Tramadol Hydrochloride And<br>Acetaminophen     |                    |                    | S               | Oral                      |                                 | 8 DAY           | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate                            |                    |                    | S               | Oral                      |                                 |                 | Not Reported |                |
|                                                                                                  | Propoxyphene Hydrochloride<br>And Acetaminophen |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Ramipril                                        |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Xanax                                           |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Loxen (Nicardipine<br>Hydrochloride)            |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Nafronyl Oxalate                                |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Bisacodyl                                       |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Lioresal                                        |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | All Other Therapeutic Products                  |                    |                    | C               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Previscan (Fluindione)                          |                    |                    | S               |                           |                                 |                 | Not Reported |                |
|                                                                                                  | Previscan (Fluindione)                          |                    |                    | S               |                           |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 25-Nov-2009                     | 7189299                  | EXPEDITED (15-DAY) | Y                  | HO              | ES-SANOFI-AVENTIS-2009SA003303 |                      | 82 YR           | Male         | ESP            |
| <u>Preferred Term</u>           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria;<br>Thrombocytopenia | Furosemide               |                    |                    | S               | Oral                           | Dosage: 1/2-0-0      |                 | Not Reported |                |
|                                 | Cipraxel                 |                    |                    | S               | Oral                           | 1-0-0                |                 | Not Reported |                |
|                                 | Urbason                  |                    |                    | C               | Oral                           | 1/2-0-0              |                 | Not Reported |                |
|                                 | Tamsulosin Hydrochloride |                    |                    | C               | Oral                           | Dosage: 1/2-0-1/2    |                 | Not Reported |                |
|                                 | Lactitol                 |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                 | Mestinon                 |                    |                    | C               | Oral                           | 1/2-0-1/2            |                 | Not Reported |                |
|                                 | Enalapril Maleate        |                    |                    | C               | Oral                           | Dosage: 1/2-0-1/2    |                 | Not Reported |                |
|                                 | Ferro "Sanol"            |                    |                    | C               | Oral                           | Dosage: 1-1-0        |                 | Not Reported |                |
|                                 | Calcium Glubionate       |                    |                    | C               | Oral                           | Cada 12 Horas        |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Nov-2009                     | 7214590                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000010202                     |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness           | Lexapro                  |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2009                     | 7153150                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000009222                     |                      | 93 YR           | Female       | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Urticaria           | Escitalopram Oxalate     |                    |                    | S               | Oral                           | 5 Mg (5 Mg) Oral     |                 | Not Reported |                |
|                                 | Risedronate (Tablets_)   |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                 | Disgren                  |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                 | Calcium -Sandoz Forte-D  |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                 | Pepticum                 |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                 | Orfidal                  |                    |                    | C               |                                |                      |                 | Not Reported |                |
|                                 | Lexatin                  |                    |                    | C               |                                |                      |                 | Not Reported |                |

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|                                                                           |                      |                    |                    |                 |                         |                               |                 |              |                |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|-------------------------------|-----------------|--------------|----------------|
| Boniva                                                                    |                      | C                  |                    | Not Reported    |                         |                               |                 |              |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2009                                                               | 7213423              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010336              |                               | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Condition Aggravated; Dysphagia; Hypertension; Swollen Tongue | Lexapro              |                    |                    | S               | Oral                    | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                           | Nexium               |                    |                    | C               |                         |                               |                 | Not Reported |                |
|                                                                           | Zopiclone            |                    |                    | C               |                         |                               |                 | Not Reported |                |
|                                                                           | Levomepromazine      |                    |                    | C               |                         |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Nov-2009                                                               | 7213448              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010328              |                               | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Drug Level Decreased; Leukopenia; Thrombocytopenia      | Escitalopram Oxalate |                    |                    | S               | Oral                    | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                           | Tamoxifen            |                    |                    | S               | Oral                    | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                           | Trimipramine         |                    |                    | S               | Oral                    | 10-40 Mg, Oral                |                 | Not Reported |                |
|                                                                           | Goserelin            |                    |                    | C               |                         |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2009                                                               | 6911385              | EXPEDITED (15-DAY) | Y                  | HO              | GB-RANBAXY-2009RR-21639 |                               | 17 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Diarrhoea; Nephritis Allergic                        | Ibuprofen            |                    |                    | S               | Oral                    | Unk                           |                 | Ranbaxy      |                |
|                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                    | 10 Mg, Unk                    |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                    | 20 Mg, Unk                    |                 | Not Reported |                |
|                                                                           | Alprazolam           |                    |                    | C               |                         | 0.5 Mg, Prn                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2009              | 7009317       | EXPEDITED (15-DAY) | Y                  | HO              | 1000006360           |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Delirium; Drug Level<br>Decreased; Hallucination;<br>Urinary Incontinence | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral       |                 | Not Reported |
|                                                                                                      | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral        |                 | Not Reported |
|                                                                                                      |                      |              |            |             | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral        |                 |              |
|                                                                                                      | Edronax              |              |            | S           | Oral         | 4 Mg (4 Mg, 4 In 1 D),Oral         |                 | Not Reported |
|                                                                                                      | Edronax              |              |            | S           |              | 8 Mg (8 Mg, 1 In 1 D),Oral         |                 | Not Reported |
|                                                                                                      | Wellbutrin           |              |            | S           | Oral         | 150 Mg (150 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                      | Lorazepam            |              |            | S           | Oral         | See Image                          |                 | Not Reported |
|                                                                                                      |                      |              |            |             | Oral         | See Image                          |                 |              |
|                                                                                                      |                      |              |            |             | Oral         | See Image                          |                 |              |
|                                                                                                      |                      |              |            |             | Oral         | See Image                          |                 |              |
|                                                                                                      | Tegretol             |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                      | Fosicomb (Tablets)   |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                      | Norvasc              |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                      | Lovenox              |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 30-Nov-2009              | 7192632       | EXPEDITED (15-DAY) | N                  | HO              | US-KINGPHARMUSA00001-K200901465 |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety Disorder; Blood<br>Pressure Increased; Drug<br>Interaction; Heart Rate<br>Increased;<br>Hyperthyroidism;<br>Restlessness | Levoxyl        |              |            | S           | Oral         | 137 Mcg, Qd        |                 | King         |
|                                                                                                                                  | Atenolol       |              |            | C           | Oral         | 25 Mg, Qd          |                 | Not Reported |
|                                                                                                                                  | Lipitor        |              |            | C           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                                                                                                  | Celexa         |              |            | C           |              | 20 Mg, Unk         |                 | Not Reported |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |             |        |              |
|----------|---|------|-------------|--------|--------------|
| Ativan   | C |      | Unk         | 39 DAY | Not Reported |
| Levoxyl  | S | Oral | 75 Mcg, Qd  | 6 DAY  | King         |
| Levoxyl  | S | Oral | 100 Mcg, Qd | 7 DAY  | King         |
| Levoxyl  | S | Oral | 125 Mcg, Qd | 4 DAY  | King         |
| Levoxyl  | S | Oral | 137 Mcg, Qd |        | King         |
| Klonopin | S | Oral | 1 Mg, Bid   |        | Not Reported |
| Klonopin | S | Oral | 1.0 Mg, Qd  |        | Not Reported |
| Klonopin | S | Oral | 0.5 Mg, Bid |        | Not Reported |
| Klonopin | S | Oral | 0.5 Mg, Qd  |        | Not Reported |
| Lexapro  | S | Oral | 20 Mg, Qd   | 25 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2009              | 7192912       | EXPEDITED (15-DAY) | Y                  | OT              | B0608394A            |                      | 37 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Chest Discomfort;<br>Dyspnoea; Pneumonia;<br>Respiration Abnormal | Lamotrigine    |              |            | S           | Unknown      | 300mg Per Day      |                 | Glaxosmithkline |
|                                                                   | Cipralelex     |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                   | Guaifenesin    |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                                   | Lithium        |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Nov-2009              | 7193516       | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2009AT46733      |                      | 57 YR      | Male       | AUT            |

| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Suicidal<br>Ideation | Diovan                 |              |            | S           |              | 2 X 80 Mg          |                 | Novartis     |
|                                  | Metformin\Vildagliptin |              |            | S           | Oral         | 50 Mg, Bid         | 33 DAY          | Not Reported |
|                                  | Seloken                |              |            | S           |              | 2 X 49.5 Mg        |                 | Not Reported |
|                                  | Cipralelex             |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
| 30-Nov-2009                                                                                                                                                          | 7193730              | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2009303725 |                             | 29 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Hepatitis; Overdose; Sinus Tachycardia; Somnolence; Suicide Attempt                                                                  | Atarax               |                    |                    | S               | Oral                     | 32 Tablets                  | 1 DAY           | Pfizer       |                |
|                                                                                                                                                                      | Paroxetine           |                    |                    | S               | Oral                     | 28 Tablets                  | 1 DAY           | Not Reported |                |
|                                                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                     | 32 Tablets                  | 1 DAY           | Not Reported |                |
|                                                                                                                                                                      | Zolpidem             |                    |                    | S               | Oral                     | 12 Tablets                  | 1 DAY           | Not Reported |                |
|                                                                                                                                                                      | Rivotril             |                    |                    | S               | Oral                     | 7 Tablets                   | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2009                                                                                                                                                          | 7217317              | EXPEDITED (15-DAY) | Y                  | CA              | 1000010233               |                             | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hydrocephalus; Maternal Drugs Affecting Foetus                                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Transplacental           | Transplacental              |                 | Not Reported |                |
|                                                                                                                                                                      | Opipramol            |                    |                    | S               | Transplacental           | Transplacental              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2009                                                                                                                                                          | 7218358              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010292               |                             | 67 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Increased; Blood Thyroid Stimulating Hormone Increased; Dizziness; Head Discomfort; Hyponatraemia; Loss Of Consciousness; Nausea; Thyroxine Decreased | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                      | Plavix               |                    |                    | C               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2009                                                                                                                                                          | 7140400              | EXPEDITED (15-DAY) | Y                  | HO              | 1000008836               |                             | 61 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Confusional State; Eating Disorder;           | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
| Electrocardiogram Repolarisation Abnormality; | Atacand              |              |            | S           | Oral         | 8 Mg (8 Mg,1 In 1 D),Oral   |                 | Not Reported |
| Hyponatraemia;                                | Fosvance             |              |            | C           |              |                             |                 | Not Reported |
| Somnolence; Status Epilepticus; Tachycardia   | Rosuvastatin         |              |            | C           |              |                             |                 | Not Reported |
|                                               | Calcium Carbonate    |              |            | C           |              |                             |                 | Not Reported |
|                                               | Nebivolol            |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2009              | 7162570       | EXPEDITED (15-DAY) | N                  | OT              | 1000005272           |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Arrhythmia                                                            | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral                               |                 | Not Reported |
| Supraventricular; Hypoaesthesia; Paraesthesia; Sinus Node Dysfunction | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                       |                |              |            |             | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral |                 |              |
|                                                                       | Erythromycin   |              |            | C           |              |                                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Dec-2009              | 7192058       | EXPEDITED (15-DAY) | Y                  | HO              | 1000009478           |                      | 85 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Bacterial Test Positive; Confusional State; Culture Urine Positive; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
| Disorientation; Escherichia Infection; Fall; Haptoglobin Increased; | Aldactone            |              |            | S           |              | 75 Mg (75 Mg,1 In 1 D)      |                 | Not Reported |
| Hyponatraemia; Malaise; Orthostatic Hypotension                     | Glucophage           |              |            | C           |              |                             |                 | Not Reported |
|                                                                     | Lorazepam            |              |            | C           |              |                             |                 | Not Reported |
|                                                                     | Levothyrox           |              |            | C           |              |                             |                 | Not Reported |
|                                                                     | Tanakan              |              |            | C           |              |                             |                 | Not Reported |
|                                                                     | Dafalgan             |              |            | C           |              |                             |                 | Not Reported |

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|                                                            | Propofan             |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
|------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|------------|----------------|
|                                                            | Diosmine             |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
|                                                            | Arixtra              |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Dec-2009                                                | 7201430              | DIRECT             |                    | OT              |                      |                                                           | 68 YR           | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                |
| Depression; Off Label Use; Suicidal Ideation               | Lexapro              |                    |                    | S               |                      | 20 Mg 1 X Day                                             | 7 YR            | Forest     |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Dec-2009                                                | 7220781              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010385           |                                                           | 65 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                |
| Toxic Skin Eruption                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral |                 |            | Not Reported   |
|                                                            |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral |                 |            |                |
|                                                            | Paracetamol          |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
|                                                            | Anti-Asthmatics      |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Dec-2009                                                | 7220827              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010382           |                                                           | 62 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u> |                |
| Agitation; Insomnia; Muscle Spasms; Restless Legs Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral                               |                 |            | Not Reported   |
|                                                            | Stresam              |                    |                    | C               |                      |                                                           |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Dec-2009                                                | 7220851              | EXPEDITED (15-DAY) | N                  | OT              | 1000010447           |                                                           | 64 YR           | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|------------------------------|----------------|
| Chills; Hyperhidrosis;<br>Hypothermia; Sinusitis                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral             |                 | Not Reported                 |                |
|                                                                                                                                  | Inexium<br>Stilnox   |                    |                    | C<br>C          |                      |                                         |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-Dec-2009                                                                                                                      | 7220979              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010349           |                                         | 17 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depressed Level Of<br>Consciousness; Suicide<br>Attempt                                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported                 |                |
|                                                                                                                                  | Zopiclone            |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported                 |                |
|                                                                                                                                  | Alprazolam           |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported                 |                |
|                                                                                                                                  | Alcohol              |                    |                    | S               |                      |                                         |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-Dec-2009                                                                                                                      | 7221366              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010379           |                                         | 29 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depressed Level Of<br>Consciousness; Hepatitis;<br>Intentional Overdose;<br>Sinus Tachycardia;<br>Somnolence; Suicide<br>Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | (640 Mg, Once), Oral                    |                 | Not Reported                 |                |
|                                                                                                                                  | Hydroxyzine          |                    |                    | S               | Oral                 | (3200 Mg, Once), Oral                   |                 | Not Reported                 |                |
|                                                                                                                                  | Zolpidem             |                    |                    | S               | Oral                 | (120 Mg, Once), Oral                    |                 | Not Reported                 |                |
|                                                                                                                                  | Clonazepam           |                    |                    | S               | Oral                 | (14 Mg, Once), Oral                     |                 | Not Reported                 |                |
|                                                                                                                                  | Paroxetine           |                    |                    | S               | Oral                 | (560 Mg, Once), Oral                    |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Dec-2009                                                                                                                      | 6550324              | EXPEDITED (15-DAY) | Y                  | HO              | S08-USA-00239-01     |                                         | 17 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Acute Kidney Injury;<br>Anaemia; Diarrhoea;<br>Eosinophil Count                                                                  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Eosinophil  
Percentage Increased;  
Faeces Discoloured;  
Tubulointerstitial Nephritis

Lexapro

S

Oral

Oral

Mg,Once A Day),Oral  
10 Mg (10 Mg,1 In 1  
D),Oral ; 20 Mg (20  
Mg,Once A Day),Oral

20 Mg (20 Mg,1 In 1  
D),Oral

Not Reported

Ibuprofen  
Alprazolam (Alprazolam)  
(Tablets) (Alprazolam)

C

C

Not Reported

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7194492       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000009962           |                      | 27 YR      | Male       | DNK            |

| <u>Preferred Term</u>         | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|--------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Inflammatory Bowel<br>Disease | Escitalopram Oxalate                                   |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                               |                                                        |              |            |             | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 |              |
|                               | Copixol-Acuphase-(Injection)<br>Quetiapine (Injection) |              |            | C           |              |                                                               |                 | Not Reported |
|                               |                                                        |              |            | C           |              |                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7198406       | EXPEDITED (15-DAY) | Y                  | OT              | DE-PFIZER INC-<br>2009304548 |                      | 36 YR      | Male       | DEU            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Somnolence; Suicide<br>Attempt | Atarax         |              |            | S           | Oral         |                    |                 | Pfizer       |
|                                | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                | Alcohol        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7222011       | EXPEDITED (15-DAY) | Y                  | OT              | 1000003345           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |                      |   |      |                               |              |
|--------------------------------------------------------------------|----------------------|---|------|-------------------------------|--------------|
| Maternal Exposure During Pregnancy; Pregnancy; Withdrawal Syndrome | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|--------------------------------------------------------------------|----------------------|---|------|-------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7222017       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010479           |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Intentional Overdose; Miosis; Somnolence; Suicide Attempt; Unevaluable Event | Escitalopram Oxalate |              |            | S           | Oral         | (1000 Mg, Once), Oral |                 | Not Reported |
|                                                                                                              | Pipamperone          |              |            | S           | Oral         | (4000 Mg, Once), Oral |                 | Not Reported |
|                                                                                                              | Alcohol              |              |            | S           | Oral         | Oral                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7222018       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010402           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Depressed Mood; Sensory Disturbance; Suicidal Ideation; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7223505       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010490           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Eosinophilia; Inflammation; Nasopharyngitis; Pleural Effusion | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Lamotrigine          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2009              | 7223514       | EXPEDITED (15-DAY) | N                  | OT              | 1000010494           |                      | 39 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
|--------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|------------------------------|----------------|
| Anxiety; Exophthalmos; Hyperthyroidism                                                                 | Escitalopram Oxalate                 |                    |                    | S               | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Dec-2009                                                                                            | 7223553                              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010400                               |                               | 50 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Agitation; Tension                                                                                     | Escitalopram Oxalate                 |                    |                    | S               | Oral                                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Dec-2009                                                                                            | 7223892                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010462                               |                               | 84 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depressed Level Of Consciousness; Drug Disorientation; Drug Interaction; Dyspnoea; Pyrexia; Somnolence | Escitalopram Oxalate                 |                    |                    | S               | Oral                                     | 5 Mg (5 Mg,1 In 1 D),Oral     |                 | Not Reported                 |                |
|                                                                                                        | Diazepam                             |                    |                    | S               | Oral                                     | Oral                          |                 | Not Reported                 |                |
|                                                                                                        | Acetaminophen\Tramadol Hydrochloride |                    |                    | S               | Oral                                     | 37.5 / 325 Mg (1 In 1 D),Oral |                 | Not Reported                 |                |
|                                                                                                        | Lyrica                               |                    |                    | S               | Oral                                     | 25 Mg (25 Mg,1 In 1 D),Oral   |                 | Not Reported                 |                |
|                                                                                                        | Tensogradal (Tablets) Omeprazole     |                    |                    | C<br>C          |                                          |                               |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 04-Dec-2009                                                                                            | 6978964                              | EXPEDITED (15-DAY) | N                  | OT              | DE-ELI_LILLY_AND_COMP ANY-DE200903000619 |                               | 33 YR           | Female                       | DEU            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Interaction; Gastrooesophageal Reflux Disease; Hiatus Hernia; Hypokalaemia;                       | Zyprexa                              |                    |                    | S               | Oral                                     | 10 Mg, Daily (1/D)            | 70 DAY          | Eli Lilly And Co             |                |
|                                                                                                        | Zopiclone                            |                    |                    | C               | Oral                                     | 7.5 Mg, Daily (1/D)           | 165 DAY         | Not Reported                 |                |
|                                                                                                        | Pantozol (Pantoprazole Sodium)       |                    |                    | C               | Oral                                     | 40 Mg, Daily (1/D)            |                 | Not Reported                 |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                                            |   |      |                     |        |                  |
|-----------------------------------|--------------------------------------------|---|------|---------------------|--------|------------------|
| Supraventricular<br>Extrasystoles | Leponex                                    | C |      | 375 Mg, Daily (1/D) | 1 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 25 Mg, Daily (1/D)  | 2 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 50 Mg, Daily (1/D)  | 2 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 75 Mg, Daily (1/D)  | 3 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 100 Mg, Daily (1/D) | 2 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 125 Mg, Daily (1/D) | 3 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 175 Mg, Daily (1/D) | 2 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 225 Mg, Daily (1/D) | 5 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 275 Mg, Daily (1/D) | 10 DAY | Not Reported     |
|                                   | Leponex                                    | C |      | 300 Mg, Daily (1/D) | 1 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 325 Mg, Daily (1/D) | 6 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 375 Mg, Daily (1/D) | 4 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 425 Mg, Daily (1/D) | 15 DAY | Not Reported     |
|                                   | Leponex                                    | C |      | 475 Mg, Daily (1/D) | 82 DAY | Not Reported     |
|                                   | Leponex                                    | C |      | 400 Mg, Daily (1/D) | 1 DAY  | Not Reported     |
|                                   | Leponex                                    | C |      | 350 Mg, Daily (1/D) |        | Not Reported     |
|                                   | Diazepam                                   | C |      | 10 D/F, Unk         | 1 DAY  | Not Reported     |
|                                   | Levothyroxine Sodium                       | C |      | 50 Ug, Daily (1/D)  |        | Not Reported     |
|                                   | Calcium Carbonate                          | C |      | 0.5 D/F, 3/D        |        | Not Reported     |
|                                   | Potassium<br>Bicarbonate\Potassium Citrate | C |      | 1 D/F, Daily (1/D)  |        | Not Reported     |
|                                   | Bifiteral                                  | C |      | 2 D/F, Daily (1/D)  | 1 DAY  | Not Reported     |
|                                   | Unizink                                    | C |      | 50 Mg, Daily (1/D)  |        | Not Reported     |
|                                   | Gastrozepin                                | C |      | 25 Mg, Daily (1/D)  |        | Not Reported     |
|                                   | Acetylsalicylic Acid                       | C |      | 100 Mg, Daily (1/D) |        | Not Reported     |
|                                   | Zyprexa                                    | S | Oral | 20 Mg, Daily (1/D)  | 57 DAY | Eli Lilly And Co |
|                                   | Zyprexa                                    | S | Oral | 10 Mg, Daily (1/D)  | 52 DAY | Eli Lilly And Co |
|                                   | Seroquel                                   | S | Oral | 75 Mg, Daily (1/D)  | 1 DAY  | Not Reported     |
|                                   | Seroquel                                   | S | Oral | 100 Mg, Daily (1/D) | 8 DAY  | Not Reported     |
|                                   | Seroquel                                   | S | Oral | 200 Mg, Daily (1/D) | 8 DAY  | Not Reported     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |                     |        |              |
|-----------|---|------|---------------------|--------|--------------|
| Seroquel  | S | Oral | 300 Mg, Daily (1/D) | 2 DAY  | Not Reported |
| Seroquel  | S | Oral | 400 Mg, Daily (1/D) | 3 DAY  | Not Reported |
| Seroquel  | S | Oral | 450 Mg, Daily (1/D) | 8 DAY  | Not Reported |
| Seroquel  | S | Oral | 550 Mg, Daily (1/D) | 29 DAY | Not Reported |
| Seroquel  | S | Oral | 650 Mg, Daily (1/D) | 17 DAY | Not Reported |
| Seroquel  | S | Oral | 550 Mg, Daily (1/D) | 1 DAY  | Not Reported |
| Seroquel  | S | Oral | 250 Mg, Daily (1/D) | 3 DAY  | Not Reported |
| Seroquel  | S | Oral | 200 Mg, Daily (1/D) | 1 DAY  | Not Reported |
| Seroquel  | S | Oral | 150 Mg, Daily (1/D) | 3 DAY  | Not Reported |
| Seroquel  | S | Oral | 100 Mg, Daily (1/D) | 1 DAY  | Not Reported |
| Cipralext | S | Oral | 15 Mg, Daily (1/D)  |        | Not Reported |
| Cipralext | S | Oral | 10 Mg, Daily (1/D)  |        | Not Reported |
| Akineton  | S | Oral | 4 Mg, Daily (1/D)   | 12 DAY | Not Reported |
| Akineton  | S | Oral | 2 Mg, Daily (1/D)   | 73 DAY | Not Reported |
| Akineton  | S | Oral | Unk, Daily (1/D)    | 20 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Dec-2009              | 7225869       | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2009-01411   |                      | 52 YR      | Male       |                |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affective Disorder; Anal   | Mirtazapine          |              |            | S           |              |                    |                 | Not Reported |
| Incontinence; Benign       | Sulpiride            |              |            | S           |              |                    |                 | Not Reported |
| Prostatic Hyperplasia;     | Venlafaxine          |              |            | S           |              |                    |                 | Not Reported |
| Bulbar Palsy; Chest Pain;  | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Deep Vein Thrombosis;      | Doxazosin            |              |            | C           |              |                    |                 | Not Reported |
| Dementia; Depression;      | Finasteride          |              |            | C           |              |                    |                 | Not Reported |
| Disorientation; Echolalia; | Piracetam            |              |            | C           |              |                    |                 | Not Reported |
| Embolism Arterial;         |                      |              |            |             |              |                    |                 |              |
| Extrapyrarnidal Disorder;  |                      |              |            |             |              |                    |                 |              |
| Fall; Gait Disturbance;    |                      |              |            |             |              |                    |                 |              |
| Head Injury; Hypoacusis;   |                      |              |            |             |              |                    |                 |              |
| Meniere'S Disease;         |                      |              |            |             |              |                    |                 |              |
| Polyneuropathy; Rhinitis;  |                      |              |            |             |              |                    |                 |              |
| Sympathetic Posterior      |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cervical Syndrome; Visual Impairment

| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 04-Dec-2009                                                                               | 7226141                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010423                    |                               | 43 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyskinesia; Dysphonia; Muscle Twitching; Tremor                                           | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                                                                           | Vitamin B12             |                           |                             | C                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Dec-2009                                                                               | 6874029                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000003213                    |                               | 29 YR                    | Female              | IRL                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Abnormal; Hallucination, Visual; Sensory Disturbance                              | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Dec-2009                                                                               | 7206943                 | DIRECT                    | N                           | OT                       |                               |                               | 38 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Educational Problem; Loss Of Personal Independence In Daily Activities; Nausea | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Dec-2009                                                                               | 7228687                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000010568                    |                               | 22 YR                    | Female              | NOR                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                     |                         |                           |                             |                          |                                  |                                  |                          |                     |                         |
|-------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|----------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| Hypermetropia; Myopia;<br>Tension Headache; Visual<br>Field Defect                  |                         | Escitalopram Oxalate      |                             | S                        |                                  | Not Reported                     |                          |                     |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>    | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Dec-2009                                                                         | 7228909                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000010529                       |                                  | 41 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>            | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Idiopathic Intracranial<br>Hypertension; Migraine                                   | Lexapro                 |                           |                             | S                        | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>    | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Dec-2009                                                                         | 7232118                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010410                       |                                  |                          | Male                | DEU                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>            | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chromatopsia; Mania                                                                 | Escitalopram Oxalate    |                           |                             | S                        | Oral                             | (3 Gitt), Oral                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>    | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Dec-2009                                                                         | 7232564                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010519                       |                                  | 22 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>            | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Concussion; Eye<br>Movement Disorder; Head<br>Injury; Neck Injury; Sports<br>Injury | Lexapro                 |                           |                             | S                        | Oral                             | Oral                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>    | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Dec-2009                                                                         | 7152822                 | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-ABBOTT-09P-056-<br>0601745-00 |                                  | 20 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>            | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ammonia Increased;                                                                  | Depakote                |                           |                             | S                        | Oral                             | Overdose                         |                          | Not Reported        |                         |
| Blood Lactic Acid<br>Increased; Brain Oedema;<br>Drug Level Above                   | Depakote                |                           |                             | S                        | Oral                             |                                  |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  |                      |   |      |          |  |              |
|----------------------------------------------------------------------------------|----------------------|---|------|----------|--|--------------|
| Therapeutic;<br>Extrapyramidal Disorder;<br>Intentional Overdose;<br>Tachycardia | Depakote             | S | Oral |          |  | Not Reported |
|                                                                                  | Escitalopram Oxalate | S | Oral | Overdose |  | Not Reported |
|                                                                                  | Escitalopram Oxalate | S | Oral |          |  | Not Reported |
|                                                                                  | Abilify              | S | Oral | Overdose |  | Not Reported |
|                                                                                  | Abilify              | S |      |          |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2009              | 7170086       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009581           |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Hyperhidrosis; Mydriasis;<br>Palpitations; Sinus<br>Tachycardia | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                 | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral   |                 | Not Reported |
|                                                                 | Allegra        |              |            | C           |              |                             |                 | Not Reported |
|                                                                 | Multi-Vitamin  |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2009              | 7210754       | EXPEDITED (15-DAY) | N                  | OT              | A0834197A            |                      |            | Male       | USA            |

| <u>Preferred Term</u>                              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Diarrhoea; Drug<br>Ineffective; Suicide<br>Attempt | Paxil                    |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                    | Wellbutrin               |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                    | Effexor Xr               |              |            | S           | Oral         | 75mg Per Day       |                 | Not Reported    |
|                                                    | Pristiq Extended Release |              |            | S           | Oral         | 50mg Per Day       |                 | Not Reported    |
|                                                    | Lexapro                  |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                    | Pexeva                   |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                    | Zoloft                   |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                    | Cymbalta                 |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                    | Prozac                   |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                    | Vitamins                 |              |            | C           |              |                    |                 | Not Reported    |
|                                                    | Fish Oil                 |              |            | C           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Dec-2009                                                                                                                                                                     | 7233411                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000010571                               |                                                            |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug Withdrawal Syndrome; Feeling Abnormal; Hallucination, Auditory; Paraesthesia                                                                                    | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                 |                         |                    |                    |                 | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 5 Mg (5 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2009                                                                                                                                                                     | 7212902                 | EXPEDITED (15-DAY) | N                  | HO              | GB-BRISTOL-MYERS SQUIBB COMPANY-14885974 |                                                            | 37 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Body Temperature Increased; Cerebrovascular Accident; Diarrhoea Infectious; Dizziness; Fatigue; Headache; Heart Rate Increased; Malaise; Nausea; Vomiting | Aripiprazole            |                    |                    | S               | Oral                                     |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                 | Clozaril                |                    |                    | S               | Oral                                     |                                                            | 2 WEEK          | Not Reported |                |
|                                                                                                                                                                                 | Diazepam                |                    |                    | S               | Oral                                     |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                                     |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Dec-2009                                                                                                                                                                     | 7234123                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000009741                               |                                                            | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Alanine Aminotransferase Increased; Alcohol Poisoning; Aspartate                                                                                                    | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | (400 Mg,Once), Oral                                        |                 | Not Reported |                |
|                                                                                                                                                                                 | Bupropion Hydrochloride |                    |                    | S               | Oral                                     | (6000 Mg,Once), Oral                                       |                 | Not Reported |                |
|                                                                                                                                                                                 | Acetaminophen           |                    |                    | S               | Oral                                     | (500 Mg,Once), Oral                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                 |         |   |                           |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|---------------------------|--------------|
| Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Intentional Overdose; Mydriasis; Suicide Attempt; Vomiting; White Blood Cell Count Increased | Alcohol | S | 1 Bottle Of Liquor (Once) | Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|---------------------------|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Dec-2009                       | 7234126                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000010597                    |                               | 81 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------|--------------------------|---------------------|
| Disorientation; Gait Disturbance; Tinnitus; Vertigo | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg (20 Mg, 1 In 1 D), Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Dec-2009                       | 7234406                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010656                    |                               |                     | Male                | DNK                     |

| <a href="#">Preferred Term</a>       | <a href="#">Product</a>           | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>          |
|--------------------------------------|-----------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|------------------------------|
| Drug Interaction; Serotonin Syndrome | Escitalopram Oxalate<br>Oxetorone |                       |                     | S<br>S               |                       |                             |                          | Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Dec-2009                       | 7234414                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000010695                    |                               |                     | Female              | DNK                     |

| <a href="#">Preferred Term</a>          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Decreased Appetite; Diarrhoea; Vomiting | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Dec-2009                       | 6884744                | NON-EXPEDITED             | N                           |                          | US-BRISTOL-MYERS SQUIBB COMPANY-14378962 |                               | 64 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |                                                                                  |                  |                    |                            |                                                 |                      |                 |                                                                                        |                |
|-----------------------------------|----------------------------------------------------------------------------------|------------------|--------------------|----------------------------|-------------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------------------------|----------------|
| Feeling Abnormal                  | Abilify                                                                          |                  | S                  | Oral                       |                                                 | 2 WEEK               | Not Reported    |                                                                                        |                |
|                                   | Lexapro                                                                          |                  | S                  | Oral                       |                                                 |                      | Not Reported    |                                                                                        |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 14-Dec-2009                       | 7214760                                                                          | NON-EXPEDITED    | N                  |                            | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14420889 |                      |                 | Female                                                                                 | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Decreased Appetite;<br>Depression | Abilify<br>Lexapro                                                               |                  |                    | S<br>S                     |                                                 |                      |                 | Not Reported<br>Not Reported                                                           |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 14-Dec-2009                       | 7214786                                                                          | NON-EXPEDITED    | Y                  |                            | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14427603 |                      |                 | Unknown                                                                                | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Weight Increased                  | Abilify<br>Lexapro                                                               |                  |                    | S<br>S                     |                                                 |                      |                 | Not Reported<br>Not Reported                                                           |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 14-Dec-2009                       | 7214796                                                                          | NON-EXPEDITED    | N                  |                            | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14429047 |                      | 57 YR           | Female                                                                                 | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Hypomania                         | Pamelor<br>Abilify<br>Abilify<br>Lexapro<br>Wellbutrin<br>Echinacea, Unspecified |                  |                    | S<br>S<br>S<br>S<br>S<br>S |                                                 |                      |                 | Sandoz<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>          | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 14-Dec-2009                       | 7214802                                                                          | NON-EXPEDITED    | N                  |                            | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14430953 |                      | 60 YR           | Female                                                                                 | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                             |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                     |                    |                  |                    |                 |                                                 |                      |                                                                         |                 |                              |
|-----------------------------------------------------|--------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-------------------------------------------------------------------------|-----------------|------------------------------|
| Oedema Peripheral                                   | Abilify            |                  | S                  |                 |                                                 |                      |                                                                         | 2 WEEK          | Not Reported                 |
|                                                     | Lexapro            |                  | S                  |                 |                                                 |                      |                                                                         |                 | Not Reported                 |
| <u>FDA Received Date</u>                            | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>                                                              | <u>Sex</u>      | <u>Country</u>               |
| 14-Dec-2009                                         | 7214913            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14456891 |                      | 26 YR                                                                   | Female          | USA                          |
| <u>Preferred Term</u>                               | <u>Product</u>     |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>                   |
| Amnesia; Fatigue;<br>Somnolence                     | Abilify<br>Lexapro |                  |                    | S<br>S          |                                                 |                      |                                                                         |                 | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                            | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>                                                              | <u>Sex</u>      | <u>Country</u>               |
| 14-Dec-2009                                         | 7215170            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14502660 |                      |                                                                         | Unknown         | USA                          |
| <u>Preferred Term</u>                               | <u>Product</u>     |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>                   |
| Feeling Abnormal; Suicidal<br>Ideation              | Abilify<br>Lexapro |                  |                    | S<br>S          |                                                 |                      |                                                                         |                 | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                            | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>                                                              | <u>Sex</u>      | <u>Country</u>               |
| 14-Dec-2009                                         | 7215398            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14533855 |                      | 42 YR                                                                   | Female          | USA                          |
| <u>Preferred Term</u>                               | <u>Product</u>     |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>                   |
| Hyperhidrosis;<br>Incontinence; Muscle<br>Twitching | Abilify<br>Lexapro |                  |                    | S<br>S          |                                                 |                      |                                                                         |                 | Not Reported<br>Not Reported |
| <u>FDA Received Date</u>                            | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>                                                              | <u>Sex</u>      | <u>Country</u>               |
| 14-Dec-2009                                         | 7215411            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14535322 |                      | 12 YR                                                                   | Female          | USA                          |
| <u>Preferred Term</u>                               | <u>Product</u>     |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>                   |
| Cough; Dizziness; Pallor                            | Abilify            |                  |                    |                 | S                                               | Oral                 | Initiated At 2mg Every<br>Day, Titrating Upto 10mg<br>At Bed Time. Dose |                 | Not Reported                 |

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| Lexapro                                  |                         | S                         |                             | Increased To 10mg Qd     |                                                 | Not Reported                  |                          |                     |                         |
|------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Amoxicillin                              |                         | C                         |                             |                          |                                                 | Not Reported                  |                          |                     |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Dec-2009                              | 7215449                 | NON-EXPEDITED             | N                           | HO                       | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14539753 |                               | 14 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Suicide Attempt                          | Abilify                 |                           |                             | S                        | Oral                                            |                               |                          |                     | Not Reported            |
|                                          | Abilify                 |                           |                             | S                        | Oral                                            |                               |                          |                     | Not Reported            |
|                                          | Lexapro                 |                           |                             | S                        |                                                 |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Dec-2009                              | 7215457                 | NON-EXPEDITED             | N                           |                          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14540769 |                               | 14 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Personality Change;<br>Suicidal Ideation | Abilify                 |                           |                             | S                        |                                                 |                               |                          |                     | Not Reported            |
|                                          | Lexapro                 |                           |                             | S                        |                                                 |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Dec-2009                              | 7215640                 | NON-EXPEDITED             | N                           | OT                       | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14568091 |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity                         | Abilify                 |                           |                             | S                        |                                                 |                               |                          |                     | Not Reported            |
|                                          | Lexapro                 |                           |                             | S                        |                                                 |                               |                          |                     | Not Reported            |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Dec-2009                              | 7215707                 | NON-EXPEDITED             | N                           |                          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14579890 |                               | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Tardive Dyskinesia                       | Abilify                 |                           |                             | S                        |                                                 | Taken 5mg Also                |                          |                     | Not Reported            |

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| Lexapro                                                |                |                  | S                  |                 |                                                 | Not Reported                                                                            |                 |              |                |
|--------------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                            | 7215733        | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14583942 |                                                                                         | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Feeling<br>Abnormal; Lethargy;<br>Somnolence | Lisinopril     |                  |                    | S               |                                                 |                                                                                         |                 | Merck        |                |
|                                                        | Abilify        |                  |                    | S               |                                                 | Took In The Morning And<br>Also At Night. Later The<br>Dose Was Switched To<br>Bedtime. | 2 DAY           | Not Reported |                |
|                                                        | Wellbutrin Sr  |                  |                    | S               |                                                 |                                                                                         |                 | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                                                 |                                                                                         |                 | Not Reported |                |
|                                                        | Xanax          |                  |                    | S               |                                                 | As Needed                                                                               |                 | Not Reported |                |
|                                                        | Antidepressant |                  |                    | C               |                                                 |                                                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                            | 7215760        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14587950 |                                                                                         | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                       | Abilify        |                  |                    | S               | Oral                                            |                                                                                         |                 | Not Reported |                |
|                                                        | Abilify        |                  |                    | S               | Oral                                            |                                                                                         |                 | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                                                 |                                                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                            | 7215852        | NON-EXPEDITED    | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14602049 |                                                                                         |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis                                           | Abilify        |                  |                    | S               |                                                 |                                                                                         |                 | Not Reported |                |
|                                                        | Lexapro        |                  |                    | S               |                                                 |                                                                                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 14-Dec-2009                                    | 7216051        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14631832 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation                              | Abilify        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                | Cymbalta       |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                | Lexapro        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                    | 7216118        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14647598 |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Speech Disorder; Tardive<br>Dyskinesia; Tremor | Abilify        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                | Lexapro        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                | Topamax        |                  |                    | C               |                                                 |                      |                 | Not Reported |                |
|                                                | Depo-Provera   |                  |                    | C               |                                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                    | 7216125        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14649461 |                      | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria                                     | Abilify        |                  |                    | S               | Oral                                            | Taken For One Month  |                 | Not Reported |                |
|                                                | Lexapro        |                  |                    | S               | Oral                                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                                    | 7216167        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14663140 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased                        | Abilify        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |
|                                                | Lexapro        |                  |                    | S               |                                                 |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| 14-Dec-2009              | 7216197        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14668230 |                                | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia                 | Abilify        |                  |                    | S               |                                                 | Initial Dose 2mg For<br>2weeks |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Dec-2009                                                                                          | 7216299        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14688253 |                                                                                           | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Anger; Ejaculation<br>Delayed; Memory<br>Impairment; Overdose;<br>Priapism | Abilify        |                  |                    | S               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Abilify        |                  |                    | S               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Lexapro        |                  |                    | S               | Oral                                            | 10mg Tab,10mg; 20mg<br>(Once Daily), 30mg (Once<br>Daily),Titrated To 40mg<br>Once Daily. |                 | Not Reported |                |
|                                                                                                      | Lexapro        |                  |                    | S               | Oral                                            | 10mg Tab,10mg; 20mg<br>(Once Daily), 30mg (Once<br>Daily),Titrated To 40mg<br>Once Daily. |                 | Not Reported |                |
|                                                                                                      | Tegretol Xr    |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Lovaza         |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Lisinopril     |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Vytorin        |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Vitamin D Nos  |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Atenolol       |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
|                                                                                                      | Topamax        |                  |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 14-Dec-2009              | 7216527        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14732283 |                      | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                        |         |   |              |              |
|------------------------|---------|---|--------------|--------------|
| Skin Hyperpigmentation | Abilify | S | Oral         | Not Reported |
|                        | Abilify | S | Oral         | Not Reported |
|                        | Lexapro | S |              | Not Reported |
|                        | Tenex   | S | Tenex .5 Am. | Not Reported |

| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Dec-2009                                                | 7216607                 | NON-EXPEDITED             | N                           |                          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14745012 |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bipolar Disorder; Drug<br>Ineffective; Drug<br>Interaction | Lexapro                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                                            | Abilify                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                                            | Tegretol                |                           |                             | S                        |                                                 | 300 Mg                        |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a>                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Dec-2009                                               | 7216684                 | NON-EXPEDITED             | N                           | OT                       | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14755821 |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fatigue; Generalised<br>Tonic-Clonic Seizure;<br>Insomnia | Abilify                 |                           |                             | S                        | Oral                                            |                               | 1 WEEK                   | Not Reported        |                         |
|                                                           | Lexapro                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Dec-2009                       | 7216730                 | NON-EXPEDITED             | N                           |                          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14765259 |                               | 61 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Tremor                            | Abilify                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
|                                   | Lexapro                 |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Dec-2009                       | 7216792                 | NON-EXPEDITED             | N                           | OT                       | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14780001 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                      |                    |                    |                 |                      |                          |                 |              |                |
|------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| Seizure                      | Abilify              |                    |                    | S               |                      |                          |                 |              | Not Reported   |
|                              | Lexapro              |                    |                    | S               |                      |                          |                 |              | Not Reported   |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                  | 7234654              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010698           |                          | 37 YR           | Female       | NOR            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort;            | Escitalopram Oxalate |                    |                    | S               |                      |                          |                 | Not Reported |                |
| Pneumonia; Respiration       | Lamotrigine          |                    |                    | S               |                      | 300 Mg (300 Mg,1 In 1 D) |                 | Not Reported |                |
| Abnormal                     | Lithium              |                    |                    | S               |                      |                          |                 | Not Reported |                |
|                              | Guaifenesin          |                    |                    | S               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2009                  | 7235525              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010644           |                          | 44 YR           | Female       | FRA            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Erythema;          | Escitalopram Oxalate |                    |                    | S               |                      | 1 Dosage Forms (1        |                 | Not Reported |                |
| Phytotherapy; Product        |                      |                    |                    |                 |                      | Dosage Forms,1 In 1 D)   |                 |              |                |
| Substitution Issue; Pruritus | Venlafaxine          |                    |                    | S               |                      | 150 Mg (150 Mg,1 In 1 D) |                 | Not Reported |                |
|                              | Atarax               |                    |                    | S               |                      | 150 Mg (150 Mg,1 In 1 D) |                 | Not Reported |                |
|                              | Effexor              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Noctamide            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Ginkor Fort          |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Xanax                |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Tegretol             |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Zyprexa              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Parkinane            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Risperdal            |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                              | Valpromide           |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2009                  | 7218371              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010261           |                          | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |

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|          |                           |   |      |                            |              |
|----------|---------------------------|---|------|----------------------------|--------------|
| Epilepsy | Escitalopram Oxalate      | S | Oral | 5 Mg (5 Mg,1 In 1 D), Oral | Not Reported |
|          | Fosavance                 | C |      |                            |              |
|          | Temerit                   | C |      |                            |              |
|          | Zanidip                   | C |      |                            |              |
|          | Bromazepam                | C |      |                            |              |
|          | Moxonidine                | C |      |                            |              |
|          | Cacit [Calcium Carbonate] | C |      |                            |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2009              | 7218566       | EXPEDITED (15-DAY) | Y                  | HO              | GB-TEVA-217442ISR    |                      | 37 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Body Temperature Increased;<br>Cerebrovascular Accident;<br>Diarrhoea Infectious;<br>Dizziness; Fatigue;<br>Headache; Heart Rate Increased;<br>Malaise;<br>Nausea; Vomiting | Diazepam             |              |            | S           | Oral         |                    |                 | Barr         |
|                                                                                                                                                                                                      | Aripiprazole         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                      | Clozapine            |              |            | S           | Oral         |                    | 2 WEEK          | Not Reported |
|                                                                                                                                                                                                      | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2009              | 7234959       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000010474           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypersensitivity; Joint Stiffness; Oculogyric Crisis | Lexapro        |              |            | S           |              | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2009              | 7236425       | EXPEDITED (15-DAY) | Y                  | HO              | 1000010647           |                      | 18 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urinary Retention     | Lexapro        |              |            | S           | Oral         | (10 Mg), Oral      |                 | Not Reported |
|                       | Nurofen        |              |            | C           |              |                    |                 | Not Reported |
|                       | Paracetamol    |              |            | C           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------------|-----------------|----------------------|----------------|
| 16-Dec-2009                                                                                                | 7219551                 | EXPEDITED (15-DAY) | N                  | OT              | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14891113 |                                                              | 38 YR           | Female               | DEU            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>           |                |
| Hypotension; Intentional Overdose; Somnolence; Suicide Attempt                                             | Metformin Hydrochloride |                    |                    | S               | Oral                                            | 1df: 5 Tablets                                               |                 | Bristol Myers Squibb |                |
|                                                                                                            | Abilify                 |                    |                    | S               |                                                 | 5 Tablets                                                    |                 | Not Reported         |                |
|                                                                                                            | Ciprallex               |                    |                    | S               |                                                 | 5 Tablets Of Ciprallex 10mg                                  |                 | Not Reported         |                |
|                                                                                                            | Pipamperone             |                    |                    | S               |                                                 | 5 Tablets Of 20mg                                            |                 | Not Reported         |                |
|                                                                                                            | Levothyroxine Sodium    |                    |                    | S               |                                                 | 1df: 5tablets                                                |                 | Not Reported         |                |
|                                                                                                            | Ramipril                |                    |                    | S               |                                                 | 5 Tablets Of Ramipril 5mg                                    |                 | Not Reported         |                |
|                                                                                                            | Tavor (Lorazepam)       |                    |                    | S               |                                                 | 15 Tablets Of Tavor 2mg                                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Dec-2009                                                                                                | 7238416                 | EXPEDITED (15-DAY) | N                  | HO              | 1000010781                                      |                                                              | 52 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>           |                |
| Abdominal Discomfort; Bipolar Disorder; Depression; Intracranial Aneurysm; Sedation; Sinusitis; Somnolence | Lexapro                 |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported         |                |
|                                                                                                            |                         |                    |                    |                 | Oral                                            | 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 |                      |                |
|                                                                                                            | Depakote                |                    |                    | S               | Oral                                            | 1000 Mg (500 Mg, 2 In 1 D), Oral                             |                 | Not Reported         |                |
|                                                                                                            | Promethazine            |                    |                    | S               | Oral                                            | 25 Mg (25 Mg, 1 In 1 Day), Oral                              |                 | Not Reported         |                |
|                                                                                                            | Risperidone             |                    |                    | S               | Oral                                            | 1 Mg (1 Mg, 1 In 1 D), Oral                                  |                 | Not Reported         |                |
|                                                                                                            | Klonopin                |                    |                    | C               |                                                 |                                                              |                 | Not Reported         |                |
|                                                                                                            | Activella               |                    |                    | C               |                                                 |                                                              |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 18-Dec-2009                                                                                                                                               | 7238484                          | EXPEDITED (15-DAY) | N                  | DE, HO          | 1000009699           |                                                              | 91 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional State; Delirium; Dysarthria; Dysphagia; Fall; General Physical Health Deterioration; Hallucination; Skin Abrasion; Skin Laceration | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg 910 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                           | Carvedilol                       |                    |                    | C               | Oral                 | 10 Mg 910 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2009                                                                                                                                               | 7238701                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000010734           |                                                              | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Parkinsonism                                                                                                                               | Escitalopram Oxalate             |                    |                    | S               | Oral                 | (5 Mg), Oral                                                 |                 | Not Reported |                |
|                                                                                                                                                           | Galantamine Hydrobromide         |                    |                    | S               | Oral                 | (8 Mg), Oral                                                 |                 | Not Reported |                |
|                                                                                                                                                           | Sinemet                          |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Idalprem                         |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Deprax (Trazodone Hydrochloride) |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Akineton                         |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Adiro                            |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Omeprazole                       |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                                                                                                                           | Belmalax                         |                    |                    | C               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Dec-2009                                                                                                                                               | 7238712                          | EXPEDITED (15-DAY) | N                  | OT              | 1000010774           |                                                              | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Feeling Abnormal; Hyperhidrosis; Memory Impairment; Sleep Disorder; Weight                                                                       | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

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|           |                             |  |   |      |                                                                 |  |  |              |  |
|-----------|-----------------------------|--|---|------|-----------------------------------------------------------------|--|--|--------------|--|
| Increased |                             |  |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |  |  |              |  |
|           | Metformin (Tablets)         |  | C |      |                                                                 |  |  | Not Reported |  |
|           | Metoprolol Succinate Retard |  | C |      |                                                                 |  |  | Not Reported |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2009              | 7238726       | EXPEDITED (15-DAY) | Y                  | HO              | 1000010779           |                      | 37 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Alanine Aminotransferase<br>Increased; Body<br>Temperature Increased;<br>Cerebrovascular Accident;<br>Diarrhoea Infectious;<br>Dizziness; Fall; Fatigue;<br>Headache; Heart Rate<br>Increased; Malaise;<br>Nausea; Neutrophil Count<br>Increased; Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Clozapine            |              |            | S           | Oral         | 200 Mg (100 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Diazepam             |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                     | Aripiprazole         |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2009              | 7238728       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010776           |                      | 62 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| General Physical Health<br>Deterioration;<br>Hypertensive Crisis | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                  | Valdispert (Tablets) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                  | Influvac (Tablets)   |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Dec-2009              | 7238729       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010780           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                      |   |              |                       |              |
|-------------------------------------------------------------------|----------------------|---|--------------|-----------------------|--------------|
| Agitation Neonatal;<br>Maternal Exposure During<br>Breast Feeding | Escitalopram Oxalate | S | Transmammary | (10 Mg), Transmammary | Not Reported |
|-------------------------------------------------------------------|----------------------|---|--------------|-----------------------|--------------|

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2009                                            | 7224969        | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-<br>2009SE06350 |                      | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Headache; Hot<br>Flush; Limb Injury; Nausea | Crestor        |                  |                    | S               | Oral                           |                      |                 | Astrazeneca  |                |
|                                                        | Lexapro        |                  |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                        | Atenolol       |                  |                    | C               |                                |                      |                 | Not Reported |                |
|                                                        | Coumadin       |                  |                    | C               |                                |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2009                                 | 7229786                  | DIRECT           | N                  | OT              |                      |                      | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Work Ability;<br>Motor Dysfunction | Paxil                    |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Lexapro                  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Pristiq Extended Release |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Effexor                  |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Lamictal                 |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Topamax                  |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 22-Dec-2009                                                  | 7143140              | EXPEDITED (15-DAY) | Y                  | OT              | 1000008923           |                         | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthma; Fall;<br>Hypersensitivity; Tremor;<br>Vision Blurred | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (10 Mg, 2 In 1 D) |                 | Not Reported |                |
|                                                              | Clonazepam           |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                                                              | Ventolin             |                    |                    | C               |                      |                         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2009              | 7164886       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009454           |                      | 35 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Abdominal Pain; Candida Infection; Constipation; Culture Stool Positive; Diarrhoea; Flatulence; Gastrointestinal Disorder; Rectal Haemorrhage | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                               | Augmentin            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                               | Bacilor              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                               | Pneumorel            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                               | Rubozinc             |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2009                                                                                                                                   | 7171568              | EXPEDITED (15-DAY) | Y                  | HO              | 1000009512           |                               | 74 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Decreased Appetite; Dysgeusia; Peripheral Coldness; Tremor; Weight Decreased                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                               | Ergenyl              |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2009                                                                                                                                   | 7196368              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010069           |                               | 76 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hypotension; Mental Impairment; Mental Status Changes; Purpura; Red Blood Cell Count Decreased; Renal Failure                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral  |                 | Not Reported |                |
|                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral  |                 | Not Reported |                |
|                                                                                                                                               | Asaflow              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                               | Diuretic             |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                               | Cholesterol Drug     |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2009                                                                                                                                   | 7196427              | EXPEDITED (15-DAY) | Y                  | DE, LT          | 1000010047           |                               | 72 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |                             |   |      |                                                                 |              |
|--------------------------------|-----------------------------|---|------|-----------------------------------------------------------------|--------------|
| Completed Suicide;<br>Drowning | Escitalopram Oxalate        | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                                |                             |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |              |
|                                | Clomipramine Hydrochloride  | C |      |                                                                 | Not Reported |
|                                | Godamed                     | C |      |                                                                 | Not Reported |
|                                | Nacom                       | C |      |                                                                 | Not Reported |
|                                | Nacom Retard                | C |      |                                                                 | Not Reported |
|                                | Pantozol                    | C |      |                                                                 | Not Reported |
|                                | Requip                      | C |      |                                                                 | Not Reported |
|                                | Stilnox                     | C |      |                                                                 | Not Reported |
|                                | Trazodone Hydrochloride     | C |      |                                                                 | Not Reported |
|                                | Torem                       | C |      |                                                                 | Not Reported |
|                                | Ximovan                     | C |      |                                                                 | Not Reported |
|                                | Atosil                      | C |      |                                                                 | Not Reported |
|                                | Terazosin Hydrochloride     | C |      |                                                                 | Not Reported |
|                                | Cefixim                     | C |      |                                                                 | Not Reported |
|                                | Simvahexal                  | C |      |                                                                 | Not Reported |
|                                | Lyrica                      | C |      |                                                                 | Not Reported |
|                                | Motilium                    | C |      |                                                                 | Not Reported |
|                                | Tavor [Lorazepam]           | C |      |                                                                 | Not Reported |
|                                | Seroquel                    | C |      |                                                                 | Not Reported |
|                                | Simethicon                  | C |      |                                                                 | Not Reported |
|                                | Ibuprofen                   | C |      |                                                                 | Not Reported |
|                                | Amitriptyline Hydrochloride | C |      |                                                                 | Not Reported |
|                                | Cymbalta                    | C |      |                                                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2009              | 7199670       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010155           |                      | 49 YR      | Female     | DNK            |

  

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Seizure               | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (0 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 20 Mg (0 Mg, 1 In 1 D),Oral |                 |              |
|                       | Serax                |              |            | C           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 22-Dec-2009                                               | 7201404                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000010121           |                                                                                                                 | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Multiforme;<br>Glossitis; Toxic Skin<br>Eruption | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In 1<br>D),Oral; 1 Dosage Forms<br>(1 Dosage Forms, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                           |                             |                    |                    |                 | Oral                 | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In 1<br>D),Oral; 1 Dosage Forms<br>(1 Dosage Forms, 1 In 1<br>D), Oral |                 |              |                |
|                                                           | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 1.5 Dosage Forms (1.5<br>Dosage Forms, 1 In 1 D),<br>Oral                                                       |                 | Not Reported |                |
|                                                           | Influenza Virus Vaccine Nos |                    |                    | S               |                      |                                                                                                                 |                 | Not Reported |                |
|                                                           | Lovenox                     |                    |                    | C               |                      |                                                                                                                 |                 | Not Reported |                |
|                                                           | Sorafenib Or Placebo        |                    |                    | C               |                      |                                                                                                                 |                 | Not Reported |                |
|                                                           | Effexor                     |                    |                    | C               |                      |                                                                                                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2009                                                                                                                                                                                                                                                            | 7220857              | EXPEDITED (15-DAY) | N                  | OT              | 1000010418           |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;<br>Amnesia; Anxiety;<br>Asthenia; Crying;<br>Decreased Appetite;<br>Dizziness; Emotional<br>Disorder; Fatigue; Feeling<br>Abnormal; Feeling Hot;<br>Feeling Of Relaxation;<br>Flushing; Heart Rate<br>Increased; Hot Flush;<br>Hunger; Hyperhidrosis; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg, Oral          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                        | Ativan               |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypersomnia; Insomnia;  
Irritability; Memory  
Impairment; Panic  
Reaction; Somnolence;  
Stress; Tachypnea;  
Unevaluable Event;  
Yawning

| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------------|-----------------|--------------|----------------|
| 22-Dec-2009                                                         | 7225873                | EXPEDITED (15-DAY) | Y                  | HO              | AU-ASTRAZENECA-2009SE32268 |                                 |                 | Female       | AUS            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Fluid Volume Decreased; Maternal Exposure During Pregnancy | Atacand                |                    |                    | S               | Oral                       |                                 |                 | Not Reported |                |
|                                                                     | Unspecified Ingredient |                    |                    | S               |                            |                                 |                 | Not Reported |                |
|                                                                     | Insulin Nos            |                    |                    | S               |                            |                                 |                 | Not Reported |                |
|                                                                     | Lexapro                |                    |                    | S               |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2009                                                         | 7226166                | EXPEDITED (15-DAY) | Y                  |                 | 1000010533                 |                                 | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Rash                                                                | Escitalopram Oxalate   |                    |                    | S               | Oral                       | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate   |                    |                    | S               | Oral                       | 15 Mg (15 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                     | Oxcarbazepine          |                    |                    | S               |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2009                                                         | 7226580                | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-2009UW00302 |                                 |                 | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Faeces Discoloured                                                  | Crestor                |                    |                    | S               | Oral                       |                                 |                 | Astrazeneca  |                |
|                                                                     | Lexapro                |                    |                    | S               | Oral                       |                                 |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|---------------------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| 22-Dec-2009                                                       | 7228695                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010508                    |                                                                           | 19 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Oropharyngeal Discomfort; Tongue Oedema                           | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral                                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                       | 7238731                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010775                    |                                                                           | 44 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Withdrawal Syndrome; Irritability; Nausea; Therapy Cessation | Escitalopram Oxalate    |                           |                             | S                        |                               | 10 Mg (10 Mg, 1 In 1 D), 10 Mg (10 Mg, 1 In 1 D),                         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                       | 7239703                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010874                    |                                                                           | 20 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pruritus; Rash; Scar                                              | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 15 Mg (15 Mg, 1 In 1 D), Oral, Oral                                       |                          | Not Reported        |                         |
|                                                                   | Seropram                |                           |                             | C                        |                               |                                                                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                       | 7239734                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000010919                    |                                                                           | 24 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Musculoskeletal Disorder; Suicidal Ideation            | Escitalopram Oxalate    |                           |                             | S                        |                               | 10 Mg (10 Mg 1 In 1 D)                                                    |                          | Not Reported        |                         |
|                                                                   | Escitalopram Oxalate    |                           |                             | S                        |                               | 20 Mg (20 Mg, 1 In 1 D); 15 Mg (15 Mg, 1 In 1 D) 20 Mg (20 Mg, 1 In 1 D); |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                          |                         |                           |                             |                          |                               |                                                     |                          |                     |                         |
|--------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------------------------|--------------------------|---------------------|-------------------------|
| Temesta (Lorazepam)                                                      |                         |                           | C                           |                          |                               | 15 Mg (15 Mg, 1 In 1 D)                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                       | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                              | 7241239                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010856                    |                                                     | 152 DAY                  | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                         | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Insomnia; Maternal Exposure During Breast Feeding; Restlessness; Tension | Escitalopram Oxalate    |                           |                             | S                        | Transmammary                  | 5 Mg, Transmammary                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                       | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                              | 7241276                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010859                    |                                                     |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                         | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Oedema Mouth; Vertigo                                                    | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 5 Mg, Oral                                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                       | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                              | 7241761                 | EXPEDITED (15-DAY)        | Y                           | DS                       | 1000010871                    |                                                     | 19 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                         | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blindness Unilateral                                                     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),Oral                        |                          | Not Reported        |                         |
|                                                                          | Birth Control Pills     |                           |                             | C                        |                               |                                                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                       | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Dec-2009                                                              | 7243266                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010794                    |                                                     | 48 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                         | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cataract                                                                 | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Terbinafine S Oral (1 Dosage Forms, 1 In 1 D), Oral Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Dec-2009                       | 7243334                | EXPEDITED (15-DAY)        | Y                           | DE, HO                   | 1000010869                    |                               |                     | Male                | DNK                     |

| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------|--------------------------|---------------------|
| Confusional State; Fall; Femur Fracture; Hyponatraemia | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Dec-2009                       | 7243450                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010852                    |                               | 36 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------|--------------------------|---------------------|
| Dermatillomania; Pruritus Generalised | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 23-Dec-2009                       | 7203765                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010132                    |                               |                     | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>         | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------------|--------------------------|---------------------|
| Crying; Depression; Feeling Abnormal; Psychiatric Symptom; Social Avoidant Behaviour; Suicidal Ideation | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                          | Not Reported        |
|                                                                                                         |                         |                       |                     |                      | Oral                  | Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                       | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-----------------------------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 23-Dec-2009                       | 7229760                | NON-EXPEDITED             | N                           |                          | US-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2009-BP-14 |                               | 62 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|                                |                         |                       |                     |                      |                       |                             |                          |                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |              |   |                          |        |                      |
|--------------|--------------|---|--------------------------|--------|----------------------|
| Constipation | Spiriva      | S | Respiratory (inhalation) | 18 Mcg | Boehringer Ingelheim |
|              | Lexapro      | S |                          |        | Not Reported         |
|              | Asa          | C |                          |        | Not Reported         |
|              | Cartia Xt    | C |                          |        | Not Reported         |
|              | Pantoprazole | C |                          |        | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2009              | 7173024       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009342           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Abortion Spontaneous; Endometriosis; Maternal Drugs Affecting Foetus; Pregnancy | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Dec-2009              | 7232108       | DIRECT           | N                  | LT              |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------|-----------------|-----------------|
| Crying; Depression; Diarrhoea; Disturbance In Attention; Emotional Disorder; Fear; Feeling Abnormal; Gastrointestinal Disorder; Mania; Restlessness; Weight Decreased | Lexapro        |              |            | S           | Oral         | 10 Miligrams Once Daily Po |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Dec-2009              | 7230901       | EXPEDITED (15-DAY) | Y                  | OT              | ES-JNJFOC-20091204475 |                      | 63 YR      | Male       | ESP            |

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Disorientation; Drug Interaction; Lethargy | Durogesic            |              |            | S           | Transdermal  |                    |                 | Not Reported |
|                                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                  |                    |                    |                 |                          |                      |                 |              |                |
|-----------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Cimetidine                                                            |                                  |                    | S                  | Oral            |                          | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Dec-2009                                                           | 7230902                          | EXPEDITED (15-DAY) | Y                  | OT              | ES-JNJFOC-20091205548    |                      | 84 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination; Parkinson'S Disease                                    | Reminyl                          |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Escitalopram Oxalate             |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Deprax (Trazodone Hydrochloride) |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Akineton                         |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Adiro                            |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Omeprazole                       |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Lactulose                        |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Lorazepam                        |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                                       | Sinemet                          |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Dec-2009                                                           | 7231931                          | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2009313148 |                      | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Arthritis; Hypoacusis; Scoliosis; Spinal Stenosis; Tinnitus | Lipitor                          |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                       | Lexapro                          |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                       | Centrum Silver                   |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                       | Ecotrin                          |                    |                    | C               |                          | 81 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                       | Calcium                          |                    |                    | C               |                          | Frequency: 4x/Day,   |                 | Not Reported |                |
|                                                                       | Coenzyme Q10                     |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                       | D3-Vicotrat                      |                    |                    | C               |                          | Unit Dose: 2000;     |                 | Not Reported |                |
|                                                                       | Ergocalciferol\Zeaxanthin        |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------------------------------------|-----------------|--------------|----------------|
| 29-Dec-2009                                                                                                                                                                             | 7220825              | EXPEDITED (15-DAY) | Y                  |                 | 1000010421                   |                                                                      | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia                                                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg ( 10 Mg, 1 In 1 D),<br>Oral                                    |                 | Not Reported |                |
|                                                                                                                                                                                         | Xanax                |                    |                    | C               |                              |                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2009                                                                                                                                                                             | 7235649              | DIRECT             | N                  | OT              |                              |                                                                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Sensation In<br>Eye; Adrenal Disorder;<br>Anxiety; Balance Disorder;<br>Dizziness; Dyskinesia;<br>Hyperacusis; Insomnia;<br>Panic Attack;<br>Photophobia; Visual<br>Impairment | Lexapro              |                    |                    | S               | Sublingual<br><br>Sublingual | 10 Mg 1/Day SI; 5 Mg<br>1/Day SI<br>10 Mg 1/Day SI; 5 Mg<br>1/Day SI |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2009                                                                                                                                                                             | 7245495              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010921                   |                                                                      |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Condition<br>Aggravated; Irritability;<br>Restlessness; Sleep<br>Disorder                                                                                                   | Escitalopram Oxalate |                    |                    | S               |                              |                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2009                                                                                                                                                                             | 7223473              | EXPEDITED (15-DAY) | Y                  | HO              | 1000009255                   |                                                                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                     |                                                          |      |                               |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|------|-------------------------------|--------------|
| Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Atelectasis; Back Pain; Bile Duct Stone; Blood Calcium Decreased; Blood Glucose Increased; Blood Potassium Decreased; Chest Pain; Dyspnoea; Fibrin D Dimer Increased; Haemangioma Of Liver; Headache; Hyponatraemia; Hypoxia; Immune Thrombocytopenic Purpura; Influenza; Injection Site Cellulitis; Injection Site Thrombosis; Lung Infection; Osteoarthritis; Radiculopathy | Lexapro<br>Pneumovax 23<br>Fluvirin Nos<br>Nexium<br>Xanax<br>Estradiol<br>Valtrex<br>Trazodone Hydrochloride<br>Wellbutrin XL<br>Colace<br>Eszopiclone<br>Zolpidem | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|------|-------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2009              | 7245724       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010934           |                      | 58 YR      | Male       | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Chest Pain; Coronary Artery Disease | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1in 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2009              | 7245810       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010935           |                      | 84 YR      | Female     | DNK            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Agitation; Poor Quality Sleep | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                               | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                               |                                 |                    | Ebixa (Tablets)<br>Tiapridal |                 |              | C<br>C               |                      |                 | D),Oral      |                |  | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|------------------------------|-----------------|--------------|----------------------|----------------------|-----------------|--------------|----------------|--|------------------------------|
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u>           | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |                              |
| 30-Dec-2009                                                                                                                                                                                   | 7300801                         | NON-EXPEDITED      | Y                            | DE              |              | 2009RR-21020         |                      | 61 YR           | Female       | USA            |  |                              |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>                   | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   |                      | <u>Duration</u> | <u>Mfr</u>   |                |  |                              |
| Completed Suicide                                                                                                                                                                             | Acetaminophen\Codeine Phosphate |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Oxycodone                       |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Escitalopram Oxalate            |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Levothyroxine Sodium            |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Unspecified Ingredient          |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Acetaminophen\Diphenhydramine   |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Estradiol                       |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Progestine                      |                    |                              | S               | Oral         | Oral                 |                      |                 | Not Reported |                |  |                              |
| <u>FDA Received Date</u>                                                                                                                                                                      | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u>           | <u>Outcomes</u> |              | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |                              |
| 31-Dec-2009                                                                                                                                                                                   | 7048841                         | EXPEDITED (15-DAY) | Y                            | HO              |              | PHHY2009FR27026      |                      | 48 YR           | Female       | FRA            |  |                              |
| <u>Preferred Term</u>                                                                                                                                                                         | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>                   | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>   |                      | <u>Duration</u> | <u>Mfr</u>   |                |  |                              |
| Balance Disorder; Cerebellar Syndrome; Eye Pain; Intracranial Pressure Increased; Meningeal Disorder; Spinal Cord Injury; Vertigo; Vision Blurred; Visual Acuity Reduced; Visual Field Defect | Femara                          |                    |                              | S               | Oral         | 2.5 Mg               |                      |                 | Novartis     |                |  |                              |
|                                                                                                                                                                                               | Femara                          |                    |                              | S               | Oral         | Unk                  |                      |                 | Novartis     |                |  |                              |
|                                                                                                                                                                                               | Escitalopram Oxalate            |                    |                              | S               | Oral         | Unk                  |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Cyamemazine                     |                    |                              | S               | Oral         | Unk                  |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Prazepam                        |                    |                              | S               | Oral         | Unk                  |                      |                 | Not Reported |                |  |                              |
|                                                                                                                                                                                               | Sectral                         |                    |                              | S               | Oral         | Unk                  |                      |                 | Not Reported |                |  |                              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|
| 31-Dec-2009                                                                                                                       | 7247566                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000005256           |                                         | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Pregnancy; Premature Labour                                                                   | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral           |                 | Not Reported |                |
|                                                                                                                                   | Olanzapine               |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral             |                 | Not Reported |                |
|                                                                                                                                   | Nicotine                 |                    |                    | S               |                      |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Dec-2009                                                                                                                       | 7247627                  | EXPEDITED (15-DAY) | Y                  | CA              | 1000010953           |                                         | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur; Congenital Inguinal Hernia; Exomphalos; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Premature Baby | Escitalopram Oxalate     |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                                                   | Olanzapine               |                    |                    | S               | Transplacental       | 5 Mg (5 Mg, 1 In 1 D), Transplacental   |                 | Not Reported |                |
|                                                                                                                                   | Nicotine                 |                    |                    | S               | Transplacental       | Transplacental                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2010                                                                                                                       | 7220935                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000010346           |                                         | 32 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Systolic Increased; Breast Mass; Dizziness; Fatigue; Galactorrhoea; Heart Rate Increased; Pallor                   | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg, Oral                             |                 | Not Reported |                |
|                                                                                                                                   | Sertindole               |                    |                    | S               | Oral                 | 4 Mg, Oral 8 Mg, Oral                   |                 | Not Reported |                |
|                                                                                                                                   |                          |                    |                    |                 | Oral                 | 4 Mg, Oral 8 Mg, Oral                   |                 |              |                |
|                                                                                                                                   | Paroxetine Hydrochloride |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                                                                                                   | Losec                    |                    |                    | C               |                      |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2010                                                                                                                       | 7249314                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000010965           |                                         | 72 YR           | Male         | GRC            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Surgery                                                                                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (10 Mg, 2 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jan-2010                                                                               | 7249315                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000010949                    |                               |                          | Female              | NOR                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Asthenia; Depression; Drug Ineffective; Listless; Paraesthesia                   | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg, Oral                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jan-2010                                                                               | 7234852                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000010703                    |                               | 38 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depression; Off Label Use                                                                 | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                                                                           | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jan-2010                                                                               | 7293254                 | DIRECT                    | Y                           | HO                       |                               |                               | 29 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Coagulopathy; Depression; Hepatitis Cholestatic; Insomnia; Mental Status Changes | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg One Daily Oral 047      | 42 DAY                   | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Jan-2010                                                                               | 7239884                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | 1000010924                    |                               | 71 YR                    | Female              | DNK                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite;<br>Dizziness; Fatigue;<br>Pulmonary Embolism | Escitalopram Oxalate |              |            | S           | Oral         | (15 Mg), Oral      |                 | Not Reported |
|                                                                  | Topamax              |              |            | S           | Oral         | (100 Mg), Oral     |                 | Not Reported |
|                                                                  | Norvasc              |              |            | S           | Oral         | (5 Mg), Oral       |                 | Not Reported |
|                                                                  | Anagastro            |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Loramet              |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Sintrom              |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Sutril               |              |            | C           |              |                    |                 | Not Reported |
|                                                                  | Tranxilium           |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2010              | 7251014       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011005           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                 | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Premature Labour | Escitalopram Oxalate       |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral             |                 | Not Reported |
|                                                                       | Pipamperone                |              |            | S           |              | 4 Dosage Forms (4<br>Dosage Forms, 1 In 1 D) |                 | Not Reported |
|                                                                       | Dihydroergotamine Mesylate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)                      |                 | Not Reported |
|                                                                       | Oxazepam                   |              |            | S           |              | 75 Mg (75 Mg, 1 In 1 D)                      |                 | Not Reported |
|                                                                       | Loprazolam                 |              |            | S           |              | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D) |                 | Not Reported |
|                                                                       | Tranxene T-Tab             |              |            | S           |              | 40 Mg (40 Mg, 1 In 1 D)                      |                 | Not Reported |
|                                                                       | Aripiprazole               |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jan-2010              | 7251016       | EXPEDITED (15-DAY) | Y                  | DS              | 1000010986           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diarrhoea; Feeling<br>Abnormal; Malaise;<br>Nausea; Palpitations;<br>Syncope; Tremor; | Escitalopram Oxalate |              |            | S           | Oral         | (5 Mg, Once), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting; Yawning

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| 06-Jan-2010                                                                                    | 7252939                    | EXPEDITED (15-DAY) | N                  | DE              | 1000011056           |                                                           | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound; Mood Swings; Self-Medication                                | Lexapro                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                             |                 | Not Reported |                |
|                                                                                                | Ativan                     |                    |                    | C               |                      |                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2010                                                                                    | 7253275                    | EXPEDITED (15-DAY) | Y                  | CA              | 1000011006           |                                                           | < 1 DAY         | Female       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Fallot'S Tetralogy; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Premature Baby | Escitalopram Oxalate       |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D),Transplacental                    |                 | Not Reported |                |
|                                                                                                | Pipamperone                |                    |                    | S               | Transplacental       | 4 Dosage Forms (4 Dosage Forms, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                | Dihydroergotamine Mesylate |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D), Transplacental                   |                 | Not Reported |                |
|                                                                                                | Oxazepam                   |                    |                    | S               | Transplacental       | 75 Mg (75 Mg, 1 In 1 D), Transplacental                   |                 | Not Reported |                |
|                                                                                                | Loprazolam                 |                    |                    | S               | Transplacental       | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                | Tranxene T-Tab             |                    |                    | S               | Transplacental       | 40 Mg (40 Mg, 1 In 1 D), Transplacental                   |                 | Not Reported |                |
|                                                                                                | Aripiprazole               |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),Transplacental                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2010                                                                                    | 7244062                    | DIRECT             | N                  | OT              |                      |                                                           | 56 YR           | Male         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| Heart Rate Irregular                             | Lexapro                       |                    |                    | S               | Oral                 | 1x Daily Po                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2010                                      | 7251252                       | EXPEDITED (15-DAY) | Y                  | OT              |                      | 1000011131                                                         | 30 YR           | Male         | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Overdose;<br>Psychomotor Hyperactivity   | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                  |                               |                    |                    |                 | Oral                 | 40 Mg (40 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                  | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jan-2010                                      | 7240758                       | EXPEDITED (15-DAY) | Y                  | DE              |                      | US-ASTRAZENECA-<br>2010SE00531                                     | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Quetiapine                    |                    |                    | S               | Oral                 |                                                                    |                 | Zeneca       |                |
|                                                  | Phenytoin                     |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Phenobarbital                 |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Trazodone Hydrochloride       |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate          |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Tenofovir                     |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Oxycodone                     |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Methylphenidate Hydrochloride |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Metformin Hydrochloride       |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Zolpidem                      |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |
|                                                  | Ondansetron                   |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported |                |

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|                                                                             | Pregabalin           |                    | S                  | Oral            |                                  |                                  |                 | Not Reported |                |
|-----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                             | Metoclopramide       |                    | S                  | Oral            |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2010                                                                 | 7255202              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011123                       |                                  | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Pneumonia Aspiration                                                        | Lexapro              |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2010                                                                 | 7082820              | EXPEDITED (15-DAY) | Y                  | OT              | 1000007934                       |                                  | 37 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Asthenia; Blood Alkaline<br>Phosphatase Increased; | Escitalopram Oxalate |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| Cholestasis; Focal<br>Nodular Hyperplasia;                                  | Escitalopram Oxalate |                    |                    | S               | Oral                             | Oral                             |                 | Not Reported |                |
| Gamma-<br>Glutamyltransferase<br>Increased                                  | Nocertone            |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                                                             | Alprazolam           |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                                                             | Zolpidem             |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                                                             | Ludeal               |                    |                    | C               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2010                                                                 | 7234376              | EXPEDITED (15-DAY) | N                  | HO              | US-ABBOTT-09P-163-<br>0616023-00 |                                  | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;                                                       | Depakote             |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Bipolar Disorder;                                                           | Lexapro              |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Depression; Headache;                                                       | Lexapro              |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Intracranial Aneurysm;                                                      | Promethazine         |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Sedation; Sinusitis;                                                        | Risperidone          |                    |                    | S               | Oral                             |                                  |                 | Not Reported |                |
| Somnolence                                                                  | Klonopin             |                    |                    | C               | Oral                             |                                  |                 | Not Reported |                |

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|                                                          |                         |                    |                    |                 |                      |                                  |                 |              |                |
|----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Activella                                                |                         |                    | C                  |                 |                      | Not Reported                     |                 |              |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2010                                              | 7254851                 | EXPEDITED (15-DAY) | N                  | OT              | 1000011163           |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Anxiety; Restlessness           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2010                                              | 7254869                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000011190           |                                  | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of<br>Consciousness;                     | Escitalopram Oxalate    |                    |                    | S               | Oral                 | (50 Mg, Once), Oral              |                 | Not Reported |                |
| Intentional Overdose;<br>Suicide Attempt                 | Mirtazapine             |                    |                    | S               | Oral                 | (600 Mg, Once), Oral             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2010                                              | 7254871                 | EXPEDITED (15-DAY) |                    | OT              | 1000011159           |                                  | 27 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety;                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| Depersonalisation/Dereali<br>sation Disorder;            | Escitalopram Oxalate    |                    |                    | S               | Oral                 | See Image                        |                 | Not Reported |                |
| Depression; Diarrhoea;                                   |                         |                    |                    |                 | Oral                 | See Image                        |                 |              |                |
| Fatigue; Hunger;                                         |                         |                    |                    |                 | Oral                 | See Image                        |                 |              |                |
| Hypersomnia; Malaise;                                    |                         |                    |                    |                 | Oral                 | See Image                        |                 |              |                |
| Metrorrhagia;                                            |                         |                    |                    |                 |                      |                                  |                 |              |                |
| Oropharyngeal Pain;                                      | Desogestrel And Ethinyl |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| Overdose; Panic Attack;                                  | Estradiol               |                    |                    |                 |                      |                                  |                 |              |                |
| Paraesthesia; Self-<br>Injurious Ideation;<br>Stomatitis |                         |                    |                    |                 |                      |                                  |                 |              |                |

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| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 11-Jan-2010                                                                                                      | 7256252              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011141           |                                  | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Arthritis;<br>Deafness Unilateral;<br>Scoliosis; Spinal Stenosis;<br>Tinnitus                          | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                  | Lipitor              |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Centrum Silver       |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Ecotrin              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Calcium              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Coenzyme Q10         |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | D3-Vicotrat          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Multi-Vitamin        |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2010                                                                                                      | 7256094              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011207           |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Fall; Jaw<br>Fracture                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                  | Lexomil              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Cialis               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Dogmatil             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Noctamide            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Teralithe            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2010                                                                                                      | 7222194              | EXPEDITED (15-DAY) | Y                  | HO              | 1000010427           |                                  |                 | Female       | AUS            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Fluid Volume<br>Decreased; Gestational<br>Diabetes; Maternal<br>Exposure During<br>Pregnancy; Pregnancy | Lexapro              |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                                  | Atacand              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Elevit Vitamins      |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                  | Insulin Nos          |                    |                    | C               |                      |                                  |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 13-Jan-2010                                           | 7245192               | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2010000966 |                      | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Doxepin Hydrochloride |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                       | Escitalopram Oxalate  |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 13-Jan-2010                               | 7245227                  | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2010001145 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Death; Respiratory Arrest | Doxepin Hydrochloride    |                    |                    | S               | Unknown                  |                      |                 | Pfizer       |                |
|                                           | Sildenafil Citrate       |                    |                    | S               | Unknown                  |                      |                 | Pfizer       |                |
|                                           | Sertraline Hydrochloride |                    |                    | S               | Unknown                  |                      |                 | Pfizer       |                |
|                                           | Oxybutynin               |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Escitalopram Oxalate     |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Alcohol                  |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Clonazepam               |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Clonidine                |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Diphenhydramine          |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                           | Duloxetine               |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 13-Jan-2010                  | 7255312              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011208           |                               | 62 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Arrhythmia; Malaise | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, `1 In 1 D),Oral |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------------------|-----------------|--------------|----------------|
| 13-Jan-2010                                                                                                                                                      | 7255399                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000011210                            |                                       | 53 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Sepsis; Tonic Clonic Movements                                                                                                                      | Escitalopram Oxalate        |                    |                    | S               | Oral                                  | Oral                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Ciprofloxacin Hydrochloride |                    |                    | S               | Intravenous (not otherwise specified) | Intravenous (Not Otherwise Specified) |                 | Not Reported |                |
|                                                                                                                                                                  | Rifater                     |                    |                    | S               | Oral                                  | Oral                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2010                                                                                                                                                      | 7223560                     | EXPEDITED (15-DAY) | Y                  | CA, HO          | 1000010428                            |                                       |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Fluid Volume Decreased; Congenital Bladder Anomaly; Foetal Disorder; Maternal Drugs Affecting Foetus; Neonatal Disorder; Nephrolithiasis; Renal Failure | Lexapro                     |                    |                    | S               | Transplacental                        | Transplacental                        |                 | Not Reported |                |
|                                                                                                                                                                  | Atacand                     |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Elevit Vitamins             |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Insulin Nos                 |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2010                                                                                                                                                      | 7246253                     | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2010001227              |                                       | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide                                                                                                                                | Verapamil Hydrochloride     |                    |                    | S               | Oral                                  |                                       |                 | Pfizer       |                |
|                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               | Oral                                  |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Sucralfate                  |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Atorvastatin                |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Acetaminophen\Hydrocodone   |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Bitartrate                  |                    |                    |                 |                                       |                                       |                 |              |                |
|                                                                                                                                                                  | Omeprazole                  |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Polyethylene Glycols        |                    |                    | C               |                                       |                                       |                 | Not Reported |                |
|                                                                                                                                                                  | Montelukast                 |                    |                    | C               |                                       |                                       |                 | Not Reported |                |

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|             |   |              |
|-------------|---|--------------|
| Zolpidem    | C | Not Reported |
| Synthroid   | C | Not Reported |
| Vitamin B12 | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2010              | 7257258       | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000028       |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Ondansetron             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Phenytoin               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Phenobarbital           |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Quetiapine              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Trazodone               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Escitalopram Oxalate    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Emtricitabine\Tenofovir |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Oxycodone               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Methylphenidate         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Metformin Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Zolpidem                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Pregabalin              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Metoclopramide          |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jan-2010              | 7259945       | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000003       |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Tramadol Hydrochloride   |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Diazepam                 |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Escitalopram Oxalate     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Paroxetine Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------|-----------------|--------------|----------------|
| 15-Jan-2010                                                                                                                                                                                                                                                                         | 7153946                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000009193               |                                | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Libality; Balance Disorder; Burning Sensation; Crying; Dizziness; Feeling Abnormal; Feeling Cold; Headache; Hyperhidrosis; Loss Of Personal Independence In Daily Activities; Movement Disorder; Muscular Weakness; Nausea; Salivary Hypersecretion; Speech Disorder; Tremor | Escitalopram Oxalate      |                    |                    | S               | Oral                     | 15 Mg (15 M G, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Mirtazapin (Tablets)      |                    |                    | C               |                          |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jan-2010                                                                                                                                                                                                                                                                         | 7247236                   | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2010001710 |                                | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                                                                                                                                   | Ziprasidone Hydrochloride |                    |                    | S               | Oral                     |                                |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                     | Escitalopram Oxalate      |                    |                    | S               | Oral                     |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                     | Lamotrigine               |                    |                    | S               | Oral                     |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                            | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2010                                                                                                                                                                                                                                                                         | 7247959                   | EXPEDITED (15-DAY) | Y                  | HO              | US-RANBAXY-2010US-30334  |                                |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                               | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Disorientation; Overdose; Seizure; Suicide Attempt                                                                                                                                                                                                                            | Isotretinoin              |                    |                    | S               | Oral                     | 20 Mg, Bid                     | 30 DAY          | Ranbaxy      |                |
|                                                                                                                                                                                                                                                                                     | Isotretinoin              |                    |                    | S               | Oral                     | 20 Mg, Tid                     | 96 DAY          | Ranbaxy      |                |
|                                                                                                                                                                                                                                                                                     | Lexapro                   |                    |                    | S               | Oral                     |                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |         |   |      |            |        |  |              |
|--|---------|---|------|------------|--------|--|--------------|
|  | Lexapro | S | Oral | Unk        |        |  | Not Reported |
|  | Celexa  | S | Oral | Unk        | 20 DAY |  | Not Reported |
|  | Ultram  | S | Oral | 50 Mg, Unk | 1 DAY  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2010              | 7221724       | EXPEDITED (15-DAY) | Y                  | HO              | CH-001179            |                      | 71 YR      | Male       | CHE            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Malaise;<br>Nausea | Minirin        |              |            | S           | Oral         | (0.1 Mg Oral)      |                 | Not Reported |
|                                   | Cipraxel       |              |            | S           | Oral         | (1 Df Oral)        |                 | Not Reported |
|                                   | Beloc-Zok      |              |            | C           |              |                    |                 | Not Reported |
|                                   | Plavix         |              |            | C           |              |                    |                 | Not Reported |
|                                   | Aspirin Cardio |              |            | C           |              |                    |                 | Not Reported |
|                                   | Neo-Mercazole  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2010              | 7249209       | EXPEDITED (15-DAY) | Y                  | OT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14934616 |                      | 37 YR      | Male       | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Depression; Infertility | Abilify              |              |            | S           | Oral         | Dose Increased To 30 Mg<br>Per Day |                 | Not Reported |
|                         | Escitalopram Oxalate |              |            | S           | Oral         | Dose Increased To 30mg<br>Per Day  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2010              | 7249428       | EXPEDITED (15-DAY) | Y                  | HO              | GB-WATSON-2010-<br>00372 |                      | 76 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Electrocardiogram Qt<br>Prolonged; Sinus<br>Bradycardia; Syncope;<br>Torsade De Pointes | Omeprazole           |              |            | S           | Oral         | 20 Mg, Daily       |                 | Watson       |
|                                                                                                              | Propranolol          |              |            | S           | Unknown      | 80 Mg, Daily       |                 | Watson       |
|                                                                                                              | Propranolol          |              |            | S           |              |                    |                 | Watson       |
|                                                                                                              | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Daily       | 6 DAY           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                      |                    |                    |                 |                      |                                  |                 |              |                |
|----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Donepezil Hydrochloride    |                      |                    | S                  | Oral            | 10 Mg, Unk           | 730 DAY                          | Not Reported    |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                | 7259189              | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000038       |                                  | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide          | Ibuprofen            |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                            | Acetaminophen        |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                            | Methylphenidate      |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                            | Alcohol              |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                | 7260312              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011275           |                                  | 52 YR           | Male         | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                | 7260885              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011291           |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Swelling; Weight Increased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                | 7260904              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011309           |                                  | 35 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Anxiety; Depression; Heart Rate Increased; Hot Flush; Hyperhidrosis; Muscle Spasms; Muscle Strain; Overdose; Palpitations; Panic Attack; Poor Quality Sleep; Tremor; Weight Increased | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Co-Codamol              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                       | Vitamin C               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                       | Zopiclone               |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Nordette                                                                                                                                                                              |                         |                    | C                  |                 |                      |                               | Not Reported    |              |                |
| Zolpidem                                                                                                                                                                              |                         |                    | C                  |                 |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                                                                                                                                                                           | 7267961                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000011273           |                               | 27 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Cyst; Breast Discomfort; Hyperprolactinaemia                                                                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Xanax                   |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2010                                                                                                                                                                           | 7269930                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000011277           |                               | 83 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Malaise; Renal Failure                                                                                                                                                 | Citalopram Hydrobromide |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                                                                                       | Lasix                   |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                       | Cordaone                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                       | Tareg                   |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                       | Metformin Hydrochloride |                    |                    | C               |                      |                               |                 | Not Reported |                |
| Previscan (Fluindione)                                                                                                                                                                |                         |                    | C                  |                 |                      |                               | Not Reported    |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |              |
|-------------|---|--------------|
| Seresta     | C | Not Reported |
| Equanil     | C | Not Reported |
| Paracetamol | C | Not Reported |
| Forlax      | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2010              | 7284316       | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000049       |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Atrioventricular Block First Degree; Blood Glucose Increased; Blood Ph Decreased; Cardiac Arrest; Completed Suicide; Electrocardiogram Abnormal; Hypotension; Intentional Self-Injury; Lethargy; Non-Cardiogenic Pulmonary Oedema; Overdose; Po2 Decreased; Poisoning; Renal Impairment; Sinus Bradycardia; Unresponsive To Stimuli; Vomiting | Verapamil Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                        | Unspecified Ingredient  |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jan-2010              | 7247794       | EXPEDITED (15-DAY) | Y                  | HO              | 1000010855           |                      | 36 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Intentional Self-Injury; Overdose | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                          | Lexapro        |              |            | S           | Oral         | >200 Mg (Once), Oral            |                 | Not Reported |
|                                                                                          | Lorazepam      |              |            | S           | Oral         | 0.5 Mg (0.5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                          | Lorazepam      |              |            | S           | Oral         | 10 Mg (Once), Oral              |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 20-Jan-2010                                                                                                    | 7249927                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | ES-PFIZER INC-2010004264 |                                                                                                    | 71 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dizziness; Fatigue;<br>Pulmonary Embolism                                               | Norvasc                 |                    |                    | S               | Oral                     | Unk                                                                                                | 905 DAY         | Pfizer       |                |
|                                                                                                                | Topamax                 |                    |                    | S               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Cipralex                |                    |                    | S               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Anagasta                |                    |                    | C               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Lormetazepam            |                    |                    | C               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Sintrom                 |                    |                    | C               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Sutril                  |                    |                    | C               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
|                                                                                                                | Clorazepate Dipotassium |                    |                    | C               | Oral                     | Unk                                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2010                                                                                                    | 7270112                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000011255               |                                                                                                    | 34 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatic Calcification;<br>Pancreatitis Acute                                                                | Escitalopram Oxalate    |                    |                    | S               | Oral                     | Oral                                                                                               |                 | Not Reported |                |
|                                                                                                                | Propranolol             |                    |                    | C               |                          |                                                                                                    |                 | Not Reported |                |
|                                                                                                                | Temesta (Lorazepam)     |                    |                    | C               |                          |                                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2010                                                                                                    | 7273500                 | EXPEDITED (15-DAY) | N                  | LT, OT          | 1000011271               |                                                                                                    | 23 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug<br>Withdrawal Syndrome;<br>Insomnia; Irritability;<br>Overdose; Suicidal<br>Ideation | Escitalopram Oxalate    |                    |                    | S               | Oral                     | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral; 15 Mg (15 Mg, 1<br>In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                |                         |                    |                    |                 | Oral                     | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1                                               |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |  |   |      |      |                                                                                                                                      |              |
|----------------------|--|---|------|------|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                      |  |   |      | Oral | D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral<br>5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |              |
| Escitalopram Oxalate |  | S | Oral |      | 20 Mg (20 Mg, 1 In 1 D), Oral                                                                                                        | Not Reported |
| Escitalopram Oxalate |  | S | Oral |      | 15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral                                                                         | Not Reported |
|                      |  |   | Oral |      | 15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral                                                                         |              |
| Diazepam             |  | C |      |      |                                                                                                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Jan-2010              | 7251786       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-JNJFOC-20100107092 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Oxybutynin               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Doxepin                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Alcohol                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Clonazepam               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Clonidine                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Unspecified Ingredient   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Diphenhydramine          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Sildenafil               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Sertraline Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Duloxetine               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                            | Escitalopram Oxalate     |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-----------------------------|-----------------------------------------------------------------------------|-----------------|--------------|----------------|
| 21-Jan-2010                                                                                                                  | 7268629                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011315                  |                                                                             | 66 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Calcium Decreased;<br>Blood Chloride<br>Decreased; Blood<br>Potassium Decreased;<br>Drug Interaction;<br>Hyponatraemia | Escitalopram Oxalate          |                    |                    | S               | Oral                        | Oral                                                                        |                 | Not Reported |                |
|                                                                                                                              | Desmopressin                  |                    |                    | S               | Respiratory<br>(inhalation) | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In1 D)<br>Respiratory (Inhalation) |                 | Not Reported |                |
|                                                                                                                              | Vagifem                       |                    |                    | C               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Toviaz                        |                    |                    | C               |                             |                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2010                                                                                                                  | 7268668                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011316                  |                                                                             | 24 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention                                                                                                            | Escitalopram Oxalate          |                    |                    | S               | Oral                        | 5 Mg (5 Mg, 1 In 1 D), Oral                                                 |                 | Not Reported |                |
|                                                                                                                              | Mirtazapine                   |                    |                    | S               | Oral                        | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2010                                                                                                                  | 7269129                       | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000136              |                                                                             | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Poisoning;<br>Respiratory Arrest;<br>Toxicity To Various Agents                                              | Doxepin Hydrochloride         |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Clonazepam                    |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Alcohol                       |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Clonidine Transdermal System  |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Unspecified Ingredient        |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Diphenhydramine Hydrochloride |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Sildenafil                    |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Sertraline                    |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Duloxetine                    |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Oxybutynin                    |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |
|                                                                                                                              | Escitalopram Oxalate          |                    |                    | S               |                             |                                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 21-Jan-2010                                           | 7269224               | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000118                                                |                      | 20 YR           | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide                                     | Valproic Acid         |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
|                                                       | Aripiprazole          |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
|                                                       | Amphetamine           |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
|                                                       | Escitalopram Oxalate  |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Jan-2010                                           | 7284446               | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000137                                                |                      | 53 YR           | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Doxepin Hydrochloride |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
|                                                       | Benzodiazepine        |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
|                                                       | Escitalopram Oxalate  |                    |                    | S               | Oral                                                          | Oral                 |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jan-2010                                           | 7042927               | EXPEDITED (15-DAY) | Y                  | DE              | 1000006963                                                    |                      |                 | Male                 | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Road Traffic Accident                                 | Escitalopram Oxalate  |                    |                    | S               |                                                               |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jan-2010                                           | 7252976               | NON-EXPEDITED      | N                  |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>BP-00 |                      | 68 YR           | Female               | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Agitation; Anxiety; Impatience; Irritability          | Spiriva               |                    |                    | S               | Respiratory (inhalation)                                      | 18 Mcg               |                 | Boehringer Ingelheim |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |              |
|---------------------|---|--------------|
| Lipitor             | S | Not Reported |
| Zyrtec              | S | Not Reported |
| Zetia               | S | Not Reported |
| Lexapro             | S | Not Reported |
| Hydrochlorothiazide | C | Not Reported |
| Levothyroxine       | C | Not Reported |
| Ambien              | C | Not Reported |
| Estradiol           | C | Not Reported |
| Tramadol            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2010              | 7253110       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20100105556 |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Tramadol                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Diazepam                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Escitalopram Oxalate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Paroxetine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2010              | 7254868       | EXPEDITED (15-DAY) | N                  | OT              | 1000011162           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Bradycardia; Chest Pain;<br>Dyspnoea | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jan-2010              | 7274376       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000009675           |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Emotional Disorder;<br>Homicide; Physical<br>Assault; Suicide Attempt | Lexapro        |              |            | S           |              | 10 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------|-----------------|--------------|----------------|
| 23-Jan-2010                                       | 7253327               | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20100106924 |                                  | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents  | Acetaminophen         |                    | Y                  | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                   | Acetaminophen         |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                   | Escitalopram Oxalate  |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                   | Ibuprofen             |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                   | Methylphenidate       |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
|                                                   | Alcohol               |                    |                    | S               | Oral                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2010                                       | 7177780               | EXPEDITED (15-DAY) | Y                  | OT              | 1000009686            |                                  | 45 YR           | Female       | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Nightmare;<br>Somnambulism                        | Escitalopram Oxalate  |                    |                    | S               | Oral                  | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2010                                       | 7246639               | EXPEDITED (15-DAY) | Y                  | OT              | 1000010920            |                                  | 60 YR           | Male         | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis;<br>Restlessness; Sleep<br>Disorder | Escitalopram Oxalate  |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                   | Mono-Mak (Tablets)    |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Monopril              |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Hypothiazid (Tablets) |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Thrombo (Tablets)     |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Atenolol              |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Glurenorm (Tablets)   |                    |                    | C               |                       |                                  |                 | Not Reported |                |
|                                                   | Lipimar (Tablets)     |                    |                    | C               |                       |                                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 25-Jan-2010                                                 | 7255391                     | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-JNJFOC-20100107079 |                                                                 | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents            | Oxycodone And Acetaminophen |                    |                    | S               | Oral                  |                                                                 |                 | Not Reported |                |
|                                                             | Acetaminophen\Hydrocodone   |                    |                    | S               | Oral                  |                                                                 |                 | Not Reported |                |
|                                                             | Unspecified Ingredient      |                    |                    | S               | Oral                  |                                                                 |                 | Not Reported |                |
|                                                             | Aripiprazole                |                    |                    | S               | Oral                  |                                                                 |                 | Not Reported |                |
|                                                             | Escitalopram Oxalate        |                    |                    | S               | Oral                  |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2010                                                 | 7275886                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000011338            |                                                                 | 70 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Retention                                           | Escitalopram Oxalate        |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D),Oral                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2010                                                 | 7275919                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000011401            |                                                                 |                 | Male         | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Genital Hypoaesthesia;<br>Libido Decreased;<br>Paraesthesia | Escitalopram Oxalate        |                    |                    | S               | Oral                  | 20 Mg (10 Mg, 1 In 1 D),<br>Oral; 10 Mg Every 2-3<br>Days, Oral |                 | Not Reported |                |
|                                                             |                             |                    |                    |                 | Oral                  | 20 Mg (10 Mg, 1 In 1 D),<br>Oral; 10 Mg Every 2-3<br>Days, Oral |                 |              |                |
|                                                             |                             |                    |                    |                 | Oral                  | 20 Mg (10 Mg, 1 In 1 D),<br>Oral; 10 Mg Every 2-3<br>Days, Oral |                 |              |                |

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| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------|-----------------|--------------|----------------|
| 26-Jan-2010                                                                            | 7169675                   | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-09P-163-0605763-00 |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Blood Pressure Fluctuation; Fall; Gait Disturbance; Headache; Seizure; Tremor | Depakote                  |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                                                        | Lexapro                   |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                                                        | Oxybutynin Chloride       |                    |                    | S               |                              |                        |                 | Not Reported |                |
|                                                                                        | Lisinopril                |                    |                    | S               |                              |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2010                                                                            | 7278212                   | EXPEDITED (15-DAY) | Y                  | DE              | 2010SCPR000179               |                        | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning                                                           | Diazepam                  |                    |                    | S               | Oral                         | Oral                   |                 | Not Reported |                |
|                                                                                        | Escitalopram Oxalate      |                    |                    | S               | Oral                         | Oral                   |                 | Not Reported |                |
|                                                                                        | Metoprolol Tartrate       |                    |                    | S               | Oral                         | Oral                   |                 | Not Reported |                |
|                                                                                        | Carisoprodol              |                    |                    | S               | Oral                         | Oral                   |                 | Not Reported |                |
|                                                                                        | Clopidogrel               |                    |                    | S               | Oral                         | Oral                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2010                                                                            | 7279849                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000011424                   |                        | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Oedema                                                                          | Escitalopram Oxalate      |                    |                    | S               |                              | 10 Mg (10 Mg, 1 In 1d) |                 | Not Reported |                |
|                                                                                        | Depakote                  |                    |                    | S               |                              |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2010                                                                            | 7289031                   | EXPEDITED (15-DAY) | Y                  | DE              | 004605                       |                        | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                      | Acetaminophen\Hydrocodone |                    |                    | S               |                              |                        |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                             |   |              |
|-----------------------------|---|--------------|
| Bitartrate                  |   |              |
| Unspecified Ingredient      | S | Not Reported |
| Oxycodone Hydrochloride And | S | Not Reported |
| Acetaminophen               |   |              |
| Aripiprazole                | S | Not Reported |
| Escitalopram Oxalate        | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2010              | 6952143       | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000005108           |                      | 44 YR      | Female     | DNK            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Leukopenia | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 10 Mg,1 In 1d |                 | Not Reported |
|                                 |                      |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 10 Mg,1 In 1d |                 |              |
|                                 | Lamotrigine          |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D),<br>Oral                |                 | Not Reported |
|                                 | Zyprexa              |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                     |                 | Not Reported |
|                                 | Valium               |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                     |                 | Not Reported |
|                                 | Lithium              |              |            | S           | Oral         | 800 Mg (400 Mg, 2 In 1 D),<br>Oral              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2010              | 7279872       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011437           |                      | 31 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Binocular Eye Movement<br>Disorder; Drug Interaction;<br>Eye Movement Disorder;<br>Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                           | Prochlorperazine     |              |            | S           | Oral         | 30 Mg, (10 Mg, 3 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jan-2010              | 7279880       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011425           |                      | 41 YR      | Female     | DNK            |

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| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|-----------------|----------------|
| Dizziness; Intentional Overdose; Sopor; Suicide Attempt; Vomiting | Escitalopram Oxalate    |                  |                    | S               | Oral                 | 20 Mg, (10 Mg, 2 In 1 D), Oral 240 Mg (240 Mg, Once) Oral |                 | Not Reported    |                |
|                                                                   |                         |                  |                    |                 | Oral                 | 20 Mg, (10 Mg, 2 In 1 D), Oral 240 Mg (240 Mg, Once) Oral |                 |                 |                |
|                                                                   | Diazepam                |                  |                    | S               | Oral                 | Oral Half A Bottle - (Once) Oral                          |                 | Not Reported    |                |
|                                                                   |                         |                  |                    |                 | Oral                 | Oral Half A Bottle - (Once) Oral                          |                 |                 |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2010                                                       | 7283356                 | DIRECT           |                    |                 |                      |                                                           |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Adverse Event                                                     | Lexapro                 |                  |                    | S               |                      |                                                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2010                                                       | 7258804                 | NON-EXPEDITED    | N                  |                 | A0771217A            |                                                           | 68 YR           | Male            | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Fatigue; Hyperhidrosis; Insomnia                                  | Wellbutrin              |                  |                    | S               | Oral                 | 300mg Per Day                                             |                 | Glaxosmithkline |                |
|                                                                   | Lexapro                 |                  |                    | S               | Oral                 | 20mg Per Day                                              |                 | Not Reported    |                |
|                                                                   | Mirtazapine             |                  |                    | S               | Oral                 | 15mg Per Day                                              |                 | Not Reported    |                |
|                                                                   | Lorazepam               |                  |                    | C               | Oral                 | 1mg Per Day                                               |                 | Not Reported    |                |
|                                                                   | Toprol XL               |                  |                    | C               | Oral                 | 25mg Per Day                                              |                 | Not Reported    |                |
|                                                                   | Isosorbide              |                  |                    | C               | Oral                 | 30mg Per Day                                              |                 | Not Reported    |                |
|                                                                   | Glipizide               |                  |                    | C               | Oral                 | 4mg Twice Per Day                                         |                 | Not Reported    |                |
|                                                                   | Metformin Hydrochloride |                  |                    | C               | Oral                 | 500mg Twice Per Day                                       |                 | Glaxosmithkline |                |
|                                                                   | Altace                  |                  |                    | C               | Oral                 | 10mg Per Day                                              |                 | Glaxosmithkline |                |
|                                                                   | Lipitor                 |                  |                    | C               | Oral                 | 10mg Per Day                                              |                 | Glaxosmithkline |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2010              | 7280933       | EXPEDITED (15-DAY) | N                  | OT              | 1000011410           |                      | 46 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Abnormal Dreams;<br>Anxiety; Bereavement;<br>Constipation; Depression;<br>Disease Recurrence; Drug<br>Ineffective; Dry Mouth;<br>Fatigue; Feeling<br>Abnormal; Flatulence;<br>Gastrointestinal Disorder;<br>Gastroesophageal Reflux<br>Disease; Headache;<br>Hypersomnia; Influenza;<br>Insomnia; Malaise;<br>Musculoskeletal Pain;<br>Nasal Congestion;<br>Nausea; Nightmare;<br>Psychotic Disorder;<br>Suicidal Ideation; Tremor;<br>Weight Increased | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Quetiapine           |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2010              | 7280982       | EXPEDITED (15-DAY) |                    | OT              | 1000011443           |                      | 61 YR      | Male       | NOR            |

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Daydreaming; Decreased<br>Appetite; Disturbance In<br>Attention; Dizziness;<br>Dyskinesia; Erectile<br>Dysfunction; Hyposmia;<br>Insomnia; Pruritus; Social<br>Avoidant Behaviour | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                   | Primoteston Depot    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                   | Levaksin             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                   | Testosterone         |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                   | Vitamin B12          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                   | Lamictal             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                   | Nebido               |              |            | C           |              |                                  |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|------------------------------|----------------|
| 28-Jan-2010                                                                                                                                                                    | 7280984                                 | EXPEDITED (15-DAY) |                    | HO, OT          | 1000011453           |                                                                    |                 | Male                         | CHN            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abdominal Distension;<br>Gastric Ulcer                                                                                                                                         | Lexapro                                 |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported                 |                |
|                                                                                                                                                                                | Diazepam                                |                    |                    | C               |                      |                                                                    |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-Jan-2010                                                                                                                                                                    | 6946357                                 | EXPEDITED (15-DAY) | N                  | HO, OT          | 1000005013           |                                                                    | 49 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Epicondylitis;<br>Fatigue; Intervertebral<br>Disc Protrusion;<br>Musculoskeletal Disorder;<br>Nausea; Neck Pain;<br>Sciatica; Suicidal Ideation;<br>Terminal Insomnia | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported                 |                |
|                                                                                                                                                                                |                                         |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |                              |                |
|                                                                                                                                                                                |                                         |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |                              |                |
|                                                                                                                                                                                | Sertraline Hydrochloride<br>Painkillers |                    |                    | C<br>C          |                      |                                                                    |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-Jan-2010                                                                                                                                                                    | 6971721                                 | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000005642           |                                                                    |                 | Unknown                      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Congenital Bladder<br>Anomaly; Maternal Drugs<br>Affecting Foetus;<br>Pulmonary Hypoplasia;<br>Stillbirth                                                                      | Escitalopram Oxalate                    |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental                         |                 | Not Reported                 |                |
|                                                                                                                                                                                | Amitriptyline                           |                    |                    | S               | Transplacental       | 25 Mg (25 Mg, 1 In 1 D),<br>Transplacental                         |                 | Not Reported                 |                |
|                                                                                                                                                                                | Diazepam                                |                    |                    | C               |                      |                                                                    |                 | Not Reported                 |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2010              | 7240650       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2009315902 |                      | 64 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Faecaloma;<br>Gastrointestinal Disorder;<br>Hyponatraemia; Urinary<br>Tract Infection Bacterial | Atarax                      |              |            | S           | Oral         | 12.5 Mg, 2x/Day    | 11 DAY          | Pfizer       |
|                                                                                                 | Omeprazole                  |              |            | S           | Oral         | 40 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate        |              |            | S           | Oral         | Unk                | 4 DAY           | Not Reported |
|                                                                                                 | Escitalopram Oxalate        |              |            | S           | Oral         | Unk                | 6 DAY           | Not Reported |
|                                                                                                 | Escitalopram Oxalate        |              |            | S           | Oral         | Unk                | 4 DAY           | Not Reported |
|                                                                                                 | Cilastatin Sodium\Imipenem  |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                 | Linezolid                   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                 | Ciprofloxacin Hydrochloride |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                 | Zelitrex                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Inexium                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Calcium Carbonate           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Domperidone                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Cortancyl                   |              |            | C           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                                                                 | Domperidone                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                 | Fresubin                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2010              | 7284507       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011472           |                      | 87 YR      | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Melaena | Escitalopram Oxalate |              |            | S           | Oral         | (10 Mg), Oral      |                 | Not Reported |
|                           | Acenocoumarol        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                           | Orfidal              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jan-2010              | 7284516       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011482           |                      | 26 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                             |                            |                    |                    |                 |                             |                                                            |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-----------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| Conversion Disorder                                                                                                                                                         | Escitalopram Oxalate       |                    | S                  | Oral            | 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported                                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2010                                                                                                                                                                 | 7287790                    | EXPEDITED (15-DAY) | Y                  | DE              | DSA_42412_2010              |                                                            | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Poisoning                                                                                                                                                | Bupropion Hydrochloride    |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
|                                                                                                                                                                             | Escitalopram Oxalate       |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jan-2010                                                                                                                                                                 | 7287910                    | EXPEDITED (15-DAY) | Y                  | DE              | DSA_42384_2010              |                                                            | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Poisoning; Respiratory Arrest                                                                                                                               | Bupropion Hydrochloride    |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
|                                                                                                                                                                             | Propoxyphene Hydrochloride |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
|                                                                                                                                                                             | Chlordiazepoxide           |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
|                                                                                                                                                                             | Methamphetamine            |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
|                                                                                                                                                                             | Escitalopram Oxalate       |                    |                    | S               | Oral                        | (Df Oral)                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                    | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2010                                                                                                                                                                 | 7243448                    | EXPEDITED (15-DAY) | N                  | OT              | 1000010834                  |                                                            | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                       | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Breast Tenderness; Contusion; Dizziness; Galactorrhoea; Leukopenia; Mastitis; Oedema Peripheral; Pruritus Generalised; Pyrexia; Rash; Syncope; Thrombocytopenia | Lexapro                    |                    |                    | S               | Oral                        | 20 Mg (20 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                             | Lexapro                    |                    |                    | S               | Oral                        | 20 Mg (20 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                             | Lexapro                    |                    |                    | S               | Oral                        | 10 Mg (10 Mg, 1 In 1 D), Oral                              |                 | Not Reported |                |
|                                                                                                                                                                             | Lexapro                    |                    |                    | S               | Oral                        | 5 Mg (5 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |

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| Lexapro                                                                                                 |                                              |                    | S                  | Oral            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                  |                      |                 | Not Reported    |                |
|---------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|-----------------|-----------------|----------------|
| Lexapro                                                                                                 |                                              |                    | S                  | Oral            | 5 Mg (5 Mg, 1 In 1 D), Oral                       |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Feb-2010                                                                                             | 7266811                                      | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201000143 |                      | 17 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                         | Acetaminophen\Hydrocodone<br>Bitartrate      |                    |                    | S               | Oral                                              | Unk                  |                 | Tyco            |                |
|                                                                                                         | Oxycodone And Acetaminophen                  |                    |                    | S               | Oral                                              | Unk                  |                 | Tyco            |                |
|                                                                                                         | Unspecified Ingredient                       |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported    |                |
|                                                                                                         | Aripiprazole                                 |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported    |                |
|                                                                                                         | Escitalopram Oxalate                         |                    |                    | S               | Oral                                              | Unk                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Feb-2010                                                                                             | 7267031                                      | NON-EXPEDITED      | N                  |                 | A0835418A                                         |                      | 35 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Chest Discomfort; Chest<br>Pain; Drug Interaction;<br>Fatigue; Feeling<br>Abnormal; Nausea;<br>Vomiting | Treximet                                     |                    |                    | S               | Oral                                              | 1tab Single Dose     | 1 DAY           | Glaxosmithkline |                |
|                                                                                                         | Lexapro                                      |                    |                    | S               |                                                   |                      | 5 YR            | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 01-Feb-2010                                                                                             | 7267610                                      | EXPEDITED (15-DAY) | Y                  | HO              | DE-MYLANLABS-<br>2010S1000957                     |                      | 58 YR           | Male            | DEU            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                      | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction;<br>Hyponatraemia                                                                      | Enalapril Maleate And<br>Hydrochlorothiazide |                    |                    | S               |                                                   |                      |                 | Not Reported    |                |
|                                                                                                         | Bisoprolol                                   |                    |                    | C               |                                                   |                      |                 | Not Reported    |                |
|                                                                                                         | Zopiclone                                    |                    |                    | C               |                                                   |                      |                 | Not Reported    |                |

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|  |           |   |                       |              |
|--|-----------|---|-----------------------|--------------|
|  | Lorazepam | C | 0.5 Mg-1mg Bei Bedarf | Not Reported |
|  | Enalapril | S |                       | Not Reported |
|  | Ciprallex | S |                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2010              | 7285513       | EXPEDITED (15-DAY) | Y                  | DE              | ALA_00412_2010       |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>           | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Metoclopramide Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Phenytoin                    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Phenobarbital                |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Quetiapine                   |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Trazodone Hydrochloride      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram Oxalate         |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Emtricitabine And Tenofovir  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Disoproxil Fumarate          |              |            |             |              |                    |                 |              |
|                                 | Oxycodone                    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Methylphenidate              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Metformin Hydrochloride      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Zolpidem                     |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Ondansetron                  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Pregabalin                   |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2010              | 7287932       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011497           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Mania; Off Label Use  | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 01-Feb-2010                     | 7288077                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000011498           |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania; Off Label Use            | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2010                     | 7288475                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000011499           |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania; Off Label Use            | Escitalopram Oxalate         |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2010                     | 7289589                      | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00054_2010       |                                  | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Metoclopramide Hydrochloride |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Phenytoin                    |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Phenobarbital                |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Quetiapine                   |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Trazodone Hydrochloride      |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Escitalopram Oxalate         |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Emtricitabine And Tenofovir  |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Disoproxil Fumarate          |                    |                    |                 |                      |                                  |                 |              |                |
|                                 | Oxycodone                    |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Methylphenidate              |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Metformin Hydrochloride      |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |
|                                 | Zolpidem                     |                    |                    | S               | Oral                 | (Df Oral)                        |                 | Not Reported |                |

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|                                                       | Ondansetron              |                    | S                  | Oral            | (Df Oral)            |                               | Not Reported    |              |                |
|-------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                       | Pregabalin               |                    | S                  | Oral            | (Df Oral)            |                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2010                                           | 7289682                  | EXPEDITED (15-DAY) | Y                  | DE, OT          | 1000011513           |                               | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Completed Suicide                        | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                       | Antipsychotics           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                       | Interferon Nos           |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2010                                           | 7286506                  | EXPEDITED (15-DAY) | Y                  | DE              | 2010S1000052         |                               | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Roxicodone               |                    |                    | S               | Oral                 | Po                            |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Po                            |                 | Not Reported |                |
|                                                       | Cocaine                  |                    |                    | S               | Oral                 | Po                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2010                                           | 7290075                  | EXPEDITED (15-DAY) | Y                  | DE              | 2010S1000091         |                               | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Respiratory Arrest                    | Oxybutynin Chloride      |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Doxepin                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Alcohol                  |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Clonazepam               |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Clonidine                |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Unspecified Ingredient   |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Diphenhydramine          |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Sildenafil Citrate       |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                       | Sertraline Hydrochloride |                    |                    | S               |                      |                               |                 | Not Reported |                |
| Duloxetine                                            |                          |                    | S                  |                 |                      |                               | Not Reported    |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                |                          |                    |                    |                 |                      |                                  |                 |              |                |
|------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                                           |                          |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2010                                                                                    | 7290231                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000011544           |                                  | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Feeling Cold;<br>Musculoskeletal Stiffness;<br>Pyrexia; Tremor; Vertigo;<br>Vomiting | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                | Diosmine                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                | Proctolog                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                | Lysanxia                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2010                                                                                    | 7291195                  | EXPEDITED (15-DAY) | Y                  | DE              | AVE_01465_2010       |                                  | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Poisoning;<br>Respiratory Arrest                                               | Clonidine                |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Doxepin                  |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Alcohol                  |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                | Clonazepam               |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Diphenhydramine          |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Sildenafil Citrate       |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Sertraline Hydrochloride |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Duloxetine               |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Oxybutynin               |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
|                                                                                                | Escitalopram Oxalate     |                    |                    | S               |                      | (Df)                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2010                                                                                    | 7291430                  | EXPEDITED (15-DAY) | Y                  | DE              | 2010S1000093         |                                  | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;                                                                                | Darvon                   |                    |                    | S               | Oral                 | Po                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                    |                               |   |      |    |              |
|--------------------|-------------------------------|---|------|----|--------------|
| Respiratory Arrest | Chlordiazepoxide              | S | Oral | Po | Not Reported |
|                    | Methamphetamine Hydrochloride | S | Oral | Po | Not Reported |
|                    | Escitalopram Oxalate          | S | Oral | Po | Not Reported |
|                    | Bupropion Hydrochloride       | S | Oral | Po | Not Reported |
|                    |                               |   |      |    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2010              | 7291682       | EXPEDITED (15-DAY) | Y                  | DE              | DEP_00324_2010       |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Poisoning | Metformin Hydrochloride                         |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Phenytoin                                       |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Phenobarbital                                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Quetiapine                                      |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Trazodone                                       |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Escitalopram Oxalate                            |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Emtricitabine And Tenofovir Disoproxil Fumarate |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Oxycodone                                       |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Methylphenidate                                 |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Zolpidem                                        |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Ondansetron                                     |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Pregabalin                                      |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              | Metoclopramide Hydrochloride                    |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                              |                                                 |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2010              | 7292943       | EXPEDITED (15-DAY) | Y                  | DE              | 2010S1000051         |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Roxicodone     |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                       | Phenytoin      |              |            | S           | Oral         | Po                 |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |      |    |              |
|------------------------------|---|------|----|--------------|
| Phenobarbital                | S | Oral | Po | Not Reported |
| Quetiapine                   | S | Oral | Po | Not Reported |
| Trazodone Hydrochloride      | S | Oral | Po | Not Reported |
| Escitalopram Oxalate         | S | Oral | Po | Not Reported |
| Emtricitabine And Tenofovir  | S | Oral | Po | Not Reported |
| Disoproxil Fumarate          |   |      |    |              |
| Methylphenidate              | S | Oral | Po | Not Reported |
| Metformin                    | S | Oral | Po | Not Reported |
| Zolpidem                     | S | Oral | Po | Not Reported |
| Ondansetron                  | S | Oral | Po | Not Reported |
| Pregabalin                   | S | Oral | Po | Not Reported |
| Metoclopramide Hydrochloride | S | Oral | Po | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7269096       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2010008249 |                      | 53 YR      | Female     | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Face Oedema; Urticaria | Xanax                |              |            | S           | Oral         | 0.25 Mg, 2x/Day    | 59 DAY          | Pfizer       |
|                        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 1x/Day      | 56 DAY          | Not Reported |
|                        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 2x/Day      | 4 DAY           | Not Reported |
|                        | Zopiclone            |              |            | S           | Oral         | 7.5 Mg, 1x/Day     | 4 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7292685       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011560           |                      | 40 YR      | Male       | DNK            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Corneal Oedema; Glaucoma; Ocular Hyperaemia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |

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| <u>FDA Received Date</u>          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 03-Feb-2010                       | 7292777              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011569           |                                 | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Fatigue;<br>Nervousness | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                   | Depakine (Valproate) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                   | Benzodiazepine       |                    |                    | C               |                      |                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Feb-2010                                      | 7293642                  | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04750_2010       |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Poisoning;<br>Respiratory Arrest | Oxybutynin               |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Doxepin                  |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Alcohol                  |                    |                    | S               |                      | ()                   |                 | Not Reported |                |
|                                                  | Clonazepam               |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Clonidine                |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Diphenhydramine          |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Sildenafil Citrate       |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Sertraline Hydrochloride |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Duloxetine               |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate     |                    |                    | S               |                      | (Df)                 |                 | Not Reported |                |

| <u>FDA Received Date</u>        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Feb-2010                     | 7293672              | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00076_2010       |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning | Ibuprofen            |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |
|                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | Df, Oral             |                 | Not Reported |                |

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|                 |   |      |          |              |
|-----------------|---|------|----------|--------------|
| Acetaminophen   | S | Oral | Df, Oral | Not Reported |
| Methylphenidate | S | Oral | Df, Oral | Not Reported |
| Alcohol         | S | Oral | Oral     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7293676       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04752_2010       |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Poisoning;<br>Respiratory Arrest | Bupropion Hydrochloride       |              |            | S           | Oral         | Df, Oral           |                 | Not Reported |
|                                                  | Propoxyphene Hydrochloride    |              |            | S           | Oral         | Df, Oral           |                 | Not Reported |
|                                                  | Chlordiazepoxide              |              |            | S           | Oral         | Df, Oral           |                 | Not Reported |
|                                                  | Methamphetamine Hydrochloride |              |            | S           | Oral         | Df, Oral           |                 | Not Reported |
|                                                  | Escitalopram Oxalate          |              |            | S           | Oral         | Df, Oral           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7294482       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_04766_2010       |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Bupropion Hydrochloride |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Escitalopram Oxalate    |              |            | S           | Oral         | Df Oral            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7299865       | EXPEDITED (15-DAY) |                    | OT              | 1000011547           |                      | 23 YR      | Unknown    | IND            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bone Pain; Chills;<br>Condition Aggravated;<br>Death Of Relative;<br>Depression; Headache;<br>Pyrexia; Suicidal Ideation | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2010              | 7301176       | EXPEDITED (15-DAY) | Y                  | DE              | 1000011540           |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Increased  | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2010              | 7140331       | EXPEDITED (15-DAY) |                    | OT              | 1000008876           |                      | 46 YR      | Female     | CAN            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Anxiety;      | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Condition Aggravated;     | Champix              |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Crying; Drug Withdrawal   |                      |              |            |             | Oral         | Oral               |                 |              |
| Syndrome; Hostility; Mood |                      |              |            |             |              |                    |                 |              |
| Swings; Muscle Tightness; |                      |              |            |             |              |                    |                 |              |
| Panic Reaction; Suicidal  |                      |              |            |             |              |                    |                 |              |
| Ideation; Surgery;        |                      |              |            |             |              |                    |                 |              |
| Vomiting                  |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2010              | 7247402       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011030           |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Lipase Increased;       | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),       |                 | Not Reported |
| Transaminases Increased | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),         |                 | Not Reported |
|                         |                      |              |            |             | Oral         | Oral, 10 Mg (10 Mg, 1 In 1 D), |                 |              |
|                         |                      |              |            |             | Oral         | Oral, 15 Mg (15 Mg, 1 In 1 D), |                 |              |
|                         |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),         |                 |              |
|                         |                      |              |            |             | Oral         | Oral, 10 Mg (10 Mg, 1 In 1 D), |                 |              |
|                         |                      |              |            |             | Oral         | Oral, 15 Mg (15 Mg, 1 In 1 D), |                 |              |
|                         |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),         |                 |              |
|                         |                      |              |            |             | Oral         | Oral, 10 Mg (10 Mg, 1 In 1 D), |                 |              |



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| Atosil                                                    |                      | C                  |                    | D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral |                      | Not Reported                                                       |                 |              |                |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------------------------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                         | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2010                                               | 7257726              | EXPEDITED (15-DAY) | Y                  | OT                                      | 1000011248           |                                                                    | 55 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                             | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Erythema Multiforme;<br>Photosensitivity Reaction         | Lexapro              |                    |                    | S                                       | Oral                 | 10 Mg, (10 Mg, 1 In 1 D),<br>Oral                                  |                 | Not Reported |                |
|                                                           | Amitriptyline        |                    |                    | C                                       |                      |                                                                    |                 | Not Reported |                |
|                                                           | Oxazepam             |                    |                    | C                                       |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                         | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2010                                               | 7295088              | EXPEDITED (15-DAY) | N                  | DE                                      | 1000011542           |                                                                    | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                             | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Condition Aggravated;<br>Depression | Lexapro              |                    |                    | S                                       | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                           |                      |                    |                    |                                         | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                         | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2010                                               | 7295212              | EXPEDITED (15-DAY) | Y                  | OT                                      | 1000011570           |                                                                    | 87 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                             | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Communication Disorder;<br>Mutism                         | Escitalopram Oxalate |                    |                    | S                                       | Oral                 | (10 Mg), Oral                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                         | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2010                                               | 7273080              | EXPEDITED (15-DAY) | N                  | HO, LT, OT                              | BR-ROCHE-683282      |                                                                    | 21 YR           | Female       | BRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|-----------------|----------------|
| Coma; Coordination Abnormal; Crying; Illiteracy; Insomnia; Memory Impairment; Nausea; Overdose; Pulmonary Oedema; Respiratory Disorder; Somatic Symptom Disorder; Suicidal Ideation; Suicide Attempt; Visual Impairment; Vomiting | Rivotril                 |                    |                    | S               | Oral                 |                                     |                 | Roche           |                |
|                                                                                                                                                                                                                                   | Rivotril                 |                    |                    | S               | Oral                 | Overdose (4 Mg, 6 Mg Or 8 Mg Daily) |                 | Roche           |                |
|                                                                                                                                                                                                                                   | Rivotril                 |                    |                    | S               | Oral                 |                                     |                 | Roche           |                |
|                                                                                                                                                                                                                                   | Pamelor                  |                    |                    | S               | Unknown              |                                     |                 | Not Reported    |                |
|                                                                                                                                                                                                                                   | Nadolol                  |                    |                    | S               | Unknown              |                                     |                 | Not Reported    |                |
|                                                                                                                                                                                                                                   | Cloxazolam               |                    |                    | S               | Unknown              |                                     |                 | Not Reported    |                |
|                                                                                                                                                                                                                                   | Escitalopram Oxalate     |                    |                    | S               | Unknown              | Drug: Exodus (Escitalopram)         |                 | Not Reported    |                |
| Depakote                                                                                                                                                                                                                          |                          |                    | S                  | Unknown         |                      |                                     | Not Reported    |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Feb-2010                                                                                                                                                                                                                       | 7274333                  | EXPEDITED (15-DAY) | N                  | HO              | B0631862A            |                                     | 55 YR           | Male            | ITA            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure Diastolic Increased; Muscle Contractions Involuntary                                                                                                                                                               | Paroxetine Hydrochloride |                    |                    | S               | Oral                 | 10mg Alternate Days                 | 13 DAY          | Glaxosmithkline |                |
|                                                                                                                                                                                                                                   | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 5drop Per Day                       | 223 DAY         | Not Reported    |                |
|                                                                                                                                                                                                                                   | Ramipril                 |                    |                    | C               |                      |                                     |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                   | Unknown                  |                    |                    | C               |                      |                                     |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 09-Feb-2010                                                                                                                                                                                                                       | 7279866                  | DIRECT             | N                  | HO              |                      |                                     | 31 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams; Balance Disorder; Confusional State; Disturbance In Attention; Malaise; Nausea; Seizure; Tremor                                                                                                                  | Escitalopram Oxalate     |                    |                    | S               |                      | 20mg 1 A Day                        |                 | Not Reported    |                |

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| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------|-----------------|--------------|----------------|
| 10-Feb-2010              | 7267710                       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-10P-056-0621442-00 |                               |                 | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Oedema            | Depakote                      |                    |                    | S               |                              |                               |                 | Not Reported |                |
|                          | Escitalopram Oxalate          |                    |                    | S               |                              |                               |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2010              | 7256593                       | EXPEDITED (15-DAY) | N                  | OT              | 1000011206                   |                               | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Legal Problem            | Lexapro                       |                    |                    | S               | Oral                         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Soma                          |                    |                    | C               |                              |                               |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2010              | 7274624                       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2009IT56912              |                               | 82 YR           | Female       | ITA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;        | Hydrochlorothiazide/Valsartan |                    |                    | S               |                              | 1 Df, Qd                      | 40 DAY          | Novartis     |                |
| Cognitive Disorder;      | Esidrex                       |                    |                    | S               | Oral                         | Unk                           | 40 DAY          | Not Reported |                |
| Hypokalaemia;            | Cipralax                      |                    |                    | S               |                              | 0.5 Df, Qd                    | 7 DAY           | Not Reported |                |
| Hypokinesia;             | Ticlopidine                   |                    |                    | C               |                              | 2 Df, Qd                      |                 | Not Reported |                |
| Hyponatraemia;           | Atenolol                      |                    |                    | C               |                              | 100 Mg, Unk                   | 23 DAY          | Not Reported |                |
| Somnolence; White Blood  | Omeprazole                    |                    |                    | C               |                              | 20 Mg, Unk                    |                 | Not Reported |                |
| Cell Count Increased     | Polase                        |                    |                    | C               |                              | 1 Sachet Daily                | 23 DAY          | Not Reported |                |
|                          | Cogiton Ar                    |                    |                    | C               |                              | Unk                           | 7 DAY           | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Feb-2010              | 7277460                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-PFIZER INC-2010014376     |                               | 66 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cystitis; Decreased Appetite; Depressed Mood; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Nausea; Nervousness; Tremor; Unevaluable Event | Zoloft                                       |              |            | S           | Oral         | 50 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                                                                                   | Propylthiouracil                             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Pristiq Extended Release                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Ciprofloxacin                                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Levothyroxine Sodium                         |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Lexapro                                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Amitriptyline                                |              |            | S           |              | 12.5 Mg, As Needed |                 | Not Reported |
|                                                                                                                                                                   | Perphenazine And Amitriptyline Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Klonopin                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Seroquel                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Levothyroxine                                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Amlodipine                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                   | Propranolol                                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2010              | 7284149       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011484           |                      | 36 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Hallucination, Auditory; Major Depression; Suicidal Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Oral; 20 Mg, Oral                |                 | Not Reported |
|                                                              | Propranolol          |              |            | S           | Oral         | 10 Mg, Oral; 20 Mg, Oral<br>80 Mg, Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2010              | 7299604       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011662           |                      | 60 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Loss Of Consciousness | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Feb-2010              | 7299606       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011636           |                      | 53 YR      | Female     | DNK            |

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| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                                | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------|------------------------|--------------------|--------------------|--------------------|---------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| Face Oedema; Skin Exfoliation; Urticaria; Xeroderma | Escitalopram Oxalate   |                    |                    | S                  | Oral                                        | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                     | Escitalopram Oxalate   |                    |                    | S                  | Oral                                        | 20 Mg (10 Mg, 2 In 1 D), Oral    |                 | Not Reported |                |
|                                                     | Zopiclone              |                    |                    | S                  | Oral                                        | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                     | Xanax                  |                    |                    | S                  | Oral                                        | 0.5 Mg (0.25 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                        | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2010                                         | 7285024                | DIRECT             | Y                  | HO                 |                                             |                                  | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                                | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                                 | Lexapro                |                    |                    | S                  | Oral                                        | 10 Mg Once Daily Po              |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                        | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2010                                         | 7385692                | DIRECT             | Y                  | DS, HO, LT, RI, OT |                                             |                                  | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                                | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Impaired Gastric Emptying                           | Cymbalta               |                    |                    | S                  | Oral                                        | 60 Mg Po Daily                   | 3 YR            | Not Reported |                |
|                                                     | Lexapro                |                    |                    | S                  |                                             |                                  |                 | Not Reported |                |
|                                                     | Geodon                 |                    |                    | S                  |                                             |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>                        | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Feb-2010                                         | 7278794                | EXPEDITED (15-DAY) | Y                  | DE                 | US-TYCO HEALTHCARE/MALLIN CKRODT-T201000148 |                                  | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>                                | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide        | Tramadol Hydrochloride |                    |                    | S                  | Oral                                        | Unk                              |                 | Tyco         |                |
|                                                     | Diazepam               |                    |                    | S                  | Oral                                        | Unk                              |                 | Not Reported |                |
|                                                     | Escitalopram Oxalate   |                    |                    | S                  | Oral                                        | Unk                              |                 | Not Reported |                |

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|                                                                                                                   |                               |                    |                    |                 |                              |                             |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------|-----------------|--------------|----------------|
| Paroxetine Hydrochloride                                                                                          |                               |                    | S                  | Oral            | Unk                          | Not Reported                |                 |              |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2010                                                                                                       | 7279524                       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJCH-2010003969          |                             | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Toxicity To Various Agents                                                                              | Pseudoephedrine Hydrochloride |                    |                    | S               | Unknown                      | Text:Unknown                |                 | Not Reported |                |
|                                                                                                                   | Escitalopram Oxalate          |                    |                    | S               | Unknown                      | Text:Unknown                |                 | Not Reported |                |
|                                                                                                                   | Fentanyl                      |                    |                    | C               | Transdermal                  | Text:Unknown                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2010                                                                                                       | 7280158                       | NON-EXPEDITED      |                    |                 | US-ABBOTT-09P-163-0611316-00 |                             | 69 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Mass; Erythema; Feeling Abnormal; Hot Flush; Hypersensitivity; Pain In Extremity; Pruritus; Rash; Swelling | Simcor                        |                    |                    | S               |                              | 1000mg                      |                 | Not Reported |                |
|                                                                                                                   | Simcor                        |                    |                    | S               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Simcor                        |                    |                    | S               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Lexapro                       |                    |                    | S               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Pioglitazone Hydrochloride    |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Metoprolol                    |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Furosemide                    |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Sitagliptin Phosphate         |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Ranitidine                    |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Topamax                       |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Aspirin                       |                    |                    | C               |                              |                             |                 | Not Reported |                |
|                                                                                                                   | Centrum Silver                |                    |                    | C               |                              |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Feb-2010                                                                                                       | 7284554                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011474                   |                             | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Calcium Decreased; Blood Chloride Decreased; Blood                                                          | Escitalopram Oxalate          |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                   | Tegretal                      |                    |                    | S               | Oral                         | 400 Mg (400 Mg, 1 In 1 D),  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                             |          |   |      |                                            |  |  |              |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|------|--------------------------------------------|--|--|--------------|--|
| Creatinine Decreased;<br>Blood Potassium<br>Increased; Blood Urea<br>Decreased; Drug<br>Interaction; Gamma-<br>Glutamyltransferase<br>Increased;<br>Hyponatraemia; Overdose | Esidrix  | S | Oral | Oral<br>400 Mg (400 Mg, 1 In 1 D),<br>Oral |  |  |              |  |
|                                                                                                                                                                             | Seroquel | C | Oral | 12.5 Mg (12.5 Mg, 1 In 1<br>D), Oral       |  |  | Not Reported |  |
|                                                                                                                                                                             | Ximovan  | C |      |                                            |  |  | Not Reported |  |
|                                                                                                                                                                             | Euthyrox | C |      |                                            |  |  | Not Reported |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2010              | 7290715       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011510           |                      | 83 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                        | <u>Product</u>                                                                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Escherichia Urinary Tract<br>Infection; Urinary<br>Retention | Escitalopram Oxalate                                                                                                               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                              | Marcumar                                                                                                                           |              |            | C           |              |                                  |                 | Not Reported |
|                                                              | Durogesic                                                                                                                          |              |            | C           |              |                                  |                 | Not Reported |
|                                                              | Co-Epril                                                                                                                           |              |            | C           |              |                                  |                 | Not Reported |
|                                                              | Transipeg (Polyethylene Glycol<br>3350\Potassium<br>Chloride\Sodium<br>Bicarbonate\Sodium<br>Chloride\Sodium Sulfate<br>Anhydrous) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2010              | 7312836       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011810           |                      | 60 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Dysuria; Urinary Retention | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                            | Temesta (Lorazepam)  |              |            | C           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2010              | 7171550       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009564           |                      | 18 YR      | Male       | IRL            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Intentional Overdose; Palpitations; Poor Quality Sleep; Toxicity To Various Agents; Tremor                                                                               | Lexapro                   |                    |                    | S               | Oral                 | (Once), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                   |                           |                    |                    |                 | Oral                 | (Once), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                   | Benzodiazepine            |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Cannabis                  |                    |                    | C               |                      |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2010                                                                                                                                                                       | 7238459                   | EXPEDITED (15-DAY) | N                  | OT              | 1000010813           |                                             | 81 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Atrial Fibrillation; Cerebrovascular Accident; Chest Pain; Condition Aggravated; Constipation; Cough; Dyspnoea; Hyperhidrosis; Hypertension; Musculoskeletal Pain | Lexapro                   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                   | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral               |                 | Not Reported |                |
|                                                                                                                                                                                   | Synthroid (100 Milligram) |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Maalox                    |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Vitamin B Complex         |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   |                           |                    |                    |                 |                      |                                             |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2010                                                                                                                                                                       | 7255216                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000011083           |                                             | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysgeusia; Macular Degeneration; Retinal Haemorrhage                                                                                                                              | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral               |                 | Not Reported |                |
|                                                                                                                                                                                   | Lexapro                   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                   | Cozaar                    |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Tylenol                   |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Synthroid                 |                    |                    | C               |                      |                                             |                 | Not Reported |                |
|                                                                                                                                                                                   | Nebulizer                 |                    |                    | C               |                      |                                             |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Feb-2010                                                                                                                                                                                       | 7271347                 | EXPEDITED (15-DAY) | Y                  | HO              | 2010SP002895         |                      | 39 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiogenic Shock; Coma; Hypotension; Intentional Overdose; Lactic Acidosis; Oxygen Saturation Decreased; Sinus Tachycardia; Suicide Attempt; Toxicity To Various Agents; Ventricular Hypokinesia | Mirtazapine             |                    |                    | S               | Oral                 | 730 Mg;Once;Po       |                 | Not Reported |                |
|                                                                                                                                                                                                   | Unspecified Ingredient  |                    |                    | S               | Oral                 | 12 Gm;Once;Po        |                 | Not Reported |                |
|                                                                                                                                                                                                   | Zolpidem                |                    |                    | S               | Oral                 | 840 Mg;Once;Po       |                 | Not Reported |                |
|                                                                                                                                                                                                   | Bromazepam (Bromazepam) |                    |                    | S               | Oral                 | 540 Mg; Once; Po     |                 | Not Reported |                |
|                                                                                                                                                                                                   | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 420 Mg;Once;Po       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2010                                                                                                                                                                                       | 7277778                 | EXPEDITED (15-DAY) | N                  | OT              | 1000011433           |                      | 27 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                                                                                                                                                                  | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2010                                                                                                                                                                                       | 7303763                 | DIRECT             | Y                  |                 |                      |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                                                                                                                                                          | Isentress               |                    |                    | S               | Oral                 | 400mg Bid Po         |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lyrica                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lexapro                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Lipitor                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                   | Requip                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2010                                                                                                                                                                                       | 7308416                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000011665           |                      | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |                      |   |      |                                                               |              |
|---------|----------------------|---|------|---------------------------------------------------------------|--------------|
| Trismus | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported |
|         |                      |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Feb-2010                       | 7308768                | EXPEDITED (15-DAY)        | N                           | HO                       | 1000011740                    |                               | 38 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a>                                                                                              | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>                                   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|---------------------------------------------------------------|--------------------------|---------------------|
| Atrial Fibrillation; Feeling Cold; Hot Flush; Influenza Like Illness; Insomnia; Supraventricular Extrasystoles; Tachycardia | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                          | Not Reported        |
|                                                                                                                             |                         |                       |                     |                      | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Feb-2010                       | 7309221                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000011712                    |                               | 78 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------|--------------------------|---------------------|
| Abdominal Pain; Agitation; Cyanosis; Diarrhoea; Haemorrhage; Hypokalaemia; Hypovolaemia; Livedo Reticularis; Seizure; Urinary Retention | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | Oral                             |                          | Not Reported        |
|                                                                                                                                         | Theophylline            |                       |                     | S                    | Oral                  | 1200 Mg (400 Mg, 3 In 1 D), Oral |                          | Not Reported        |
|                                                                                                                                         | Athymil                 |                       |                     | C                    |                       |                                  |                          | Not Reported        |
|                                                                                                                                         | Allopurinol             |                       |                     | C                    |                       |                                  |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Feb-2010                       | 7310474                | EXPEDITED (15-DAY)        | N                           | OT                       | 1000011718                    |                               | 28 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Agitation; Anger; Anxiety; Fatigue; Feelings Of | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | Oral, 20 Mg (20 Mg, 1 In 1  |                          | Not Reported        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                              |                                                                     |             |      |                                                    |                                              |
|------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------|------|----------------------------------------------------|----------------------------------------------|
| Worthlessness; Mood<br>Altered; Obsessive<br>Thoughts; Poor Quality<br>Sleep | Wellbutrin XL<br>Prenasone (Corticosteroid Nos)<br>Ortho Tri Cyclen | S<br>C<br>C | Oral | D), Oral<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral | Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------|------|----------------------------------------------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2010              | 7310525       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011613           |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Cytomegalovirus Test<br>Positive; Hepatitis;<br>Hepatocellular Injury | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                       | Xanax                |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2010              | 7311141       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011715           |                      | 40 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Accommodation Disorder;<br>Blood Glucose<br>Fluctuation; Dizziness;<br>Drug Withdrawal<br>Syndrome; Radicular Pain;<br>Tachycardia | Escitalopram Oxalate |              |            | S           |              | (10 Mg) ; (5 Mg)<br>(10 Mg) ; (5 Mg) | 6 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2010              | 7311788       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011664           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Drug Abuse; Fatigue   | Escitalopram Oxalate |              |            | S           | Oral         | (10 Mg,Once), Oral      |                 | Not Reported |
|                       | Lyrica               |              |            | S           | Oral         | (100 Mg,Once), Oral     |                 | Not Reported |
|                       | Promethazine         |              |            | S           | Oral         | (25 Mg,Once), Oral      |                 | Not Reported |
|                       | Zopiclone            |              |            | S           | Oral         | (2 Dosage Forms, Once), |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Oral                                |                      |                    |                    |                 |                                              |                             |                 |            |                |
|-------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------|-----------------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2010                         | 7314359              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011809                                   |                             |                 | Male       | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Disinhibition; Suicidal Ideation    | Escitalopram Oxalate |                    |                    | S               | Oral                                         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                     | Lexomil              |                    |                    | C               |                                              |                             |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2010                         | 7075992              | EXPEDITED (15-DAY) |                    | DS              | US-ROXANE LABORATORIES, INC.-2009-RO-00780RO |                             | 30 YR           | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Breathing-Related Sleep Disorder    | Methadone            |                    |                    | S               |                                              | 45 Mg                       |                 |            | Roxane         |
|                                     | Methadone            |                    |                    | S               |                                              |                             |                 |            | Roxane         |
|                                     | Diazepam             |                    |                    | S               |                                              |                             |                 |            | Roxane         |
|                                     | Diazepam             |                    |                    | S               |                                              |                             |                 |            | Roxane         |
|                                     | Escitalopram Oxalate |                    |                    | S               |                                              |                             |                 |            | Not Reported   |
|                                     | Escitalopram Oxalate |                    |                    | S               |                                              |                             |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2010                         | 7222019              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010481                                   |                             | 14 YR           | Female     | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Tongue Disorder                     | Escitalopram Oxalate |                    |                    | S               | Oral                                         | 5 Mg, Oral                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2010                         | 7225874              | EXPEDITED (15-DAY) | Y                  | CA              | AU-ASTRAZENECA-2009SE32262                   |                             | 121 DAY         | Unknown    | AUS            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Maternal Exposure During Pregnancy; | Atacand              |                    |                    | S               | Transplacental                               |                             |                 |            | Not Reported   |

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|                                |                   |   |                |              |
|--------------------------------|-------------------|---|----------------|--------------|
| Nephrolithiasis; Renal Failure | Minerals/Vitamins | S | Transplacental | Not Reported |
|                                | Insulin Nos       | S | Transplacental | Not Reported |
|                                | Lexapro           | S | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2010              | 7284464       | EXPEDITED (15-DAY) | Y                  | HO              | GXKR2010GB01763      |                      | 36 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Hallucination, Auditory; Psychotic Disorder; Suicidal Ideation | Propranolol          |              |            | S           | Oral         | 80 Mg/Day          | 29 DAY          | Novartis     |
|                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg/Day          |                 | Not Reported |
|                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg/Day          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2010              | 7313827       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011870           |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u>             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Breast Enlargement; Synovial Cyst | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2010              | 7313843       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011862           |                      | 36 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Leukopenia; Neutropenia | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Zyprexa              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Zyprexa              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Oxazepam             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Oxazepam             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                         | Combivir             |              |            | C           |              |                    |                 | Not Reported |
|                         | Kaletra              |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                | Zyprexa              |                    |                    | C               |                      |                                                                  |                 |              | Not Reported   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                | Seresta              |                    |                    | C               |                      |                                                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2010                                                                                                                                                                    | 7313953              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011817           |                                                                  | 32 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Restlessness                                                                                                                                                          | Lexapro              |                    |                    | S               | Oral                 | 5 Mg 95 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                |                      |                    |                    |                 | Oral                 | 5 Mg 95 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                                                                                                                                | Cortison             |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                | Clonazepam           |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2010                                                                                                                                                                    | 7316886              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011811           |                                                                  | 60 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hydronephrosis; Urinary<br>Retention                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                      |                 | Not Reported |                |
|                                                                                                                                                                                | Zanidip              |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                | Zestril              |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                                | Bisoprolol Fumarate  |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Feb-2010                                                                                                                                                                    | 7299859              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000011541           |                                                                  | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect; Base<br>Excess; Drug Withdrawal<br>Syndrome Neonatal;<br>Maternal Drugs Affecting<br>Foetus; Oxygen Saturation<br>Decreased; Patent Ductus<br>Arteriosus | Escitalopram Oxalate |                    |                    | S               | Transplacental       | Transplacental                                                   |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 19-Feb-2010                                                                                                                    | 7315684                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000011848           |                                                                                  |                 | Female                                       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Drug Ineffective;<br>Drug Interaction; Mood<br>Swings; Restlessness;<br>Unevaluable Event                             | Escitalopram Oxalate<br>Sandimmune     |                    |                    | S<br>S          |                      | 150 Mg (75 Mg,2 In 1 D)                                                          |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Feb-2010                                                                                                                    | 7315703                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000011530           |                                                                                  | 32 YR           | Female                                       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Caesarean Section;<br>Gestational Diabetes;<br>Maternal Exposure During<br>Pregnancy; Meconium In<br>Amniotic Fluid; Pregnancy | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | Oral                                                                             |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Feb-2010                                                                                                                    | 7318633                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000011882           |                                                                                  | 25 YR           | Male                                         | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Intentional Overdose;<br>Sopor; Suicide Attempt                                                                                | Escitalopram Oxalate<br>Ibu<br>Alcohol |                    |                    | S<br>S<br>S     | Oral<br>Oral<br>Oral | (500 Mg,Once), Oral<br>(13200 Mg,Once), Oral<br>1 Liter Of Vodka (Once),<br>Oral |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                             | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 19-Feb-2010                                                                                                                    | 7319680                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000011450           |                                                                                  | 52 YR           | Female                                       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>                                   |                |

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|                            |                      |   |      |             |              |
|----------------------------|----------------------|---|------|-------------|--------------|
| Accidental Overdose;       | Escitalopram Oxalate | S | Oral | 30 Mg,Oral  | Not Reported |
| Arthralgia; Discomfort;    | Escitalopram Oxalate | S | Oral | 10 Mg, Oral | Not Reported |
| Musculoskeletal Stiffness; | Zopiclone            | C |      |             | Not Reported |
| Polyneuropathy;            | Xanax (25 Milligram) | C |      |             | Not Reported |
| Unevaluable Event          |                      |   |      |             |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2010              | 7085340       | EXPEDITED (15-DAY) | Y                  | OT              | 1000007976           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Somnambulism          | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 22-Feb-2010              | 7289066       | EXPEDITED (15-DAY) | Y                  | DE              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>DE-00 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Death                 | Clonidine                |              |            | S           | Unknown      |                    |                 | Boehringer Ingelheim |
|                       | Sertraline Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Duloxetine               |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Doxepin                  |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Clonazepam               |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Unspecified Ingredient   |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Diphenhydramine          |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Sildenafil Citrate       |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Oxybutynin               |              |            | S           | Unknown      |                    |                 | Not Reported         |
|                       | Escitalopram Oxalate     |              |            | S           | Unknown      |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2010              | 7289156       | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-10P-163-   |                      | 17 YR      | Male       | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

0626726-00

| <u>Preferred Term</u>                           | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Acetaminophen\Hydrocodone |              |            | S           |              | Ingestion          |                 | Not Reported |
|                                                 | Bitartrate                |              |            |             |              |                    |                 |              |
|                                                 | Benzodiazepine            |              |            | S           |              | Ingestion          |                 | Not Reported |
|                                                 | Acetaminophen W/Oxycodone |              |            | S           |              | Ingestion          |                 | Not Reported |
|                                                 | Aripiprazole              |              |            | S           |              | Ingestion          |                 | Not Reported |
|                                                 | Escitalopram Oxalate      |              |            | S           |              | Ingestion          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2010              | 7101275       | EXPEDITED (15-DAY) | Y                  | OT              | 1000008195           |                      | 49 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Cyst;<br>Generalised Tonic-Clonic<br>Seizure; Hallucination,<br>Visual; Stress | Lexapro        |              |            | S           | Oral         | 10 Mg, Once, Oral  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2010              | 7260871       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011281           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Dermatomyositis; Myalgia;<br>Rash | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                 | Influenza Virus Vaccine Nos |              |            | S           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2010              | 7281048       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011452           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                             |                                       |   |      |                                                                                     |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|---|------|-------------------------------------------------------------------------------------|--------------|
| Acute Kidney Injury;<br>Cardiogenic Shock; Coma;<br>Disturbance In Attention;<br>Electroencephalogram<br>Abnormal; Intentional<br>Overdose; Lactic Acidosis;<br>Suicide Attempt;<br>Tachycardia; Ventricular<br>Hypokinesia | Escitalopram Oxalate                  | S | Oral | 420 Mg (420 Mg, Once),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral                    | Not Reported |
|                                                                                                                                                                                                                             | Aceprometazine<br>Maleate\Meprobamate | S | Oral | 12 Gm (12 Gm, Once),<br>Oral, 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                                                                                                                                                             | Zolpidem                              | S | Oral | 840 Mg (840 Mg, Once),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral                    | Not Reported |
|                                                                                                                                                                                                                             | Bromazepam                            | S | Oral | 540 Mg (540 Mg, Once),<br>Oral, 3 Mg (3 Mg, 1 In 1<br>D),Oral                       | Not Reported |
|                                                                                                                                                                                                                             | Mirtazapine                           | S | Oral | 730 Mg (730 Mg, Once),<br>Oral, 15 Mg (15 Mg, 1 In 1<br>D), Oral                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2010              | 7299902       | DIRECT           | N                  |                 |                      |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agoraphobia; Anxiety;<br>Dizziness; Drug<br>Ineffective; Hyperhidrosis;<br>Impaired Work Ability;<br>Increased Appetite;<br>Insomnia; Nausea; Panic<br>Attack; Personality<br>Disorder; Pyrexia; Swollen<br>Tongue; Vision Blurred;<br>Visual Acuity Reduced;<br>Weight Increased | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2010              | 7318916       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000011878           |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                 |         |   |      |                                 |              |
|-------------------------------------------------------------------------------------------------|---------|---|------|---------------------------------|--------------|
| Brain Death; Coma;<br>Herpes Zoster;<br>Respiratory Arrest;<br>Tachycardia; Weight<br>Increased | Lexapro | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral     | Not Reported |
|                                                                                                 |         |   | Oral | 10 Mg (10 Mg,1 In 1 D),Oral     |              |
|                                                                                                 | Zyprexa | S | Oral | 10 Mg (10 Mg,1 In 1 D),<br>Oral | Not Reported |
|                                                                                                 | Fanapt  | S | Oral | 2 Mg (1 Mg,2 In 1 D),Oral       | Not Reported |
|                                                                                                 | Sonata  | C |      |                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7280951       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011466           |                      | 36 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Chorioretinopathy;<br>Fatigue; Macular<br>Degeneration;<br>Unevaluable Event; Visual<br>Impairment | Escitalopram Oxalate  |              |            | S           | Oral         | 10 Mg (10 Mg,1 In1 D),Oral |                 | Not Reported |
|                                                                                                    | Xyzal                 |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                    | Motilium              |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                    | Oktanol               |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                    | Cromohexal (Solution) |              |            | C           |              |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7292018       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201000454 |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Oxycodone                   |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Methylin                    |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Phenytoin                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Phenobarbital               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Quetiapine                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trazodone                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Emtricitabine And Tenofovir |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Disoproxil Fumarate         |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |      |              |
|------------------------------|---|------|--------------|
| Metformin Hydrochloride      | S | Oral | Not Reported |
| Zolpidem                     | S | Oral | Not Reported |
| Ondansetron                  | S | Oral | Not Reported |
| Pregabalin                   | S | Oral | Not Reported |
| Metoclopramide Hydrochloride | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7292024       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201000475 |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Temazepam            |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Duloxetine           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Zolpidem             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alcohol              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7292029       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201000456 |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Methylin             |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Acetaminophen        |              |            | S           |              |                    |                 | Not Reported |
|                       | Ibuprofen            |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alcohol              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7292030       | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201000458 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                      |   |      |              |
|----------------------------|----------------------|---|------|--------------|
| Cardio-Respiratory Arrest; | Oxycodone            | S | Oral | Tyco         |
| Completed Suicide          | Escitalopram Oxalate | S | Oral | Not Reported |
|                            | Cocaine              | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7292102       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010019849 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anger; Drug Interaction; Personality Disorder | Chantix        |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                          | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7302776       | DIRECT           |                    | OT              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Product Contamination; Rash | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     | 8 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7317648       | DIRECT           | N                  |                 |                      |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Drug Withdrawal Syndrome; Dysphonia; Fatigue; Nightmare; Product Substitution Issue; Somnolence | Citalopram              |              |            | S           | Oral         | 60 Mg Daily Oral   |                 | Mylan        |
|                                                                                                                   | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2010              | 7317996       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011980           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                      |   |      |                            |              |
|----------------------------------------------------|----------------------|---|------|----------------------------|--------------|
| Fatigue; Feeling Abnormal;<br>Somnambulism; Tetany | Escitalopram Oxalate | S | Oral | 5 Mg (5 Mg,1 In 1 D), Oral | Not Reported |
|                                                    | Oligosol Lithium     | C |      |                            | Not Reported |
|                                                    | Contraceptives Nos   | C |      |                            | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-Feb-2010                       | 7319989                | EXPEDITED (15-DAY)        | N                           | OT                       | 1000011845                    |                               | 43 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                        | <a href="#">Product</a>           | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------|-----------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Confusional State;<br>Dizziness; Lethargy;<br>Seizure | Lexapro                           |                       |                     | S                    | Oral                  | 10 Mg (10 Mg,Once), Oral    |                          | Not Reported        |
|                                                       | Lamictal (200 Milligram, Tablets) |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                       | Aricept (1 Milligram, Tablets)    |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                       | Xanax (1 Milligram, Tablets)      |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                       | Keppra (500 Milligram, Tablets)   |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 24-Feb-2010                       | 7320807                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000011947                    |                               |                     | Female              | DNK                     |

| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Bacterial Infection;<br>Chromaturia | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | Oral                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Feb-2010                       | 7293740                | EXPEDITED (15-DAY)        | Y                           | DE                       | US-RANBAXY-2010US-31277       |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a>                  | <a href="#">Product</a>                  | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------|------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide | Hydrocodone Bitartrate And Acetaminophen |                       |                     | S                    | Oral                  | Unk, Unk                    |                          | Ranbaxy             |
|                                                 | Escitalopram Oxalate                     |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                 | Oxycodone And Acetaminophen              |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                 | Aripiprazole                             |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 25-Feb-2010                       | 7321120                | EXPEDITED (15-DAY)        | Y                           | DE                       | 100218-0000207                |                               | 20 YR               | Female              | USA                     |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Death                                                                                                                                                                                           | Methamphetamine Hydrochloride |                    |                    | S               | Oral                 | Po                                            |                 | Not Reported |                |
|                                                                                                                                                                                                 | Propoxyphene Hydrochloride    |                    |                    | S               | Oral                 | Po                                            |                 | Not Reported |                |
|                                                                                                                                                                                                 | Chlordiazepoxide              |                    |                    | S               | Oral                 | Po                                            |                 | Not Reported |                |
|                                                                                                                                                                                                 | Escitalopram Oxalate          |                    |                    | S               | Oral                 | Po                                            |                 | Not Reported |                |
|                                                                                                                                                                                                 | Bupropion                     |                    |                    | S               | Oral                 | Po                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2010                                                                                                                                                                                     | 7322248                       | EXPEDITED (15-DAY) | Y                  | OT              | IDA-00332            |                                               | 36 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Hallucination, Auditory; Psychotic Disorder; Suicidal Ideation                                                                                                | Propranolol                   |                    |                    | S               | Oral                 | 80 Mg Daily Oral                              | 29 DAY          | Not Reported |                |
|                                                                                                                                                                                                 | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg Daily / 20 Mg Daily Oral / Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Feb-2010                                                                                                                                                                                     | 7324397                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011984           |                                               | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Headache; Hepatic Function Abnormal; Overdose; Transaminases Increased; Vomiting | Escitalopram Oxalate          |                    |                    | S               |                      | 40 Mg (40 Mg, 1 In 1 D); 5 Mg (5 Mg,1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                                 | Edronax                       |                    |                    | S               |                      | 12 Mg (12 Mg, 1 In 1 D)                       |                 | Not Reported |                |
|                                                                                                                                                                                                 | Abilify                       |                    |                    | S               |                      | 1 0 Mg (10 Mg, 1 In 1 D)                      |                 | Not Reported |                |
|                                                                                                                                                                                                 | Seroquel                      |                    |                    | S               |                      | 25 Mg (25 Mg, 1 In 1 D)                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                     | 7234849                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009359           |                                               | 25 YR           | Female       | FIN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| Abortion Spontaneous;<br>Endometriosis; Maternal<br>Exposure During<br>Pregnancy; Platelet Count<br>Decreased; Pregnancy;<br>Small For Dates Baby                                                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 15 Mg (15 Mg,1 In 1 D),<br>Oral    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                                                 | 7234856                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000009358           |                                    | 24 YR           | Female       | FIN            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Ovulation<br>Pain; Polycystic Ovaries;<br>Pregnancy                                                                                                         | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                                                 | 7243464                 | EXPEDITED (15-DAY) | N                  | OT              | 1000010827           |                                    | 37 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Depressed Mood;<br>Dissociation; Dizziness;<br>Drug Ineffective; Fatigue;<br>Hyperhidrosis; Insomnia;<br>Nightmare; Overdose;<br>Presyncope; Self-Injurious<br>Ideation; Somnolence;<br>Suicidal Ideation; Vomiting | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Quetiapine              |                    |                    | S               | Oral                 | 50 Mg (50 Mg,1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Quetiapine              |                    |                    | S               | Oral                 | 200 Mg (200 Mg,1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Wellbutrin              |                    |                    | S               | Oral                 | 150 Mg (150 Mg,1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Bupropion Hydrochloride |                    |                    | S               | Oral                 | 300 Mg (150 Mg,2 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Quetiapine              |                    |                    | C               | Oral                 | 300 Mg (300 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                             | Sleeping Pill           |                    |                    | C               |                      |                                    |                 | Not Reported |                |



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|                                                                                                                                                                                                                                                           |                                              |                    |                    |                 |                      |                      |                 |                 |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| Premarin                                                                                                                                                                                                                                                  |                                              |                    | C                  |                 |                      | Not Reported         |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                                                                               | 7251247                                      | EXPEDITED (15-DAY) |                    | OT              | 1000011129           |                      | 46 YR           | Female          | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Amnesia; Diarrhoea;<br>Dizziness; Dry Eye; Ear<br>Pain; Fatigue; Headache;<br>Hyperhidrosis;<br>Hypotension; Mental<br>Disorder; Myalgia; Neck<br>Pain; Oropharyngeal Pain;<br>Somnolence; Urine Output<br>Increased; Vision Blurred;<br>Weight Decreased | Lexapro                                      |                    |                    | S               | Oral                 | 10 Mg, Oral          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                                                                               | 7289679                                      | EXPEDITED (15-DAY) | Y                  | HO              | 1000011489           |                      | 58 YR           | Male            | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction;<br>Hyponatraemia                                                                                                                                                                                                                        | Escitalopram Oxalate                         |                    |                    | S               |                      | 5 Mg                 |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Enalapril Maleate                            |                    |                    | S               |                      | 20 Mg                |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Enalapril Maleate And<br>Hydrochlorothiazide |                    |                    | S               |                      | 10/25 Mg             |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Biosoprolol                                  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Zopiclone                                    |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Lorazepam                                    |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                           | Amlodipine                                   |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                  | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 26-Feb-2010                                                                                                                                                                                                                                               | 7296303                                      | NON-EXPEDITED      | Y                  | HO              | A0770993A            |                      |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                     | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Seizure                                                                                                                                                                                                                                                   | Lamictal                                     |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |

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|                                                                                                                                |                      |                    |                    |                 |                                |                                 |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|---------------------------------|-----------------|--------------|----------------|
| Lexapro                                                                                                                        |                      | S                  |                    | Not Reported    |                                |                                 |                 |              |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Feb-2010                                                                                                                    | 7304273              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011759                     |                                 |                 | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Decreased;<br>Bradycardia; Cerebral<br>Ischaemia; Dizziness;<br>Loss Of Consciousness;<br>Off Label Use; Seizure | Escitalopram Oxalate |                    |                    | S               | Oral                           | 20 Mg (20 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                           | 15 Mg (15 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                                                                                                    | 7125735              | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-<br>2009SE14097 |                                 | 27 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiometabolic<br>Syndrome                                                                                                    | Seroquel             |                    |                    | S               | Oral                           |                                 | 242 DAY         | Not Reported |                |
|                                                                                                                                | Seroquel             |                    |                    | S               | Oral                           |                                 | 29 DAY          | Not Reported |                |
|                                                                                                                                | Lithium              |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                                                                                | Aripiprazole         |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                                                                                | Paliperidone         |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                                                                                | Olanzapine           |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                                                                                | Ciprallex            |                    |                    | S               | Oral                           |                                 | 14 DAY          | Not Reported |                |
|                                                                                                                                | Ciprallex            |                    |                    | S               | Oral                           |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                                                                                                    | 7290264              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011562                     |                                 | 45 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Dyskinesia; Ejaculation<br>Disorder; Libido<br>Decreased                                                  | Escitalopram Oxalate |                    |                    | S               |                                | 20 Mg (20 Mg, 1 In 1 D)         |                 | Not Reported |                |
|                                                                                                                                | Escitalopram Oxalate |                    |                    | S               |                                | 10 Mg (10 Mg, 1 In 1 D)         |                 | Not Reported |                |
|                                                                                                                                | Abilify              |                    |                    | S               |                                | 15 Mg (15 Mg, 1 In 1 D)         |                 | Not Reported |                |
|                                                                                                                                | Abilify              |                    |                    | S               |                                | 15 Mg (15 Mg, 1 In 1 D);        |                 | Not Reported |                |

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|         |  |   |                                                                                                    |              |
|---------|--|---|----------------------------------------------------------------------------------------------------|--------------|
|         |  |   | 10 Mg (10 Mg, 1 In 1 D)<br>15 Mg (15 Mg, 1 In 1 D);<br>10 Mg (10 Mg, 1 In 1 D)                     |              |
| Edronax |  | S | 2 Mg (2 Mg, 1 In 1 D)                                                                              | Not Reported |
| Edronax |  | S | 4 Mg (4 Mg, 1 In 1 D), 2<br>Mg (2 Mg, 1 In 1 D)<br>4 Mg (4 Mg, 1 In 1 D), 2<br>Mg (2 Mg, 1 In 1 D) | Not Reported |
| Zyprexa |  | C |                                                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2010              | 7300184       | EXPEDITED (15-DAY) | Y                  | DE              | CHPA2010US03729      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Diphenhydramine Hydrochloride |              | Y          | S           |              |                    |                 | Novartis     |
|                       | Doxepin                       |              |            | S           |              |                    |                 | Not Reported |
|                       | Alcohol                       |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonazepam                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonidine                     |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient        |              |            | S           |              |                    |                 | Not Reported |
|                       | Sildenafil Citrate            |              |            | S           |              |                    |                 | Not Reported |
|                       | Sertraline Hydrochloride      |              |            | S           |              |                    |                 | Not Reported |
|                       | Duloxetine                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Oxybutynin                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2010              | 7304457       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erectile Dysfunction  | Lexapro        |              |            | S           | Oral         | 10 Mg Daily Po     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2010              | 7307454       | DIRECT           | N                  | OT              |                      |                      | 77 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Staring                                               | Lexapro                  |                    |                    | S               |                      | 10/Mg 1x Daily In The Morning<br>10/Mg 1x Daily In The Morning<br>10/Mg 1x Daily In The Morning |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                           | 7324682                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000012072           |                                                                                                 | 18 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate     |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Tramadol Hydrochloride   |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Diazepam                 |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Paroxetine Hydrochloride |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                           | 7324688                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000012069           |                                                                                                 | 53 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide          | Escitalopram Oxalate     |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Duloxetine               |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Zolpidem                 |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Temazepam                |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Alcohol                  |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                           | 7324691                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000012074           |                                                                                                 | 26 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate     |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Oxycodone                |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |
|                                                       | Cocaine                  |                    |                    | S               |                      |                                                                                                 |                 | Not Reported |                |

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| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Mar-2010                                     | 7324700                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012070           |                      | 53 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Doxepin                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Benzodiazepine                |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                     | 7324707                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012073           |                      | 20 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Propoxyphene Hydrochloride    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Methamphetamine Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Bupropion Hydrochloride       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Chlordiazepoxide              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                 |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                     | 7324716                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012084           |                      | 21 YR           | Male         | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Acetaminophen                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Ibuprofen                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Methylphenidate               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Alcohol                       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Mar-2010                                     | 7324722                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012081           |                      | 51 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest                       | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |   |  |              |
|--|--------------------------|---|--|--------------|
|  | Doxepin                  | S |  | Not Reported |
|  | Alcohol                  | S |  | Not Reported |
|  | Clonazepam               | S |  | Not Reported |
|  | Clonidine                | S |  | Not Reported |
|  | Unspecified Ingredient   | S |  | Not Reported |
|  | Diphenhydramine          | S |  | Not Reported |
|  | Sildenafil Citrate       | S |  | Not Reported |
|  | Sertraline Hydrochloride | S |  | Not Reported |
|  | Duloxetine               | S |  | Not Reported |
|  | Oxybutynin               | S |  | Not Reported |

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Mar-2010                                     | 7324839              | EXPEDITED (15-DAY) | Y                  | DE              | 1000012126           |                      | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide | Citalopram           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Venlafaxine          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                 | Alcohol              |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Mar-2010                                              | 7325506              | EXPEDITED (15-DAY) | Y                  | DE              | 10000012068          |                      | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Metoprolol           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Carisoprodol         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Clopidogrel          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                          | Diazepam             |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 02-Mar-2010                                                   | 7276587              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011372           |                                  | 52 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Symptom;<br>Epistaxis; Gingival<br>Bleeding; Oedema | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                      |   |      |                                                              |              |
|------------------------------|----------------------|---|------|--------------------------------------------------------------|--------------|
| Peripheral; Vascular Rupture | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|                              |                      |   | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |              |
|                              | Q10                  | C |      |                                                              | Not Reported |
|                              | Lovaza               | C |      |                                                              | Not Reported |
|                              | Halibut              | C |      |                                                              | Not Reported |
|                              | Femoston             | C |      |                                                              | Not Reported |
|                              | Dafalgan             | C |      |                                                              | Not Reported |
|                              | Aspirin              | C |      |                                                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2010              | 7301627       | EXPEDITED (15-DAY) | Y                  | DE              | US-WYE-H13727410     |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide     | Ibuprofen            |              |            | S           | Oral         | Unknown            |                 | Wyeth      |
|                       | Alcohol              |              |            | S           | Oral         | Unknown            |                 | Unknown    |
|                       | Methylphenidate      |              |            | S           | Oral         | Unknown            |                 | Unknown    |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Unknown            |                 | Unknown    |
|                       | Acetaminophen        |              |            | S           | Oral         | Unknown            |                 | Unknown    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2010              | 7302220       | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-H13738510     |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>            |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------------|
| Hyponatraemia         | Inipomp              |              |            | S           | Oral         | Daily Dose Unknown |                 | Wyeth                 |
|                       | Furosemide           |              |            | S           | Oral         | Unknown            |                 | Unknown               |
|                       | Digoxine             |              |            | S           | Oral         | Unknown            |                 | Unknown               |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Unknown            |                 | Lundbeck              |
|                       | Prinzide             |              |            | S           | Oral         | Unknown            |                 | Merck Sharp And Dohme |
|                       | Vastarel             |              |            | C           |              | 35 Mg, Frequency   |                 | Not Reported          |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                        |   |                             |                             |              |
|--|------------------------|---|-----------------------------|-----------------------------|--------------|
|  | Ferrous Sulfate        | C | Unknown                     | 80 Mg, Frequency<br>Unknown | Not Reported |
|  | Prednisone             | C | 20 Mg, Frequency<br>Unknown | Unknown                     |              |
|  | Previscan (Fluindione) | C | Unknown                     | Not Reported                |              |

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2010                                                 | 7307039        | DIRECT           | N                  |                 |                      |                      | 61 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Alcoholism; Loss Of<br>Consciousness | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Once Daily Po  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2010                                                                                         | 7326639                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000012046           |                      | 87 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Systolic<br>Increased; Loss Of<br>Consciousness; Malaise;<br>Orthostatic Hypotension | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                     | Lisinopril              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                     | Digoxin                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                     | Digoxine                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Inipomp                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Previscan (Fluindione)  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Vastarel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                     | Prednisolone\Prednisone |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 02-Mar-2010              | 7326643              | EXPEDITED (15-DAY) |                    | OT              | 1000012079           |                          | 43 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Apathy; Crying; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg, Oral; 10 Mg, Oral; |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                         |               |  |  |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--|--|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--------------|
| Depression; Disturbance<br>In Attention; Drug<br>Ineffective; Fatigue;<br>Feeling Hot; Feeling Of<br>Despair; Irritability;<br>Lethargy; Merycism; Panic<br>Disorder; Paraesthesia;<br>Restlessness; Scratch;<br>Terminal Insomnia; Weight<br>Increased |               |  |  | Oral | 15 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral<br>5 Mg, Oral; 10 Mg, Oral;<br>15 Mg, Oral; 20 Mg, Oral |  |  |  |              |
|                                                                                                                                                                                                                                                         | Buspar        |  |  | C    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  | Not Reported |
|                                                                                                                                                                                                                                                         | Amitriptyline |  |  | C    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2010              | 7289166       | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-10P-163-0626528-00 |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Valproic Acid        |              |            | S           |              | Ingestion          |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              | Ingestion          |                 | Not Reported |
|                       | Aripiprazole         |              |            | S           |              | Ingestion          |                 | Not Reported |
|                       | Amphetamine          |              |            | S           |              | Ingestion          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Mar-2010              | 7304245       | NON-EXPEDITED    | Y                  |                 | US-ABBOTT-09P-163-0609101-00 |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Drug Interaction | Biaxin               |              |            | S           | Oral         |                    |                 | Not Reported |
|                             | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                          |                                      |                    |                    |                 |                      |                                  |                 |                              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|------------------------------|----------------|
| Escitalopram Oxalate                                                                                                                                     |                                      |                    | S                  |                 |                      | Not Reported                     |                 |                              |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Mar-2010                                                                                                                                              | 7307603                              | DIRECT             | N                  | LT              |                      |                                  | 17 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Behaviour;<br>Abnormal Dreams;<br>Emotional Disorder;<br>Hallucination, Visual;<br>Insomnia; Psychomotor<br>Hyperactivity; Thinking<br>Abnormal | Cymbalta<br>Lexapro                  |                    |                    | S<br>S          |                      |                                  |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Mar-2010                                                                                                                                              | 7310456                              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011812           |                                  | 47 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Hypersensitivity;<br>Skin Exfoliation                                                                                                               | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |                |
|                                                                                                                                                          | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |                |
|                                                                                                                                                          | Lorazepam                            |                    |                    | C               |                      |                                  |                 | Not Reported                 |                |
|                                                                                                                                                          | Aspirin                              |                    |                    | C               |                      |                                  |                 | Not Reported                 |                |
|                                                                                                                                                          | Oxycodone Hcl Controlled-<br>Release |                    |                    | C               |                      |                                  |                 | Not Reported                 |                |
|                                                                                                                                                          | Nicotine                             |                    |                    | C               |                      |                                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 03-Mar-2010                                                                                                                                              | 7327600                              | EXPEDITED (15-DAY) | Y                  | DE              | 2010020075           |                                  | 54 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide                                                                                                                                        | Carisoprodol                         |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported                 |                |
|                                                                                                                                                          | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported                 |                |

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|                                                                           | Metoprolol                     |                    | S                  | Oral            | Oral                  |                               | Not Reported    |              |                |
|---------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                           | Clopidogrel                    |                    | S                  | Oral            | Oral                  |                               | Not Reported    |              |                |
|                                                                           | Diazepam                       |                    | C                  | Oral            | Oral                  |                               | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2010                                                               | 7327623                        | EXPEDITED (15-DAY) | Y                  | OT              | 1000012133            |                               | 19 YR           | Male         | NLD            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Condition Aggravated; Hostility                               | Lexapro                        |                    |                    | S               | Oral                  | Oral                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2010                                                               | 7345048                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000012497            |                               | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Breast Discomfort                                            | Escitalopram Oxalate           |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                           | Xanax                          |                    |                    | C               |                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2010                                                               | 7177203                        | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-MERCK-0911FRA00030 |                               | 57 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Asthenia; Diarrhoea; Hyperkalaemia; Nausea; Vomiting | Januvia                        |                    |                    | S               | Oral                  |                               | 1 MTH           | Merck        |                |
|                                                                           | Metformin                      |                    |                    | S               | Oral                  |                               | 1 MTH           | Not Reported |                |
|                                                                           | Hydrochlorothiazide\Irbesartan |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate           |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                           | Esomeprazole Magnesium         |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                           | Clonazepam                     |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                           | Potassium Chloride             |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
|                                                                           | Fenofibrate                    |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acepromazine\Aceprometazine\  
Clorazepate Dipotassium  
Alprazolam

C Unknown  
C Unknown

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7207642       | EXPEDITED (15-DAY) | N                  | OT              | A0832872A            |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anxiety; Drug Intolerance;<br>Fall; Nausea; Petit Mal<br>Epilepsy; Seizure; Suicidal<br>Ideation; Visual<br>Impairment | Lamictal       |              |            | S           | Oral         | 200mg Per Day      |                 | Glaxosmithkline |
|                                                                                                                        | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                                                                        | Keppra         |              |            | S           | Oral         |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7220906       | EXPEDITED (15-DAY) | Y                  | DE, LT          | 1000010345           |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Anaemia; Drug Interaction;<br>Inflammation; International<br>Normalised Ratio<br>Increased; Muscle<br>Haemorrhage; Necrosis;<br>Sepsis | Escitalopram Oxalate                    |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                            |                 | Not Reported |
|                                                                                                                                        | Acetaminophen\Tramadol<br>Hydrochloride |              |            | S           | Oral         | 2 Dosage Forms (2<br>Dosages Forms, 1 In 1 D),<br>Oral      |                 | Not Reported |
|                                                                                                                                        | Previscan (Fluindione)                  |              |            | S           | Oral         | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                                                        | Previscan (Fluindione)                  |              |            | S           | Oral         | 0.25 Dosage Forms (0.25<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                        | Loxen (Nifedipine<br>Hydrochloride)     |              |            | C           |              |                                                             |                 | Not Reported |
|                                                                                                                                        | Triatec (Ramipril)                      |              |            | C           |              |                                                             |                 | Not Reported |
|                                                                                                                                        | Nafronyl Oxalate                        |              |            | C           |              |                                                             |                 | Not Reported |
|                                                                                                                                        | Contalax                                |              |            | C           |              |                                                             |                 | Not Reported |
|                                                                                                                                        | Xanax                                   |              |            | C           |              |                                                             |                 | Not Reported |
|                                                                                                                                        | Lioresal                                |              |            | C           |              |                                                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Propoxyphene Hydrochloride  
And Acetaminophen

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7237039       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010668           |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------------------------|
| Rectal Haemorrhage;<br>Vaginal Haemorrhage | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported                 |
|                                            | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |
|                                            | Citalopram<br>Xanax  |              |            | C<br>C      |              |                                  |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7305140       | EXPEDITED (15-DAY) | N                  | OT              | ES-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14993265 |                      | 67 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Blindness; Glaucoma   | Hydrochlorothiazide\Irbesartan |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                       | Cipralext                      |              |            | S           | Oral         |                    |                 | Not Reported         |
|                       | Pantoprazole                   |              |            | S           | Oral         |                    |                 | Not Reported         |
|                       | Seroquel                       |              |            | S           | Oral         |                    |                 | Not Reported         |
|                       | Gemfibrozil                    |              |            | S           | Oral         |                    |                 | Sandoz               |
|                       | Alendronate Sodium             |              |            | C           | Oral         |                    |                 | Not Reported         |
|                       | Ropinirole Hydrochloride       |              |            | C           | Oral         |                    |                 | Not Reported         |
|                       | Cholecalciferol                |              |            | C           | Oral         |                    |                 | Not Reported         |
|                       | Simvastatin                    |              |            | C           | Oral         |                    |                 | Not Reported         |
|                       | Torsemide                      |              |            | C           | Oral         |                    |                 | Not Reported         |
|                       | Zolpidem                       |              |            | C           | Oral         |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7305869       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2010RR-<br>31735 |                      | 21 YR      | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Acetaminophen        |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Ibuprofen            |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Methylphenidate      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alcohol              |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7305889       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2010RR-31727 |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Phenobarbital               |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Phenytoin                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Quetiapine                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Trazodone Hydrochloride     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Emtricitabine And Tenofovir |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Disoproxil Fumarate         |              |            |             |              |                    |                 |              |
|                       | Oxycodone                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Methylphenidate             |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Metformin Hydrochloride     |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Zolpidem                    |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                       | Ondansetron                 |              |            | S           | Oral         |                    |                 | Natco Pharma |
|                       | Pregabalin                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Metoclopramide              |              |            | S           | Oral         |                    |                 | Ipca         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7329074       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012132           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                  |                                                            |                      |      |                                  |                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|----------------------|------|----------------------------------|------------------------------------------------------------------|
| Alcohol Use; Dysphagia;<br>Fall; Food Intolerance;<br>Gastrointestinal Disorder;<br>Head Injury;<br>Hypokalaemia; Iatrogenic<br>Injury; Inappropriate<br>Antidiuretic Hormone<br>Secretion; Seizure;<br>Vomiting | Escitalopram Oxalate<br><br>Seresta<br>Stilnox<br>Gaviscon | S<br><br>C<br>C<br>C | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|----------------------|------|----------------------------------|------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Mar-2010              | 7329554       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012189           |                      | 88 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Blood Creatinine<br>Increased; Blood Glucose<br>Increased; Drug<br>Interaction; Gamma-<br>Glutamyltransferase<br>Increased; Hyponatraemia | Escitalopram Oxalate                    |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                           | Omeprazole                              |              |            | S           | Oral         | 40 Mg, Oral                      |                 | Not Reported |
|                                                                                                                                           | Spirolactone                            |              |            | S           | Oral         | 25 Mg, Oral                      |                 | Not Reported |
|                                                                                                                                           | Atacand                                 |              |            | S           | Oral         | 16 Mg, Oral                      |                 | Not Reported |
|                                                                                                                                           | Levothyroxine Sodium                    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Metamizol                               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Carmen [Lercanidipine<br>Hydrochloride] |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Metformin Hydrochloride                 |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Aspirin                                 |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Sotalol Hydrochloride                   |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                           | Diclofenac                              |              |            | C           |              |                                  |                 | Not Reported |
| Nitrospray                                                                                                                                |                                         |              | C          |             |              |                                  | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Mar-2010              | 6944812       | EXPEDITED (15-DAY) | N                  | OT              | 1000000357           |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anal Incontinence;<br>Anxiety; Blood Pressure<br>Increased; Burning<br>Sensation; Cardiac | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                           | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Murmur; Hot Flush;<br>Hyperhidrosis; Muscular<br>Weakness; Myalgia;<br>Palpitations;<br>Supraventricular<br>Tachycardia; Tinnitus;<br>Urinary Incontinence;<br>Withdrawal Syndrome | Lexapro              |                    | S                  | Oral            | Oral                                                             |                        |                 |              | Not Reported   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------------------------------|------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                    | Lexapro              |                    | S                  | Oral            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                 |                        |                 |              | Not Reported   |
|                                                                                                                                                                                    |                      |                    |                    | Oral            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                        |                 |              | Not Reported   |
|                                                                                                                                                                                    | Metoprolol           |                    | C                  |                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                        |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                             | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2010                                                                                                                                                                        | 7170403              | EXPEDITED (15-DAY) | N                  | OT              | 1000003105                                                       |                        | 35 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                     | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcohol Use;<br>Feeling Abnormal;<br>Homicide                                                                                                                           | Lexapro              |                    |                    | S               |                                                                  |                        |                 | Not Reported |                |
|                                                                                                                                                                                    | Xanax                |                    |                    | C               |                                                                  |                        |                 | Not Reported |                |
|                                                                                                                                                                                    | Alcohol              |                    |                    | C               |                                                                  |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                             | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2010                                                                                                                                                                        | 7284530              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011473                                                       |                        | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                     | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Headache; Menstruation<br>Irregular                                                                                                                  | Escitalopram Oxalate |                    |                    | S               |                                                                  | 15 Mg (15 Mg,1 In 1 D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                             | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2010                                                                                                                                                                        | 7288507              | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | 1000011493                                                       |                        | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                     | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Fall                                                                                                                                                            | Escitalopram Oxalate |                    |                    | S               |                                                                  | 15-20 Mg Daily         |                 | Not Reported |                |
|                                                                                                                                                                                    | Risperdal            |                    |                    | S               |                                                                  | 6 Mg (6 Mg, 1 In 1 D)  |                 | Not Reported |                |
|                                                                                                                                                                                    | Akineton             |                    |                    | S               |                                                                  | 4 Mg (4 Mg, 1 In 1 D)  |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 05-Mar-2010                                             | 7291851                  | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2010US-31191 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Intentional Overdose | Verapamil Hydrochloride  |                    |                    | S               | Oral                    | Unk, Unk             |                 | Ranbaxy      |                |
|                                                         | Escitalopram Oxalate     |                    |                    | S               | Oral                    | Un, Unk              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2010                                             | 7306000                  | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2010RR-31974 |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Death                        | Sertraline Hydrochloride |                    |                    | S               | Unknown                 |                      |                 | Ranbaxy      |                |
|                                                         | Doxepin                  |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Alcohol                  |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Clonazepam               |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Clonidine                |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Diphenhydramine          |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Sildenafil               |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Duloxetine               |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Oxybutynin               |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
|                                                         | Escitalopram Oxalate     |                    |                    | S               | Unknown                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2010                                             | 7306069                  | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2010RR-32001 |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                       | Zolpidem                 |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                                                         | Escitalopram Oxalate     |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                         | Duloxetine               |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |              |
|-----------|---|------|--------------|
| Temazepam | S | Oral | Not Reported |
| Alcohol   | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 05-Mar-2010              | 7306871       | EXPEDITED (15-DAY) | Y                  | OT              | US-AMGEN-<br>QUU395312 |                      |            | Female     | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Mental Disorder | Sensipar       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                   | Zoloft         |              |            | S           |              |                    |                 | Not Reported |
|                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Mar-2010              | 7330161       | EXPEDITED (15-DAY) | N                  | OT              | 1000011799           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Malaise; Maternal Exposure During Pregnancy; Mental Disorder; Pregnancy; Suicidal Ideation | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Mar-2010              | 7330667       | EXPEDITED (15-DAY) | Y                  | HO              | DSA_42676_2010       |                      | 63 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Gastric Ulcer; Gastritis; Haemoglobin Decreased; Rectal Haemorrhage; Vertigo | Mono-Tildiem                       |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Folic Acid                         |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Zopiclone                          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Plavix                             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Kardegic (Acetylsalicylate Lysine) |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Escitalopram Oxalate               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                                        | Nicobion                           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |      |           |              |
|-----------------------------|---|------|-----------|--------------|
| Glucophage                  | S | Oral | (Df Oral) | Not Reported |
| Micardis                    | S | Oral | (Df Oral) | Not Reported |
| Esomeprazole (Esomeprazole) | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2010              | 6150289       | EXPEDITED (15-DAY) | Y                  | OT              | S06-NOR-04143-01     |                      | 34 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Pregnancy | Cipralext      |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                               |                 | Not Reported |
|                                                                           | Cipralext      |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                           |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Mar-2010              | 7308065       | EXPEDITED (15-DAY) | N                  | DE              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14998264 |                      | 49 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Abilify                            |              |            | S           | Oral         |                    | 1 YR            | Not Reported |
|                       | Abilify                            |              |            | S           | Oral         |                    | 1 YR            | Not Reported |
|                       | Donormyl (Doxylamine<br>Succinate) |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate               |              |            | S           |              |                    |                 | Not Reported |
|                       | Equanil                            |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2010              | 7314243       | DIRECT           | N                  | OT              |                      |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                               |                      |                    |                    |                 |                       |                                     |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------------|-----------------|--------------|----------------|
| Confusional State;<br>Dizziness; Headache                                                                                                                                     |                      | Lexapro            | S                  | Oral            | 10 Mg Once Per Day Po | 6 MTH                               | Forest          |              |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2010                                                                                                                                                                   | 7332562              | EXPEDITED (15-DAY) | Y                  | HO              | 1000012300            |                                     | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Paresis; Seizure                                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg (10 Mg,1 In 1 D),<br>Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                                                                                                                                                                   | 7043355              | EXPEDITED (15-DAY) | N                  | LT              | 1000007006            |                                     | 30 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>General Physical Health<br>Deterioration; Gun Shot<br>Wound; Hallucination,<br>Auditory; Mental<br>Impairment; Suicidal<br>Ideation; Suicide Attempt | Lexapro              |                    |                    | S               | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral         |                 | Not Reported |                |
|                                                                                                                                                                               | Xanax                |                    |                    | S               | Oral                  | 0.75 Mg (0.25 Mg,3 In 1<br>D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                                                                                                                                                                   | 7182202              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000009815            |                                     | 36 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Blood<br>Cholesterol Increased;<br>Gynaecomastia; Hiatus<br>Hernia; Pain                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                  | 15 Mg (15 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                               | Clonazepam           |                    |                    | S               | Oral                  | 1 Mg (0.5 Mg, 2 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                               | Clonazepam           |                    |                    | S               | Oral                  | 1 Mg (0.5 Mg, 2 In 1 D),<br>Oral    |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Mar-2010                | 7318582              | DIRECT             | N                  | LT              |                      |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased   | Lexapro              |                    |                    | S               | Oral                 | 1 10mg Daily Po      |                 | Forest       |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                | 7320390              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000011881           |                      | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Ataxia; | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Blood Creatinine           | Olanzapine           |                    |                    | S               |                      | (300 Mg, Once)       |                 | Not Reported |                |
| Increased; Muscle          | Chlorpromazine       |                    |                    | S               |                      | (700 Mg, Once)       |                 | Not Reported |                |
| Rigidity; Neuroleptic      |                      |                    |                    |                 |                      |                      |                 |              |                |
| Malignant Syndrome;        |                      |                    |                    |                 |                      |                      |                 |              |                |
| Overdose; Pneumonia        |                      |                    |                    |                 |                      |                      |                 |              |                |
| Aspiration; Poisoning      |                      |                    |                    |                 |                      |                      |                 |              |                |
| Deliberate; Urinary        |                      |                    |                    |                 |                      |                      |                 |              |                |
| Incontinence               |                      |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                | 7331682              | EXPEDITED (15-DAY) | Y                  | HO              | 1000012306           |                      | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness;       | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Gastritis; Haemoglobin     | Plavix               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Decreased; Rectal          | Aspirin Lysine       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Haemorrhage; Ulcer         | Nicobion             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Glucophage           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Micardis             |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Speciafoldine        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Mono-Tildiem         |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Imovane              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                            | Inexium              |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 09-Mar-2010                                                           | 7331689                               | EXPEDITED (15-DAY) | Y                  | OT              | 1000012284           |                                    | 55 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemoptysis;<br>Metrorrhagia                                          | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                                                           | 7331776                               | EXPEDITED (15-DAY) | Y                  | OT              | 1000012320           |                                    | 67 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Glaucoma                                                   | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                       | Pantoprazole                          |                    |                    | S               | Oral                 | 80 Mg (40 Mg, 2 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                       | Seroquel                              |                    |                    | S               | Oral                 | (100 Mg), Oral                     |                 | Not Reported |                |
|                                                                       | Gemfibrozil                           |                    |                    | S               | Oral                 | 600 Mg (600 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                       | Irbesartan And<br>Hydrochlorothiazide |                    |                    | S               | Oral                 | 150/12.5 Mg, Oral                  |                 | Not Reported |                |
|                                                                       | Alendronate                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                       | Ropinirole Hydrochloride              |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                       | Bonesil D Flas                        |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                       | Simvastatin                           |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                       | Torasemide                            |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                       | Zolpidem                              |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Mar-2010                                                           | 7331859                               | EXPEDITED (15-DAY) | Y                  | OT              | 1000012281           |                                    | 88 YR           | Male         | SWE            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Confusional State;<br>Hallucination; Loss Of | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | (10 Mg), Oral                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Personal Independence In  
Daily Activities

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Mar-2010              | 7350757        | NON-EXPEDITED    | N                  |                 | 2010SP000842         |                      | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness                | Saphris        |                  |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                      | 20 Mg                |                 | Not Reported |                |
|                          | Plavix         |                  |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 10-Mar-2010                | 7313854        | EXPEDITED (15-DAY) | N                  | OT              | A0849203A            |                      | 37 YR           | Female          | CAN            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Apathy; Chest Discomfort;  | Wellbutrin Sr  |                    |                    | S               | Oral                 | 150mg Per Day        | 1 MTH           | Glaxosmithkline |                |
| Crying; Decreased          | Wellbutrin Sr  |                    |                    | S               | Oral                 | 150mg Twice Per Day  |                 | Glaxosmithkline |                |
| Interest; Depressed Mood;  | Cipralelex     |                    |                    | S               | Oral                 | 10mg Per Day         |                 | Not Reported    |                |
| Dissociation; Dizziness;   | Cipralelex     |                    |                    | S               | Oral                 | 20mg Per Day         |                 | Not Reported    |                |
| Drug Ineffective; Fatigue; | Cipralelex     |                    |                    | S               | Oral                 | 30mg Per Day         |                 | Not Reported    |                |
| Feeling Hot;               | Quetiapine     |                    |                    | S               | Oral                 | 200mg Per Day        | 1 DAY           | Glaxosmithkline |                |
| Hyperhidrosis;             | Quetiapine     |                    |                    | S               | Oral                 | 100mg Per Day        | 1 DAY           | Glaxosmithkline |                |
| Inappropriate Affect;      | Quetiapine     |                    |                    | S               | Oral                 | 50mg Per Day         | 1 DAY           | Glaxosmithkline |                |
| Insomnia; Negative         | Quetiapine     |                    |                    | S               | Oral                 | 300mg Per Day        | 31 DAY          | Glaxosmithkline |                |
| Thoughts; Presyncope;      | Premarin       |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| Somnolence; Suicidal       | Sleeping Pill  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
| Ideation; Vomiting         |                |                    |                    |                 |                      |                      |                 |                 |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 10-Mar-2010              | 7320192        | EXPEDITED (15-DAY) | Y                  | OT              | 1000011892           |                          | 22 YR           | Female       | NLD            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Euphoric Mood;           | Lexapro        |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypomania; Tremor

Oral

Remeron

C

Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Mar-2010                       | 7334350                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000012288                    |                               |                     | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Hepatic Steatosis              | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Mar-2010                       | 7334351                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000011582                    |                               | 55 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------|--------------------------|---------------------|
| Ageusia; Decreased Appetite; Weight Decreased | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |
|                                               | Lexomil                 |                       |                     | C                    |                       |                               |                          | Not Reported        |
|                                               | Ipten                   |                       |                     | C                    |                       |                               |                          | Not Reported        |
|                                               | Celiprolol              |                       |                     | C                    |                       |                               |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 11-Mar-2010                       | 7213206                | EXPEDITED (15-DAY)        | Y                           | OT                       | DK-ABBOTT-09P-044-0612025-00  |                               | 46 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>                  | <a href="#">Product</a>                                                | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------|------------------------------------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Depression; Libido Decreased; Suicidal Ideation | Humira                                                                 |                       |                     | S                    | Subcutaneous          |                             |                          | Not Reported        |
|                                                 | Humira                                                                 |                       |                     | S                    | Subcutaneous          |                             |                          | Not Reported        |
|                                                 | Cipralex                                                               |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                 | Cipralex                                                               |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                                 | Pantoprazole                                                           |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                 | Omega-3-Triglycerides Incl. Other Esters/Acids(Pikasol Gi 60, Axellus) |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                 | Folic Acid                                                             |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                 | Isoniazid                                                              |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                 | Methotrexate                                                           |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                 | Paracetamol                                                            |                       |                     | C                    |                       |                             |                          | Not Reported        |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 11-Mar-2010                                                                                | 7290477              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011528           |                                                                                                          | 27 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Drug Interaction; Erectile<br>Dysfunction; Loss Of<br>Libido | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                                         |                 | Not Reported |                |
|                                                                                            | Amisulpride          |                    |                    | S               | Oral                 | 200 Mg (200 Mg, 1 In 1 D),<br>Oral 300 Mg (300 Mg, 1 In<br>1 D), Oral 400 Mg (400<br>Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                            |                      |                    |                    |                 | Oral                 | 200 Mg (200 Mg, 1 In 1 D),<br>Oral 300 Mg (300 Mg, 1 In<br>1 D), Oral 400 Mg (400<br>Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                            |                      |                    |                    |                 | Oral                 | 200 Mg (200 Mg, 1 In 1 D),<br>Oral 300 Mg (300 Mg, 1 In<br>1 D), Oral 400 Mg (400<br>Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                            | Quilonum             |                    |                    | C               |                      |                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Mar-2010                                                                                | 7330332              | EXPEDITED (15-DAY) | Y                  | CA              | 1000012166           |                                                                                                          |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroschisis; Maternal<br>Drugs Affecting Foetus;<br>Talipes                              | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Mar-2010                                                                                | 7323393              | DIRECT             | Y                  | DE              |                      |                                                                                                          | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Completed<br>Suicide; Feeling Of<br>Despair; Insomnia;                          | Lexapro              |                    |                    | S               |                      | Unknown                                                                                                  | 2 WEEK          | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Medication Error; Product  
Prescribing Error

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2010              | 7336245       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012338           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Blood Insulin Increased;<br>Hypoglycaemia; Insulin C-<br>Peptide Increased;<br>Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                        | Teralithe (Tablets)  |              |            | C           |              |                                                       |                 | Not Reported |
|                                                                                        | Lysanxia             |              |            | C           |              |                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7261279       | EXPEDITED (15-DAY) | Y                  | DE              | 2010VX000024         |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block    | Diastat                      |              |            | S           |              |                    |                 | Not Reported |
| Complete; Blood Pressure  | Escitalopram Oxalate         |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Catheter Site  | Metoprolol                   |              |            | S           |              |                    |                 | Not Reported |
| Haemorrhage; Completed    | Carisoprodol                 |              |            | S           |              |                    |                 | Not Reported |
| Suicide;                  | Clopidogrel                  |              |            | S           |              |                    |                 | Not Reported |
| Electrocardiogram Qrs     | Candesartan Cilexetil        |              |            | C           |              |                    |                 | Not Reported |
| Complex Prolonged;        | Verapamil Hydrochloride      |              |            | C           |              |                    |                 | Not Reported |
| Peritoneal Haemorrhage;   | Conjugated                   |              |            | C           |              |                    |                 | Not Reported |
| Poisoning; Sinus          | Estrogen/Medroxyprogesterone |              |            |             |              |                    |                 |              |
| Bradycardia; Urine Output | Acetate                      |              |            |             |              |                    |                 |              |
| Decreased; Vomiting       | Zolpidem Tartrate            |              |            | C           |              |                    |                 | Not Reported |
|                           | Cetirizine Hydrochloride     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7261530       | EXPEDITED (15-DAY) | Y                  | DE              | 2010VX000049         |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Areflexia; Aspiration; Brain | Diastat                |              |            | S           |              |                    |                 | Not Reported |
| Death; Brain Oedema;         | Tramadol Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                                                        |                                                  |        |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------|------------------------------|
| Completed Suicide; Heart Rate Increased; Hypoxic-Ischaemic Encephalopathy; Intentional Overdose; Poisoning; Pulse Absent; Pupil Fixed; Respiration Abnormal; Respiratory Distress; Thrombosis; Unresponsive To Stimuli | Escitalopram Oxalate<br>Paroxetine Hydrochloride | S<br>S | Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7308368       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011813           |                      | 99 YR      | Female     | DNK            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Loss Of Consciousness; Petit Mal Epilepsy | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                           | Lamictal             |              |            | C           |              |                             |                 | Not Reported |
|                                           | Levothyrox           |              |            | C           |              |                             |                 | Not Reported |
|                                           | Bumex                |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7319606       | EXPEDITED (15-DAY) | Y                  | OT              | DE-ROXANE LABORATORIES, INC.-2010-RO-00249RO |                      | 23 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Apathy; Asthenia; Autonomic Nervous System Imbalance; Drug Abuse; Drug Dependence; Panic Attack; Rhinalgia; Tachycardia | Cocaine              |              |            | S           |              |                    |                 | Roxane       |
|                                                                                                                                          | Bupropion            |              |            | S           |              | 150 Mg             |                 | Not Reported |
|                                                                                                                                          | Bupropion            |              |            | S           |              | 300 Mg             |                 | Not Reported |
|                                                                                                                                          | Bupropion            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                          | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                          | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7325584       | DIRECT           | Y                  | DS, LT, OT      |                      |                      | 18 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                           |         |   |      |                                 |        |              |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|---------------------------------|--------|--------------|
| Dissociation;<br>Hypersomnia; Incorrect<br>Dose Administered;<br>Intentional Self-Injury;<br>Liver Disorder; Suicide<br>Attempt; Vomiting | Lexapro | S | Oral | Lexapro /1 Tab/10mg Q<br>Day Po | 14 DAY | Not Reported |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|---------------------------------|--------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7339001       | EXPEDITED (15-DAY) | Y                  | DE              | 2010VX000097         |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Poisoning; Pulmonary<br>Oedema; Toxicity To<br>Various Agents | Chlordiazepoxide Hydrochloride   |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Propoxyphene Hydrochloride       |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Methamphetamine<br>Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Escitalopram Oxalate             |              |            | S           |              |                    |                 | Not Reported |
|                                                               | Bupropion                        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2010              | 7339917       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012427           |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------|-----------------|--------------|
| Ankle Fracture        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |
|                       |                      |              |            |             | Oral         | 10 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      |                         |                    |                    |                 |                                |                                                                      |                 |              |                |
|--------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------------------------------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                                 |                         |                    |                    | S               | Oral                           | 30 Mg, Oral; 20 Mg, Oral;<br>30 Mg, Oral; 35 Mg, Oral<br>40 Mg, Oral | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Mar-2010                                                                          | 7340626                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000012376                     |                                                                      | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning;<br>Intentional Overdose;<br>Suicide Attempt;<br>Unevaluable Event | Escitalopram Oxalate    |                    |                    | S               | Oral                           | Dosage (Once), Oral                                                  |                 | Not Reported |                |
|                                                                                      | Alcohol                 |                    |                    | S               | Oral                           | (Once), Oral                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2010                                                                          | 7321346                 | EXPEDITED (15-DAY) | Y                  | HO              | US-ASTRAZENECA-<br>2010SE07606 |                                                                      | 88 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                                                   | Atacand                 |                    |                    | S               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Levothyroxine Sodium    |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Dipyrene                |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Lercanidipine           |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Metformin Hydrochloride |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Aspirin                 |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Sotalol                 |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Diclofenac              |                    |                    | C               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Nitrospray              |                    |                    | C               |                                | Two Puffs In Case Of<br>Need                                         |                 | Not Reported |                |
|                                                                                      | Omeprazole              |                    |                    | S               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Cipralext               |                    |                    | S               | Oral                           |                                                                      |                 | Not Reported |                |
|                                                                                      | Spironolactone          |                    |                    | S               | Oral                           |                                                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 17-Mar-2010                                                                                                                                                                        | 7317320                                     | EXPEDITED (15-DAY) | N                  | LT, OT          | 1000011855           |                                                                                             | 29 YR           | Female       | NLD            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Ineffective; Dry Mouth; Fatigue; Headache; Homicidal Ideation; Hyperhidrosis; Insomnia; Panic Attack; Self-Injurious Ideation; Suicidal Ideation; Tremor | Lexapro                                     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                                               |                 | Not Reported |                |
|                                                                                                                                                                                    | Lexapro                                     |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                    |                                             |                    |                    |                 | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral |                 |              |                |
|                                                                                                                                                                                    |                                             |                    |                    |                 | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 2.5 Mg (5 Mg, 1 In 2 D), Oral |                 |              |                |
|                                                                                                                                                                                    | Lexapro                                     |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                    | Lexapro                                     |                    |                    | S               | Oral                 | 2 Mg (2 Mg, 1 In 1 D), Oral                                                                 |                 | Not Reported |                |
|                                                                                                                                                                                    | Lexapro Oral Soution (Escitalopram Oxalate) |                    |                    | C               |                      |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Mar-2010                                                                                                                                                                        | 7344582                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000012501           |                                                                                             | 15 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania; Off Label Use                                                                                                                                                           | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | (10 Mg), Oral                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                    | Clorazepate Dipotassium                     |                    |                    | C               |                      |                                                                                             |                 | Not Reported |                |
|                                                                                                                                                                                    | Risperdal                                   |                    |                    | C               |                      |                                                                                             |                 | Not Reported |                |
|                                                                                                                                                                                    | Toprimate                                   |                    |                    | C               |                      |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Mar-2010                                                                                                                                                                        | 6928396                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000004763           |                                                                                             | 70 YR           | Female       | ITA            |

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| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Mania; Paranoia       | Memantine Hydrochloride |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                       | Escitalopram Oxalate    |              |            | S           | Oral         | (10 Mg) Oral       |                 | Not Reported |
|                       | Donepezil Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2010              | 7241583       | EXPEDITED (15-DAY) | Y                  | OT              | 1000010863           |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Fall; Nausea; Overdose; Petit Mal Epilepsy; Seizure; Suicidal Ideation; Visual Impairment | Lexapro        |              |            | S           | Oral         | (10 Mg), Oral; (30 Mg), Oral                                                     |                 | Not Reported |
|                                                                                                    | Lamictal       |              |            | S           | Oral         | (1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral |                 | Not Reported |
|                                                                                                    |                |              |            |             | Oral         | (1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral |                 |              |
|                                                                                                    |                |              |            |             | Oral         | (1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral |                 |              |
|                                                                                                    |                |              |            |             | Oral         | (1 In 1 D), Oral; (100 Mg), Oral; (200 Mg), Oral; (475 Mg), Oral; (500 Mg), Oral |                 |              |
|                                                                                                    | Keppra         |              |            | S           | Oral<br>Oral | Oral; (3000 Mg), Oral<br>Oral; (3000 Mg), Oral                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2010              | 7346643       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012533           |                      | 63 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Depression Suicidal; Off Label Use; Panic Reaction | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 19-Mar-2010                                                                               | 7214107                | EXPEDITED (15-DAY) | Y                  | HO              | 1000008874                                      |                                                              | 92 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                                                          | Escitalopram Oxalate   |                    |                    | S               | Oral                                            | 10 Mg (10 Mg,1 In 1 D),Oral                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2010                                                                               | 7269303                | EXPEDITED (15-DAY) | N                  | DE, HO          | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14927875 |                                                              | 55 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Hyperhidrosis;<br>Restlessness;<br>Schizoaffective Disorder | Abilify                |                    |                    | S               | Oral                                            | Approximately 20mg Dose<br>Increased To 20mg From<br>12aug09 |                 | Not Reported |                |
|                                                                                           | Unspecified Ingredient |                    |                    | S               |                                                 |                                                              |                 | Not Reported |                |
|                                                                                           | Cipralelex             |                    |                    | S               | Oral                                            |                                                              |                 | Not Reported |                |
|                                                                                           | Cipralelex             |                    |                    | S               | Oral                                            |                                                              |                 | Not Reported |                |
|                                                                                           | Seroquel               |                    |                    | S               | Oral                                            |                                                              |                 | Not Reported |                |
|                                                                                           | Tavor (Lorazepam)      |                    |                    | S               | Oral                                            |                                                              |                 | Not Reported |                |
|                                                                                           | Levothyroxine Sodium   |                    |                    | C               | Oral                                            |                                                              |                 | Not Reported |                |
|                                                                                           | Simeticone             |                    |                    | C               | Oral                                            | 1 Df= 3x40 Gtts                                              |                 | Not Reported |                |
|                                                                                           | Movicol                |                    |                    | C               | Oral                                            | 1 Df= 1 Bag                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2010                                                                               | 7330066                | DIRECT             | N                  | HO, LT, OT      |                                                 |                                                              | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Tightness;<br>Palpitations;<br>Supraventricular<br>Tachycardia; Treatment          | Lexapro                |                    |                    | S               |                                                 | 10mg 1x Day                                                  |                 | Forest       |                |



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Failure

| <u>FDA Received Date</u>                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|
| 19-Mar-2010                                                    | 7330469                           | DIRECT             | N                  | OT              |                      |                                         | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms; Muscle Twitching                                | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg 1/Day Po                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2010                                                    | 7346975                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000012409           |                                         |                 | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Growth Restriction; Maternal Drugs Affecting Foetus     | Escitalopram Oxalate              |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                | Risperidone                       |                    |                    | S               | Transplacental       | 2 In 1 D, Transplacental                |                 | Not Reported |                |
|                                                                | Echinacea Angustifolia            |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                                | Ascorbic Acid                     |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                                | Multivitamins, Other Combinations |                    |                    | C               |                      |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2010                                                    | 7153955                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000009197           |                                         | 88 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness; Loss Of Consciousness; Presyncope; Tremor | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral            |                 | Not Reported |                |
|                                                                | Enalapril Maleate                 |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral            |                 | Not Reported |                |
|                                                                | Kaleorid                          |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                                | Hjerdyl                           |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                                | Furosemid                         |                    |                    | C               |                      |                                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------|-----------------|------------------------------|----------------|
| 22-Mar-2010                                                                  | 7331694               | EXPEDITED (15-DAY) | Y                  | DE, OT          | 1000011778           |                                                               | 77 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Circulatory Collapse;<br>Coma; Hallucination,<br>Visual                      | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                   |                 | Not Reported                 |                |
|                                                                              | Antihypertensives     |                    |                    | C               |                      |                                                               |                 | Not Reported                 |                |
|                                                                              | Antiaggregant Therapy |                    |                    | C               |                      |                                                               |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 22-Mar-2010                                                                  | 7348986               | EXPEDITED (15-DAY) | Y                  | OT              | 1000012563           |                                                               | 44 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Deafness Unilateral;<br>Sudden Hearing Loss                                  | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                              |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 23-Mar-2010                                                                  | 7336990               | EXPEDITED (15-DAY) | Y                  | OT              | 1000012382           |                                                               | 36 YR           | Female                       | EST            |
| <u>Preferred Term</u>                                                        | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dermatitis Allergic; Eye<br>Swelling; Menorrhagia;<br>Oedema Mouth; Pruritus | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral                                     |                 | Not Reported                 |                |
|                                                                              | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral                                     |                 | Not Reported                 |                |
|                                                                              | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 | Not Reported                 |                |
|                                                                              |                       |                    |                    |                 | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 5 Mg (5 Mg,1 In 1<br>D),Oral |                 |                              |                |
|                                                                              | Xanax<br>Retafer      |                    |                    | C<br>C          |                      |                                                               |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 24-Mar-2010                                                                  | 7329066               | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000012161           |                                                               | 47 YR           | Female                       | DEU            |

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| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| Bradycardia; Intentional Overdose; Sopor; Suicide Attempt                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | (Once), Oral                           |                 | Not Reported |                |
|                                                                                                                                                                                                          | Bromazepam           |                    |                    | S               | Oral                 | (300 Mg,Once), Oral                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2010                                                                                                                                                                                              | 7348927              | EXPEDITED (15-DAY) | Y                  | HO              | 1000012608           |                                        | 19 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cheilitis; Dysphagia; Oral Disorder; Rash Vesicular; Toxic Skin Eruption                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                                   |                 | Not Reported |                |
|                                                                                                                                                                                                          | Tegretol             |                    |                    | S               | Oral                 | Oral                                   |                 | Not Reported |                |
|                                                                                                                                                                                                          | Keppra               |                    |                    | C               |                      |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2010                                                                                                                                                                                              | 7350937              | EXPEDITED (15-DAY) | Y                  | DE              | 1000012605           |                                        | 30 YR           | Female       | PRT            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Sudden Death                                                                                                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg (10 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Mar-2010                                                                                                                                                                                              | 7257121              | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000011230           |                                        | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Apathy; Body Temperature Decreased; Confusional State; Decreased Appetite; Disturbance In Attention; Dizziness; Dry Mouth; Fatigue; Fear; Hypoaesthesia; Incoherent; Muscle Tightness; Muscular | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg), Oral                      |                 | Not Reported |                |
|                                                                                                                                                                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg), Oral, 5 Mg (5 Mg), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                          |                      |                    |                    |                 | Oral                 | 10 Mg (10 Mg), Oral, 5 Mg (5 Mg), Oral |                 |              |                |
|                                                                                                                                                                                                          | Imovane              |                    |                    | C               |                      |                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Sobril               |                    |                    | C               |                      |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weakness; Nausea; Off  
Label Use; Restlessness;  
Suicidal Ideation;  
Tachyphrenia; Tremor

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------------------------------------------------------------|-----------------|----------------------|----------------|
| 25-Mar-2010                                                                                                               | 7331508              | EXPEDITED (15-DAY) | Y                  | OT              | US-BAXTER-2010BH007086                   |                                                                             | 52 YR           | Male                 | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>           |                |
| Haemolytic Anaemia                                                                                                        | Gammagard Liquid     |                    |                    | S               | Intravenous (not otherwise specified)    |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Gammagard Liquid     |                    |                    | S               | Intravenous (not otherwise specified)    |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Gammagard Liquid     |                    |                    | S               | Intravenous (not otherwise specified)    |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Gammagard Liquid     |                    |                    | S               | Intravenous (not otherwise specified)    |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Lexapro              |                    |                    | S               | Unknown                                  |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Tylenol              |                    |                    | C               |                                          |                                                                             |                 | Not Reported         |                |
|                                                                                                                           | Benadryl             |                    |                    | C               |                                          |                                                                             |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 25-Mar-2010                                                                                                               | 7331660              | EXPEDITED (15-DAY) | N                  | HO, LT          | FR-BRISTOL-MYERS SQUIBB COMPANY-15025307 |                                                                             | 64 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>           |                |
| Altered State Of Consciousness;<br>Bradycardia; Confusional State; Drug Interaction;<br>Hypothermia; Pneumonia Aspiration | Buspar               |                    |                    | S               |                                          |                                                                             |                 | Bristol Myers Squibb |                |
|                                                                                                                           | Tiaprider            |                    |                    | S               |                                          | 1 Dosage Form = 1.5 (Units Not Mentioned).Tiapridal 100mg                   | 3 DAY           | Not Reported         |                |
|                                                                                                                           | Escitalopram Oxalate |                    |                    | S               |                                          | Interrupted On 06nov2009. Restarted With 20 Mg/D On 07nov2009 And 08nov2009 |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |   |                                                                                    |              |
|----------------------------|---|------------------------------------------------------------------------------------|--------------|
| Valium                     | S | 17-Oct-2009 To 26-Oct-2009, Then ½ In The Evening From 26-Oct-2009 To 08-Nov-2009. | Not Reported |
| Aceprometazine\Meprobamate | S | 1 Dosage Form = 1 Tablet.                                                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2010              | 7332054       | EXPEDITED (15-DAY) | Y                  | OT              | DE-JNJFOC-20100304894 |                      | 59 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Intentional Overdose; Suicide Attempt; Tachycardia | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                 | Seroquel       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                 | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2010              | 7332140       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-03464 |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Chlordiazepoxide Hydrochloride |              |            | S           |              |                    |                 | Watson       |
|                       | Bupropion Hydrochloride        |              |            | S           |              |                    |                 | Watson       |
|                       | Propoxyphene Hydrochloride     |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient         |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2010              | 7332328       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-03586 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Temazepam            |              |            | S           |              |                    |                 | Watson       |
|                       | Zolpidem Tartrate    |              |            | S           |              |                    |                 | Watson       |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Duloxetine           |              |            | S           |              |                    |                 | Not Reported |
|                       | Alcohol              |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| 25-Mar-2010                                                                                                                                                                                                                                       | 7351836              | EXPEDITED (15-DAY) | N                  | OT              | 1000012584           |                                                       |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Headache;<br>Muscle Spasms; Seizure                                                                                                                                                                                                      | Lexapro              |                    |                    | S               | Oral                 | (1 In 1 D), Oral                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Mar-2010                                                                                                                                                                                                                                       | 7353844              | EXPEDITED (15-DAY) | Y                  | HO              | 1000012631           |                                                       | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrolyte Imbalance;<br>Hyperkalaemia;<br>Hyponatraemia                                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Spironolactone       |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Diffu K              |                    |                    | S               | Oral                 | Oral                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Trivastal            |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Kardegic             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Dafalgan             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2010                                                                                                                                                                                                                                       | 7220777              | EXPEDITED (15-DAY) | N                  | OT              | 1000010422           |                                                       |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;<br>Decreased Appetite;<br>Dizziness; Dysarthria;<br>Feeling Abnormal;<br>Malaise; Multiple Allergies;<br>Nausea; Paraesthesia;<br>Presyncope; Suicidal<br>Ideation; Swelling Face;<br>Swollen Tongue;<br>Withdrawal Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                 | (10 Mg),Oral                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | (5 Mg),Oral                                           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                   |                      |                    |                    |                 |                      |                                                       |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2010              | 7332779       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20100306041 |                      | 96 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Bladder<br>Dilatation; Blood 25-<br>Hydroxycholecalciferol<br>Decreased; General<br>Physical Health<br>Deterioration;<br>Haematoma; Pyrexia;<br>Respiratory Acidosis;<br>Respiratory Disorder;<br>Somnolence | Durogesic            |              |            | S           | Transdermal  |                    | 8 DAY           | Not Reported |
|                                                                                                                                                                                                                        | Celebrex             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                                                        | Piracetam            |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2010              | 7333741       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-03555 |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Fortamet                      |              |            | S           |              | Unk                |                 | Watson       |
|                       | Metoclopramide Hydrochloride  |              |            | S           |              | Unk                |                 | Watson       |
|                       | Trazodone Hydrochloride       |              |            | S           |              | Unk                |                 | Watson       |
|                       | Oxycodone Hydrochloride       |              |            | S           |              | Unk                |                 | Watson       |
|                       | Methylphenidate Hydrochloride |              |            | S           |              | Unk                |                 | Watson       |
|                       | Zolpidem Tartrate             |              |            | S           |              | Unk                |                 | Watson       |
|                       | Phenytoin                     |              |            | S           |              |                    |                 | Not Reported |
|                       | Phenobarbital                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
|                       | Emtricitabine\Tenofovir       |              |            | S           |              |                    |                 | Not Reported |
|                       | Ondansetron                   |              |            | S           |              |                    |                 | Not Reported |
|                       | Pregabalin                    |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 26-Mar-2010              | 7333748                       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-03561     |                      | 21 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Ibuprofen                     |                    |                    | S               |                          | Unk                  |                 | Watson       |                |
|                          | Methylphenidate Hydrochloride |                    |                    | S               |                          | Unk                  |                 | Watson       |                |
|                          | Escitalopram Oxalate          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Acetaminophen                 |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Alcohol                       |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2010              | 7333749                       | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-03615     |                      | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Verapamil Hydrochloride       |                    |                    | S               |                          |                      |                 | Watson       |                |
|                          | Escitalopram Oxalate          |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Diphenhydramine Hydrochloride |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2010              | 7333858                       | EXPEDITED (15-DAY) | Y                  | OT              | ZA-PFIZER INC-2010035241 |                      | 84 YR           | Female       | ZAF            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Thrombocytopenia         | Atorvastatin Calcium          |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Lyrica                        |                    |                    | S               | Oral                     | 150 Mg, 2x/Day       |                 | Pfizer       |                |
|                          | Escitalopram Oxalate          |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                          | Diclofenac                    |                    |                    | S               | Unknown                  | Unk                  |                 | Not Reported |                |
|                          | Cozaar                        |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Mar-2010              | 7333981                       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2010034686 |                      | 96 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                      |   |             |       |              |
|--------------------------------------------|----------------------|---|-------------|-------|--------------|
| Asthenia; Respiratory Disorder; Somnolence | Celebrex             | S | 200 Mg, Unk | 8 DAY | Pfizer       |
|                                            | Piracetam            | S | Unk         |       | Not Reported |
|                                            | Durogesic            | S | Unk         |       | Not Reported |
|                                            | Escitalopram Oxalate | S | Unk         |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2010              | 7341832       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009316           |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Affective Disorder; Amnesia; Emotional Disorder; Fear; Head Injury; High Risk Sexual Behaviour; Judgement Impaired; Overdose; Personality Change; Road Traffic Accident | Lexapro        |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2010              | 7300633       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011505           |                      | 80 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Agitation; Anxiety; Disease Recurrence; Dysphoria; Major Depression; Suicidal Ideation | Escitalopram Oxalate      |              |            | S           | Oral         | 20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral |                 | Not Reported |
|                                                                                        |                           |              |            |             | Oral         | 20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral |                 |              |
|                                                                                        |                           |              |            |             | Oral         | 20 Mg, Oral; 10 Mg, Oral; 15 Mg, Oral |                 |              |
|                                                                                        | Lisinopril                |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                        | Calcium                   |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                        | Centrum Silver (Capsules) |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                        | Aspirin                   |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                        | Vitamin C                 |              |            | C           |              |                                       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Mar-2010              | 7334894       | EXPEDITED (15-DAY) |                    | HO, OT          | AU-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-00309RO |                      | 60 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antipsychotic Drug Level<br>Below Therapeutic; Blood<br>Creatine Phosphokinase<br>Increased; Confusional<br>State; Delirium;<br>Hypertonia; Lower<br>Respiratory Tract<br>Infection; Myalgia;<br>Neuroleptic Malignant<br>Syndrome; Pyrexia;<br>Tachycardia | Clarithromycin       |              |            | S           |              | 500 Mg             | 2 WEEK          | Roxane       |
|                                                                                                                                                                                                                                                             | Lithium Carbonate    |              |            | S           |              |                    |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Lithium Carbonate    |              |            | S           |              | 500 Mg             |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Diazepam             |              |            | S           | Oral         | 40 Mg              |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Diazepam             |              |            | S           | Oral         | 2 Mg               |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Diazepam             |              |            | S           | Oral         |                    |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Digoxin              |              |            | S           |              | 62.5 Mcg           |                 | Roxane       |
|                                                                                                                                                                                                                                                             | Periciazine          |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Quetiapine           |              |            | S           |              | 125 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Quetiapine           |              |            | S           |              | 25 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Escitalopram Oxalate |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Aspirin              |              |            | S           |              | 100 Mg             |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Perindopril          |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Simvastatin          |              |            | S           |              | 80 Mg              |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Bromocriptine        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Bromocriptine        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Bromocriptine        |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                             | Bromocriptine        |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 29-Mar-2010                                                            | 7355316              | EXPEDITED (15-DAY) | N                  | OT              | 1000012658           |                      | 16 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health<br>Deterioration;<br>Hyperventilation; Loss Of | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                        | Zoloft               |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                     |   |              |
|------------------------|---------------------|---|--------------|
| Consciousness; Seizure | Propavan (Tablets)  | C | Not Reported |
|                        | Symbicort (Tablets) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2010              | 7355318       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012688           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Depression; Fatigue; Loss<br>Of Libido; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2010              | 9529017       | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | 0002350              |                      | 45 YR      | Male       | DEU            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Abnormal Dreams;            | Rotigotine              |              |            | S           | Transdermal  |                                                                    |                 | Not Reported |
| Anxiety; Chills; Cognitive  | Ropinirole              |              |            | S           |              |                                                                    |                 | Not Reported |
| Disorder; Decreased         | Azilect                 |              |            | S           |              |                                                                    |                 | Not Reported |
| Activity; Depression;       | Sifrol                  |              |            | S           |              | (0.35 Mg, Frequency<br>Dose: 2 X 1.5 And 1 X 1)                    |                 | Not Reported |
| Dizziness; Drug             |                         |              |            |             |              | (0.35 Mg, Frequency<br>Dose: 3 X 1.5)                              |                 |              |
| Intolerance; Hallucination; |                         |              |            |             |              | 0.18 Mg (Other 3x 1.5))                                            |                 |              |
| Hallucinations, Mixed;      |                         |              |            |             |              |                                                                    |                 |              |
| Nightmare; Parkinson'S      |                         |              |            |             |              |                                                                    |                 |              |
| Disease; Pyrexia;           | Motilium                |              |            | C           |              |                                                                    |                 | Not Reported |
| Restlessness; Sleep         | Aspirine /00002701/     |              |            | C           |              |                                                                    |                 | Not Reported |
| Disorder; Syncope;          | Delix /00885601/        |              |            | S           |              |                                                                    |                 | Not Reported |
| Therapeutic Product Effect  | Metformin               |              |            | C           |              |                                                                    |                 | Not Reported |
| Decreased; Thinking         | Pravastatin             |              |            | C           |              |                                                                    |                 | Not Reported |
| Abnormal; Tremor            | Seroquel                |              |            | S           |              | 25 Mg Tid, 1 - 2 - 0<br>25 Mg Qid, Frequency<br>Dose: 1 X 1, 1 X 3 |                 | Not Reported |
|                             | Opipramol               |              |            | S           |              |                                                                    |                 | Not Reported |
|                             | Citalopram (Citalopram) |              |            | S           |              |                                                                    |                 | Not Reported |
|                             | Cipralex                |              |            | S           |              |                                                                    |                 | Not Reported |
|                             | Clozapin                |              |            | S           |              | 25 Mg, Frequency: Other<br>2x1/4<br>25 Mg, Frequency: Other        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |   |                                                                                                           |              |
|--------------------------------------|---|-----------------------------------------------------------------------------------------------------------|--------------|
|                                      |   | 2x1/4 And 1x1/2<br>25 Mg, Frequency: Other<br>2x1/2 And 1x3/4<br>25 Mg, Frequency: Other<br>2x1/2 And 1x1 |              |
| Tavor /00273201/                     | S | 1 Mg As Required<br>4 Times                                                                               | Not Reported |
| Truxal                               | S |                                                                                                           | Not Reported |
| Amaryl                               | C |                                                                                                           | Not Reported |
| Locol (Fluvastatin Sodium)           | C |                                                                                                           | Not Reported |
| Irenat                               | C |                                                                                                           | Not Reported |
| Apo-Primidone                        | C |                                                                                                           | Not Reported |
| Obsidan (Propranolol Hydrochloride)  | C |                                                                                                           | Not Reported |
| Neurocil (Levomepromazine)           | C |                                                                                                           | Not Reported |
| Benserazide Hydrochloride W/Levodopa | C |                                                                                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2010              | 7336351       | EXPEDITED (15-DAY) | Y                  | OT              | US-WYE-H14189210     |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>            |
|----------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------------|
| Cataract; Eye Laser Surgery; Medication Error; Visual Acuity Reduced; Weight Decreased | Pristiq Extended Release |              |            | S           | Oral         |                    |                 | Wyeth                 |
|                                                                                        | Celebrex                 |              |            | S           | Oral         |                    |                 | Not Reported          |
|                                                                                        | Lexapro                  |              |            | S           | Oral         | Unknown            |                 | Lundbeck              |
|                                                                                        | Synthroid                |              |            | C           | Oral         | 125 Mcg Daily      |                 | Not Reported          |
|                                                                                        | Prilosec                 |              |            | C           |              | Unknown            |                 | Merck Sharp And Dohme |
|                                                                                        | Prilosec                 |              |            | C           |              |                    |                 | Merck Sharp And Dohme |
|                                                                                        | Folic Acid               |              |            | C           |              | Unknown            |                 | Unknown               |
|                                                                                        | Actonel                  |              |            | C           | Oral         | Unknown            |                 | Procter And Gamble    |
|                                                                                        | Glucose                  |              |            | C           |              | Unknown            |                 | Unknown               |
|                                                                                        | Calcium                  |              |            | C           |              | Unknown            |                 | Unknown               |
|                                                                                        | Vitamin B Complex        |              |            | C           |              | Unknown            |                 | Unknown               |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |         |                       |
|------------|---|------|---------|-----------------------|
| Vitamin D2 | C |      | Unknown | Unknown               |
| Zocor      | C | Oral |         | Merck Sharp And Dohme |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2010              | 7336419       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ROCHE-693611      |                      | 64 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Altered State Of Consciousness; Bradycardia; Confusional State; Drug Interaction; Hypothermia | Valium                     |              |            | S           | Oral         |                    |                 | Roche        |
|                                                                                               | Valium                     |              |            | S           | Oral         | In The Evening     |                 | Roche        |
|                                                                                               | Escitalopram Oxalate       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                               | Escitalopram Oxalate       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                               | Escitalopram Oxalate       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                               | Tiapride                   |              |            | S           | Oral         | In The Evening     |                 | Not Reported |
|                                                                                               | Aceprometazine\Meprobamate |              |            | S           | Unknown      | Taken Once         |                 | Not Reported |
|                                                                                               | Buspar                     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2010              | 7337754       | EXPEDITED (15-DAY) | Y                  | DE              | US-NICOBREVP-2010-03583 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Clonazepam                    |              |            | S           |              |                    |                 | Watson       |
|                       | Doxepin Hydrochloride         |              |            | S           |              |                    |                 | Watson       |
|                       | Clonidine Transdermal System  |              |            | S           |              |                    |                 | Watson       |
|                       | Diphenhydramine Hydrochloride |              |            | S           |              |                    |                 | Watson       |
|                       | Sertraline Hydrochloride      |              |            | S           |              |                    |                 | Watson       |
|                       | Oxytrol                       |              |            | S           |              |                    |                 | Watson       |
|                       | Alcohol                       |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient        |              |            | S           |              |                    |                 | Not Reported |
|                       | Sildenafil Citrate            |              |            | S           |              |                    |                 | Not Reported |
|                       | Duloxetine                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |

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### Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 30-Mar-2010                                                      | 7344690              | DIRECT             |                    | DS              |                       |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Hyperhidrosis; Muscle Twitching; Nerve Injury; Tremor | Lexapro              |                    |                    | S               |                       | 1 A Day              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2010                                                      | 7309172              | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20100301425 |                      | 13 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Intentional Self-Injury; Malaise           | Risperdal            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Omeprazole           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Aspirin              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Enalapril Maleate    |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Ciprallex            |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                  | Lucen (Esomeprazole) |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2010                                                      | 7346106              | DIRECT             | N                  | HO, RI, OT      |                       |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychiatric Evaluation; Suicidal Ideation                        | Lexapro              |                    |                    | S               | Oral                  | 1/2 Tab Every Day Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2010                                                      | 7357852              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012689            |                      | 74 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disinhibition                                                    | Lexapro              |                    |                    | S               | Oral                  | 10 Mg, Oral          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------|-----------------|--------------|----------------|
| 01-Apr-2010                                                                    | 7340985              | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-10P-163-0633967-00 |                               | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Dizziness; Loss Of Consciousness; Suicidal Ideation; Weight Increased | Divalproex Sodium    |                    |                    | S               | Oral                         |                               |                 | Not Reported |                |
|                                                                                | Lexapro              |                    |                    | S               | Oral                         |                               |                 | Not Reported |                |
|                                                                                | Buspirone            |                    |                    | C               | Oral                         |                               |                 | Not Reported |                |
|                                                                                | Albuterol            |                    |                    | C               | Respiratory (inhalation)     |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2010                                                                    | 7359578              | EXPEDITED (15-DAY) | Y                  | DE              | 1000012713                   |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Serotonin Syndrome                              | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2010                                                                    | 7359789              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012726                   |                               | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Asthenia                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg, Oral                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2010                                                                    | 7332571              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012246                   |                               | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Eating Disorder; Malaise; Nausea; Vomiting               | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg (5 Mg, 2 In 1 D), Oral  |                 | Not Reported |                |

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|                         |   |      |                             |              |
|-------------------------|---|------|-----------------------------|--------------|
| Escitalopram Oxalate    | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported |
| Avonex                  | C |      |                             | Not Reported |
| Oral Antidiabetic Drugs | C |      |                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2010              | 7359554       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000012904           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Altered State Of Consciousness;                               | Escitalopram Oxalate               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral              |                 | Not Reported |
| Bradycardia; Confusional State; Drug Interaction;             | Escitalopram Oxalate               |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral; 20 Mg, Oral |                 | Not Reported |
| Hypothermia; Pneumonia Aspiration; Toxicity To Various Agents |                                    |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral; 20 Mg, Oral |                 |              |
|                                                               | Valium                             |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral              |                 | Not Reported |
|                                                               | Valium                             |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                |                 | Not Reported |
|                                                               | Tiapride                           |              |            | S           | Oral         | 150 Mg (150 Mg, 1 In 1 D), Oral            |                 | Not Reported |
|                                                               | Aceprometazine Maleate\Meprobamate |              |            | S           | Oral         | (Once), Oral                               |                 | Not Reported |
|                                                               | Buspar                             |              |            | S           | Oral         | 30 Mg (10 Mg, 3 In 1 D), Oral              |                 | Not Reported |
|                                                               | Previscan (Fluindione)             |              |            | C           |              |                                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2010              | 7359556       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012784           |                      | 96 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Bladder Dilatation; General Physical Health               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Deterioration; Pyrexia; Respiratory Acidosis; Respiratory Disorder; | Durogesic            |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Celebrex             |              |            | S           |              |                    |                 | Not Reported |
|                                                                     | Piracetam            |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Somnolence; Vitamin D  
Deficiency

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2010              | 7303464       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011742           |                      | 57 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Hepatitis             | Lexapro                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       | Tradazolam (Tablets)   |              |            | C           |              |                              |                 | Not Reported |
|                       | Omeprazole             |              |            | C           |              |                              |                 | Not Reported |
|                       | Lormetazepam (Tablets) |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Apr-2010              | 7344689       | EXPEDITED (15-DAY) | Y                  | OT              | GB-MYLANLABS-2010S1004817 |                      |            | Female     | GBR            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Spontaneous;    | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Matrix       |
| Maternal Exposure During | Cipralext               |              |            | S           |              |                    |                 | Not Reported |
| Pregnancy                | Pregabalin              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Apr-2010              | 7323411       | EXPEDITED (15-DAY) | Y                  | HO, LT          | AU-JNJFOC-20100303179 |                      | 21 YR      | Female     | AUS            |

| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Drug Interaction;        | Tramadol Hydrochloride |              |            | S           | Oral         | Estimated Dosage Of 3 G    |                 | Not Reported |
| Electrocardiogram Qt     | Risperidone            |              |            | S           | Oral         | Estimated Dosage Of 120 Mg |                 | Not Reported |
| Prolonged;               | Lithium                |              |            | S           | Oral         | Estimated Dosage: 13 G     |                 | Not Reported |
| Electrocardiogram T Wave | Escitalopram Oxalate   |              |            | S           | Oral         | Estimated Dosage: 560 Mg   |                 | Not Reported |
| Inversion; Overdose;     | Mirtazapine            |              |            | S           | Unknown      | Estimated Dosage: 315 Mg   |                 | Not Reported |
| Serotonin Syndrome       |                        |              |            |             |              |                            |                 |              |

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|                                                                        | Quetiapine              |                    | S                  | Oral            |                            | Estimated Dosage: 15 G                                      |                 | Not Reported |                |
|------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                        | Fluoxetine              |                    | S                  | Oral            |                            | Estimated Dosage: 1.1 G                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2010                                                            | 7345358                 | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20100400017      |                                                             | 40 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Sluggishness; Sopor                           | Haldol                  |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |
|                                                                        | Cipralex                |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |
|                                                                        | Trazodone Hydrochloride |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |
|                                                                        | Valium                  |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2010                                                            | 7360751                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000012927                 |                                                             | 31 YR           | Unknown      | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Euphoric Mood; Middle Insomnia; Suicidal Ideation                      | Escitalopram Oxalate    |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D) Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2010                                                            | 7158158                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2009SE20715 |                                                             | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased; Bronchitis; Drug Interaction; Ischaemic Stroke | Omeprazole              |                    |                    | S               | Oral                       |                                                             | 3 YR            | Not Reported |                |
|                                                                        | Tianeptine              |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |
|                                                                        | Forsteo                 |                    |                    | C               | Subcutaneous               |                                                             |                 | Not Reported |                |
|                                                                        | Tareg                   |                    |                    | C               | Oral                       |                                                             |                 | Not Reported |                |
|                                                                        | Dafalgan                |                    |                    | C               | Unknown                    |                                                             |                 | Not Reported |                |
|                                                                        | Inexium                 |                    |                    | S               | Oral                       |                                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  |                      |                    |                    |                 |                      |                                                                               |                 |              |                |
|----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                             |                      |                    | S                  | Oral            |                      | 1 YR                                                                          | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2010                                                                      | 7269276              | EXPEDITED (15-DAY) | Y                  | OT              | 1000011332           |                                                                               | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Faeces Hard; Rectal Haemorrhage; Refusal Of Treatment By Patient | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg ( 5mg, 1 In 1 D), Oral                                                   |                 | Not Reported |                |
|                                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                                 |                 | Not Reported |                |
|                                                                                  | Zolpidem             |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                  | Ginko Biloba         |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2010                                                                      | 7351082              | DIRECT             | Y                  | DS, RI          |                      |                                                                               | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia Areata                                                                  | Lexapro              |                    |                    | S               |                      |                                                                               |                 | Forest       |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2010                                                                      | 7362059              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012818           |                                                                               | 61 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Memory Impairment                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2010                                                                      | 7362062              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012162           |                                                                               | 65 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease Recurrence; Overdose; Phobia; Suicidal Ideation              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 |                 | Not Reported |                |

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|                  |      |                                                                                                                     |              |
|------------------|------|---------------------------------------------------------------------------------------------------------------------|--------------|
|                  | Oral | In 1 D),Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral; 30 Mg (30 Mg, 1<br>In 1 D),Oral |              |
|                  | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral; 30 Mg (30 Mg, 1<br>In 1 D),Oral                 |              |
| Plavix           | C    |                                                                                                                     | Not Reported |
| Aspirin          | C    |                                                                                                                     | Not Reported |
| Crestor          | C    |                                                                                                                     | Not Reported |
| Inexium          | C    |                                                                                                                     | Not Reported |
| Tanakan          | C    |                                                                                                                     | Not Reported |
| Nafronyl Oxalate | C    |                                                                                                                     | Not Reported |
| Lysanxia         | C    |                                                                                                                     | Not Reported |
| Cyamemazine      | C    |                                                                                                                     | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 07-Apr-2010                       | 7362086                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000012814                    |                               | 89 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>     | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|---------------------------------|--------------------------|---------------------|
| Agitation; Ocular<br>Hyperaemia; Palpitations | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 07-Apr-2010                       | 7362335                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000012957                    |                               |                     | Male                | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 08-Apr-2010                       | 7196238                | EXPEDITED (15-DAY)        |                             | LT, OT                   | 1000010004                    |                               | 49 YR               | Female              | GBR                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                             |                             |   |      |                                                                    |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---|------|--------------------------------------------------------------------|--------------|
| Abnormal Dreams;<br>Adjustment Disorder;<br>Condition Aggravated;<br>Cough; Crying;<br>Depression; Dizziness;<br>Drug Ineffective; Eczema;<br>Emotional Disorder; Fall;<br>Fatigue; Feeling<br>Abnormal; Hyperphagia;<br>Insomnia; Intentional<br>Overdose; Intentional Self-<br>Injury; Nasopharyngitis;<br>Neck Pain; Oropharyngeal<br>Pain; Suicidal Ideation;<br>Unevaluable Event;<br>Weight Increased | Escitalopram Oxalate        | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (10 Mg, 2 In 1<br>D), Oral | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             |                             |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (10 Mg, 2 In 1<br>D), Oral |              |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate        | S | Oral | 30 Mg, Oral; Reduced<br>From 30 Mg Daily (Nos),<br>Oral            | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             |                             |   | Oral | 30 Mg, Oral; Reduced<br>From 30 Mg Daily (Nos),<br>Oral            |              |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Amitriptyline Hydrochloride | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Levothyroxine               | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Diclofenac                  | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Paracetamol                 | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Iron                        | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Diazepam                    | C |      |                                                                    | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                             | Sleeping Tablets (Nos)      | C |      |                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2010              | 7348236       | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-<br>20100400351 |                      | 63 YR      | Female     | ITA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Self-Injury | Risperdal      |              |            | S           | Oral         |                    |                 | Not Reported |
|                         | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2010              | 7356497       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012705           |                      | 52 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Toxicity To Various Agents | Lexapro                 |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |
|                            | Vistaril                |              |            | S           | Oral         | 100 Mg (50 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                            | Methadone Hydrochloride |              |            | C           |              |                                   |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2010              | 7361767       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000012930           |                      | 40 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------|-----------------|--------------|
| Agitation;<br>Electrocardiogram<br>Repolarisation<br>Abnormality; Intentional<br>Overdose; Overdose;<br>Sinus Bradycardia | Escitalopram Oxalate |              |            | S           | Oral         | (14 Dosage Forms, Once),<br>Oral; 40 Mg (20 Mg, 2 In 1<br>D), Oral   |                 | Not Reported |
|                                                                                                                           | Delorazepam          |              |            | S           | Oral         | (20 Dosage Forms, Once),<br>Oral; 6 Mg (2 Mg, 3 In 1<br>D), Oral     |                 | Not Reported |
|                                                                                                                           | Akineton             |              |            | S           | Oral         | (10 Dosage Forms, Once),<br>Oral; 8 Mg (4 Mg, 2 In 1<br>D), Oral     |                 | Not Reported |
|                                                                                                                           | Lithium Carbonate    |              |            | S           | Oral         | (10 Dosage Forms, Once),<br>Oral; 900 Mg (300 Mg, 3 In<br>1 D), Oral |                 | Not Reported |
|                                                                                                                           | Risperdal            |              |            | C           |              |                                                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2010              | 7299857       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011496           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Arrhythmia; Chest Pain;<br>Dizziness; Headache;<br>Hyperhidrosis;<br>Hyperphagia; Suicidal<br>Ideation; Weight Increased | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg,1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                          | Escitalopram Oxalate |              |            | S           |              | Oral                            |                 | Not Reported |
|                                                                                                                          | Rivotril             |              |            | S           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Apr-2010              | 7304306       | EXPEDITED (15-DAY) | N                  | OT              | 1000011470           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Agitation; Anxiety; Crying;<br>Depression; Disease | Escitalopram Oxalate |              |            | S           | Oral         | Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Recurrence; Disturbance  
In Attention; Drug  
Ineffective; Thinking  
Abnormal

Oral

Oral, 20 Mg (20 Mg, 1 In 1  
D), Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Apr-2010              | 7349934       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2010040671 |                      | 74 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Discomfort;       | Zoloft         |              |            | S           |              | Unk                |                 | Pfizer       |
| Abdominal Pain Upper;       | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
| Abnormal Dreams;            | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
| Anxiety; Condition          |                |              |            |             |              |                    |                 |              |
| Aggravated; Diverticulitis; |                |              |            |             |              |                    |                 |              |
| Hallucination;              |                |              |            |             |              |                    |                 |              |
| Hypertension; Insomnia;     |                |              |            |             |              |                    |                 |              |
| Mental Impairment           |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Apr-2010              | 7350064       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-<br>2010041208 |                      | 44 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dyspnoea; Erythema;   | Atarax               |              |            | S           | Oral         | 150 Mg, 1x/Day     |                 | Pfizer       |
| Pruritus              | Venlafaxine          |              |            | S           | Oral         | 75 Mg, 2x/Day      | 1 DAY           | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                       | Lormetazepam         |              |            | C           |              |                    |                 | Not Reported |
|                       | Troxerutin           |              |            | C           |              |                    |                 | Not Reported |
|                       | Xanax                |              |            | C           |              | Unk                |                 | Not Reported |
|                       | Tegretol             |              |            | C           |              | Unk                |                 | Not Reported |
|                       | Zyprexa              |              |            | C           |              | Unk                | 15 DAY          | Not Reported |
|                       | Trihexyphenidyl      |              |            | C           |              | Unk                | 7 DAY           | Not Reported |
|                       | Risperdal            |              |            | C           |              |                    |                 | Not Reported |
|                       | Valproate Sodium     |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 09-Apr-2010                                                                                                                                                                                                                                                                                            | 7359630                                                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000012273           |                                  | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis; Hydronephrosis;<br>Renal Impairment;<br>Thrombocytopenia                                                                                                                                                                                                                                    | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | (5 Mg), Oral                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | 10 Mg, Oral                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Tilcotil                                                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Lamotrigine                                               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Oxapax                                                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Lactulose                                                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2010                                                                                                                                                                                                                                                                                            | 6900063                                                   | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000003587           |                                  | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence;<br>Anxiety; Cholestasis;<br>Decreased Appetite;<br>Fatigue; Headache;<br>Hepatitis; Hepatitis<br>Alcoholic; Hepatomegaly;<br>Hypoaesthesia;<br>Hypokalaemia; Motor<br>Dysfunction; Sleep<br>Disorder; Tension; Urinary<br>Incontinence; Weight<br>Decreased; Withdrawal<br>Syndrome | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Tianeptine                                                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Seresta                                                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Aotal                                                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                        | Intrauterine Contraceptive<br>Device With Levonorgestrel) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                               | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2010                                                                                                                                                                                                                                                                                            | 7249843                                                   | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2010BE01035      |                                  | 36 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                  | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                      |   |            |              |
|---------------------------|----------------------|---|------------|--------------|
| Abnormal Behaviour;       | Leponex              | S | 500 Mg/Day | Novartis     |
| Antipsychotic Drug Level  | Telzir               | C | 700 Mg     | Not Reported |
| Below Therapeutic;        | Truvada              | C | Unk        | Not Reported |
| Anxiety; Depression; Drug | Norvir               | C |            | Not Reported |
| Interaction; Overdose;    | Pravastatin Sodium   | C |            | Not Reported |
| Suicide Attempt           | Leponex              | S | 600 Mg/Day | Novartis     |
|                           | Escitalopram Oxalate | S | Unk        | Not Reported |
|                           | Fluvoxamine Maleate  | S | 50 Mg, Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Apr-2010              | 7352068       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010042037 |                      | 20 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Dissociation; | Chantix        |              |            | S           | Oral         | 0.5 Mg, 1x/Day     |                 | Pfizer       |
| Drug Interaction          | Chantix        |              |            | S           | Oral         | 1 Mg, 2x/Day       |                 | Pfizer       |
|                           | Seroquel       |              |            | S           | Oral         | 300 Mg, 1x/Day     |                 | Not Reported |
|                           | Lexapro        |              |            | S           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2010              | 7357866       | DIRECT           | Y                  | DE              |                      |                      | 54 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Completed Suicide;      | Lexapro        |              |            | S           | Ophthalmic   | 10 Mg Daily Ophthalmic | 2 WEEK          | Not Reported |
| Intentional Self-Injury |                |              |            |             |              |                        |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2010              | 7361385       | EXPEDITED (15-DAY) | N                  | OT              | 1000012956           |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Energy Increased;       | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |
| Homicide; Imprisonment; |                |              |            |             |              | Oral                     |                 |              |
| Insomnia                | Ativan         |              |            | C           |              |                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Apr-2010                                              | 7364976                 | EXPEDITED (15-DAY) | Y                  | HO              | 6059258                      |                                                                  | 57 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Deep Vein Thrombosis;<br>Muscle Haemorrhage;<br>Sciatica | Levothyroxine Sodium    |                    |                    | S               | Oral                         | 1 Df Oral                                                        |                 | Not Reported |                |
|                                                          | Previscan (Fluindione)  |                    |                    | S               | Oral                         | 1 Df Oral                                                        | 9 DAY           | Not Reported |                |
|                                                          | Fondaparinux            |                    |                    | S               | Subcutaneous                 | 1 Df Subcutaneous                                                | 7 DAY           | Not Reported |                |
|                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 1 Df Oral                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2010                                              | 7375434                 | NON-EXPEDITED      | N                  |                 | 1000010793                   |                                                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dizziness                                     | Bystolic                |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D), Oral                                      |                 | Not Reported |                |
|                                                          | Lexapro                 |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2010                                              | 7309628                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000009096                   |                                                                  | 56 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                  | Lexapro                 |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D), Oral                                      |                 | Not Reported |                |
|                                                          | Lexapro                 |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                          |                         |                    |                    |                 | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                          | Memantine Hydrochloride |                    |                    | S               | Oral<br>Oral<br>Oral<br>Oral | See Image<br>See Image<br>See Image<br>See Image                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |                                                                                                |              |
|-------------------------|---|------|------------------------------------------------------------------------------------------------|--------------|
| Memantine Hydrochloride | S | Oral | 20 Mg (10 Mg, 2 In 1 D),<br>Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral | Not Reported |
|                         |   | Oral | 20 Mg (10 Mg, 2 In 1 D),<br>Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral |              |
|                         |   | Oral | 20 Mg (10 Mg, 2 In 1 D),<br>Oral; 15 Mg (7.5 Mg, 2 In 1 D), Oral; 10 Mg (5 Mg, 2 In 1 D), Oral |              |
| Osteophos D3 (Solution) | C |      |                                                                                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2010              | 7352052       | EXPEDITED (15-DAY) | Y                  | DS, OT          | GXKR2010DK03519      |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Back Pain; Bone Disorder;<br>Burning Sensation;<br>Decreased Vibratory<br>Sense; Drug Interaction;<br>Musculoskeletal Pain;<br>Musculoskeletal Stiffness;<br>Oedema Peripheral; Pain<br>In Extremity;<br>Polyneuropathy; Tendon<br>Calcification; Tendon<br>Disorder; Tenolysis; Urge<br>Incontinence | Sertraline           |              |            | S           | Oral                        | 50 Mg, Qd          |                 | Novartis     |
|                                                                                                                                                                                                                                                                                                       | Zovirax              |              |            | C           | Oral                        |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                       | Symbicort            |              |            | C           | Respiratory<br>(inhalation) |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                       | Cipramil             |              |            | C           |                             |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                       | Terbinafine          |              |            | S           | Oral                        | 250 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                       | Escitalopram Oxalate |              |            | S           | Oral                        | 10 Mg, Unk         | 489 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2010              | 7360130       | DIRECT           |                    |                 |                      |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Alcohol Interaction;<br>Alcohol Poisoning;<br>Amnesia; Loss Of | Lexapro        |              |            | S           | Oral         | 20mg Once Per Day Po |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Consciousness; Product  
Quality Issue; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2010              | 7382547       | NON-EXPEDITED    | Y                  | DE              | 004597               |                      | 21 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Methylphenidate      |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Acetaminophen        |              |            | S           |              |                    |                 | Not Reported |
|                       | Ibuprofen            |              |            | S           |              |                    |                 | Not Reported |
|                       | Alcohol              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2010              | 7362392       | DIRECT           | Y                  | OT              |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pruritus; Rash        | Lexapro        |              |            | S           | Oral         | 10 Mg Po Daily     |                 | Not Reported |
| Erythematous          | Benadryl       |              |            | S           | Oral         | 50 Mg Po Q6 Prn    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2010              | 7362393       | DIRECT           | Y                  | OT              |                      |                      |            | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Chronic Fatigue<br>Syndrome; Fibromyalgia | Prozac         |              |            | S           | Oral         | 20 - 60 Mg Daily Po<br>1990'S - 2008     |                 | Not Reported |
|                                           | Lexapro        |              |            | S           | Oral         | 20 Mg Daily Po 2009 (Mar)<br>- 210 (Mar) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Apr-2010              | 7366651       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013053           |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cerebrovascular Accident; Escitalopram Oxalate S 10 Mg (10 Mg, 1 In 1 D) Not Reported  
Hypotonia; Overdose;  
Salivary Hypersecretion

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2010              | 7213404       | EXPEDITED (15-DAY) | N                  | OT              | 1000010309           |                      | 24 YR      | Male       | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Aggression; Anxiety;         | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg), Oral, 10 Mg    |                 | Not Reported |
| Apathy; Blepharospasm;       |                      |              |            |             | Oral         | (10 Mg), Oral               |                 |              |
| Blood Glucose Decreased;     |                      |              |            |             |              | 5 Mg (5 Mg), Oral, 10 Mg    |                 |              |
| Depression; Derealisation;   |                      |              |            |             |              | (10 Mg), Oral               |                 |              |
| Drug Withdrawal              | Escitalopram Oxalate |              |            | S           | Oral         | 2.5 Mg (5 Mg, 1 In 2 D),    |                 | Not Reported |
| Syndrome; Fatigue;           |                      |              |            |             |              | Oral                        |                 |              |
| Feeling Abnormal;            | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg), Oral, 10     |                 | Not Reported |
| Hyperhidrosis;               |                      |              |            |             |              | Mg (10 Mg), Oral            |                 |              |
| Hyperreflexia; Irritability; |                      |              |            |             | Oral         | 10 Mg (10 Mg), Oral, 10     |                 |              |
| Mania; Nausea; Panic         |                      |              |            |             |              | Mg (10 Mg), Oral            |                 |              |
| Attack; Paraesthesia;        | Ciprofloxacin        |              |            | S           | Oral         | 2 In 1 D, Oral              |                 | Not Reported |
| Paranoia; Pyrexia;           | Flagyl               |              |            | S           |              |                             |                 | Not Reported |
| Somnolence; Suicidal         | Clonazepam           |              |            | S           | Oral         | 0.25 Mg (0.25 Mg, 1 In 1    |                 | Not Reported |
| Ideation; Tinnitus; Urinary  |                      |              |            |             |              | D), Oral, 0.5 Mg (0.5 Mg, 1 |                 |              |
| Tract Infection              |                      |              |            |             | Oral         | In 1 D), Oral               |                 |              |
|                              |                      |              |            |             |              | 0.25 Mg (0.25 Mg, 1 In 1    |                 |              |
|                              |                      |              |            |             |              | D), Oral, 0.5 Mg (0.5 Mg, 1 |                 |              |
|                              |                      |              |            |             |              | In 1 D), Oral               |                 |              |
|                              | Paroxetine           |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),    |                 | Not Reported |
|                              |                      |              |            |             |              | Oral                        |                 |              |
|                              | Milnacipran          |              |            | S           | Oral         | 50 Mg, Oral                 |                 | Not Reported |
|                              | Zoloft               |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D),    |                 | Not Reported |
|                              |                      |              |            |             |              | Oral                        |                 |              |
|                              | Azitrax              |              |            | C           |              |                             |                 | Not Reported |
|                              | Curam                |              |            | C           |              |                             |                 | Not Reported |
|                              | Doxycycline          |              |            | C           |              |                             |                 | Not Reported |
|                              | Creatine Monohydrate |              |            | C           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 15-Apr-2010                                                                                                         | 7243275              | EXPEDITED (15-DAY) | Y                  | OT              | 1000010596           |                               | 50 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Family Stress; Muscle Contractions Involuntary; Restless Legs Syndrome; Stress; Treatment Noncompliance | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2010                                                                                                         | 7273662              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011407           |                               | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder; Gait Inability; Hypotonia; Muscle Spasms                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                     | Marijuana            |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2010                                                                                                         | 7367150              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000013156           |                               | 81 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Lower Gastrointestinal Haemorrhage; Off Label Use                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                     | Ibuprofen            |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                     | Tiotropium           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                     | Salmeterol           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                     | Risperidone          |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                     | Benserazide          |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Apr-2010                                                                                                         | 7367794              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013148           |                               | 67 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                        |   |      |                               |              |
|----------------------------|------------------------|---|------|-------------------------------|--------------|
| Transient Ischaemic Attack | Lexapro                | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                            | Tramadol Hydrochloride | C |      |                               | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Apr-2010                       | 7365601                | DIRECT                    | N                           | RI                       |                               |                               | 76 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>             | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------------------|--------------------------|---------------------|
| Tinnitus                       | Lexapro                 |                       |                     | S                    | Oral                  | One Half Of A 10 Mg. Tablet Each Day Po | 7 DAY                    | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Apr-2010                       | 7366176                | DIRECT                    | Y                           | OT                       |                               |                               | 30 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                           | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>    |
|--------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|------------------------|
| Dizziness; Dry Mouth; Dry Throat; Feeling Hot; Rash Erythematous; Tremor | Lexapro<br>Protonix     |                       |                     | S<br>S               |                       |                             |                          | Forest<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 19-Apr-2010                       | 6096214                | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | S06-NLD-02883-01              |                               | 75 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a>                                                                                                                  | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>     | <a href="#">Duration</a> | <a href="#">Mfr</a>                                          |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|---------------------------------|--------------------------|--------------------------------------------------------------|
| Cardiac Arrest; Cardiac Failure Congestive; Dyspnoea; Electrocardiogram Qt Prolonged | Lexapro<br>Pantozol (Pantoprazole Sodium)<br>Salbutamol Aer (Salbutamol) (100 Microgram) (Salbutamol)<br>Seretide Aerosol (25 Microgram) |                       |                     | S<br>C<br>C<br>C     | Oral                  | 20 Mg (20 Mg, Once A Day), Oral |                          | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 19-Apr-2010                       | 7178821                | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | PHHY2009FR48631               |                               |                     | Male                | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                      |   |             |                                      |              |
|-----------------------------------------------|----------------------|---|-------------|--------------------------------------|--------------|
| Creatinine Renal Clearance Decreased; Seizure | Exelon               | S | Transdermal | 9.5 Mg Daily                         | Novartis     |
|                                               | Exelon               | S | Transdermal | Unk                                  | Novartis     |
|                                               | Escitalopram Oxalate | S |             | 10 Mg In Morning And 5 Mg In Evening | Not Reported |
|                                               | Escitalopram Oxalate | S |             | 5 Mg/Day                             | Not Reported |
|                                               | Aldactazine          | C |             |                                      | Not Reported |
|                                               | Ginkor               | C |             |                                      | Not Reported |
|                                               | Meteospasmyl         | C |             |                                      | Not Reported |
|                                               | Phenobarbital        | C |             |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2010              | 7277782       | EXPEDITED (15-DAY) | Y                  | OT              | 1000011446           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Paraesthesia; Psychomotor Hyperactivity | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                         | Ativan               |              |            | C           |              |                         |                 | Not Reported |
|                                         | Zopiclone            |              |            | C           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2010              | 7299605       | EXPEDITED (15-DAY) | N                  | OT              | 1000011659           |                      | 28 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abdominal Discomfort; Anxiety; Disease Recurrence; Drug Ineffective; Fatigue; Feeling Abnormal; Restlessness; Terminal Insomnia | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Apr-2010              | 7315644       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000011919           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                      |                    |                    |                 |                          |                               |                 |              |                |
|----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| Cardiac Arrest                                                 | Lexapro              |                    | S                  | Oral            | Oral                     |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2010                                                    | 7358671              | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2010046461 |                               | 52 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                     | Vistaril             |                    |                    | S               | Oral                     | 50 Mg, 2x/Day                 |                 | Pfizer       |                |
|                                                                | Lexapro              |                    |                    | S               | Oral                     | 20 Mg, 1x/Day                 |                 | Not Reported |                |
|                                                                | Lexapro              |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                                | Methadone            |                    |                    | C               |                          | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2010                                                    | 7369586              | EXPEDITED (15-DAY) | N                  | OT              | 1000013226               |                               |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Mood; Feeling Abnormal; Restlessness                 | Escitalopram Oxalate |                    |                    | S               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2010                                                    | 7375427              | EXPEDITED (15-DAY) | Y                  | OT              | 100009197                |                               | 88 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Dizziness; Loss Of Consciousness; Presyncope; Tremor | Escitalopram Oxalate |                    |                    | S               | Oral                     | 0 Mg (10 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                | Enalapril Maleate    |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                | Kaleorid             |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                | Hjerdyl              |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                | Furosemid            |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                | Vagifem              |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2010                                                    | 7371017              | EXPEDITED (15-DAY) | Y                  | CA              | 1000013235               |                               |                 | Unknown      | DNK            |

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| <u>Preferred Term</u>                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| Cytogenetic Abnormality;<br>Maternal Drugs Affecting<br>Foetus | Escitalopram Oxalate       |                    |                    | S               | Transplacental       | Transplacental                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Apr-2010                                                    | 8092175                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000013206           |                                    | 74 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                             | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                | Valproate Sodium           |                    |                    | S               | Oral                 | 500 Mg (500 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                | Valproate Sodium           |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                | Risperdal                  |                    |                    | S               | Oral                 | 1 Mg (1 Mg, 1 In 1 D), Oral        |                 | Not Reported |                |
|                                                                | Risperdal                  |                    |                    | S               |                      | 1 Mg (1 Mg, 1 In 1 D)              |                 | Not Reported |                |
|                                                                | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 80 Mg (80 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                | Prothipendyl Hydrochloride |                    |                    | S               | Oral                 | 120 Mg (120 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                | Magnetrans                 |                    |                    | C               |                      |                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2010                                                    | 7340605                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000012469           |                                    | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                      | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral        |                 | Not Reported |                |
|                                                                | Dostinex                   |                    |                    | C               |                      |                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------|---------------------------------|-----------------|--------------|----------------|
| 21-Apr-2010                                                                                                                                                                                                                                                                      | 7369094                 | DIRECT             | N                  | HO              |                       |                                 | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus; Restless Legs Syndrome                                                                                                                                                                                                                                                | Lexapro                 |                    |                    | S               | Oral                  | 10 Mg 1x Daily Po               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2010                                                                                                                                                                                                                                                                      | 7373527                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000013286            |                                 | 90 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Hallucination, Visual;<br>Somnolence                                                                                                                                                                                                                      | Escitalopram Oxalate    |                    |                    | S               | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Escitalopram Oxalate    |                    |                    | S               | Oral                  | 2.5 Mg (2.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Trinitrine              |                    |                    | C               |                       |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Verapamil Hydrochloride |                    |                    | C               |                       |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Trimetazidine           |                    |                    | C               |                       |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Tramadol Hydrochloride  |                    |                    | C               |                       |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2010                                                                                                                                                                                                                                                                      | 7307008                 | NON-EXPEDITED      | N                  |                 | US-JNJFOC-20100300561 |                                 | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anxiety;<br>Depression; Gait<br>Disturbance; Injection Site<br>Pain; Insomnia; Irritability;<br>Mania; Migraine; Mood<br>Altered; Psychotic<br>Disorder; Restlessness;<br>Seizure; Therapeutic<br>Response Decreased;<br>Wrong Technique In<br>Product Usage Process | Risperdal Consta        |                    |                    | S               | Intramuscular         |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Risperdal Consta        |                    |                    | S               | Intramuscular         |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Risperdal Consta        |                    |                    | S               | Intramuscular         |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Risperdal Consta        |                    |                    | S               | Intramuscular         |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Topamax                 |                    |                    | S               | Oral                  |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Lexapro                 |                    |                    | S               | Oral                  |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Prozac                  |                    |                    | S               | Oral                  |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                  | Vyvanse                 |                    |                    | C               | Oral                  |                                 |                 | Not Reported |                |

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| Reclipsen                      |                         |                    | C                  |                 | Oral                                     |                      |                 | Not Reported |                |
|--------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2010                    | 7362777                 | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2009SE18009               |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor; Vasodilation Procedure | Toprol XL               |                    |                    | S               | Oral                                     |                      | 2 YR            | Not Reported |                |
|                                | Toprol XL               |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                | Lexapro                 |                    |                    | S               | Oral                                     |                      | 2 YR            | Not Reported |                |
|                                | Lexapro                 |                    |                    | S               | Oral                                     |                      | 5 DAY           | Not Reported |                |
|                                | Lexapro                 |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                | Xanax                   |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                | Metformin Hydrochloride |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                | Prilosec                |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                | Evista                  |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                | Unithroid               |                    |                    | C               |                                          |                      |                 | Not Reported |                |
|                                | Vitamins Nos            |                    |                    | C               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2010                    | 7362964                 | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS SQUIBB COMPANY-15015597 |                      | 11 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oesophageal Spasm              | Abilify                 |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                | Abilify                 |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                | Abilify                 |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                | Lexapro                 |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                | Seroquel                |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                | Daytrana                |                    |                    | S               |                                          | Patch                |                 | Not Reported |                |
|                                | Clonidine               |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2010                    | 7375488                 | EXPEDITED (15-DAY) | Y                  | LT              | 1000013204                               |                      | 47 YR           | Female       | DNK            |

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| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Malaise; Off Label Use;<br>Torsade De Pointes                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                               | Inipomp                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Xanax                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Imovane                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Panos                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Takadol                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Dafalgan                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2010                                                   | 7375523                   | EXPEDITED (15-DAY) | N                  | HO              | 1000013330           |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation;<br>Therapeutic Product Effect<br>Decreased | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                               | Zuclopenthixol            |                    |                    | S               | Intramuscular        | See Image                        |                 | Not Reported |                |
|                                                               | Tropatepine Hydrochloride |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Lysanxia                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2010                                                   | 7360968                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000012816           |                                  | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Encephalopathy                                                | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                               | Insulin                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Lisinopril                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Lasix                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Toprol XL                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                               | Cardizem                  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2010                                                   | 7361315                   | EXPEDITED (15-DAY) | N                  | OT              | US-RB-001798-10      |                                  | 48 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Dyskinesia; Hallucination;<br>Hand Fracture; Influenza<br>Like Illness; Poor Quality<br>Sleep | Suboxone       |              |            | S           | Sublingual   |                        |                 | Not Reported |
|                                                                                               | Lexapro        |              |            | S           | Unknown      | Dosing Details Unknown |                 | Not Reported |
|                                                                                               | Wellbutrin     |              |            | S           | Unknown      | Dosing Details Unknown |                 | Not Reported |
|                                                                                               | Lunesta        |              |            | S           | Unknown      | Dosing Details Unknown |                 | Not Reported |
|                                                                                               | Ambien         |              |            | S           | Unknown      | 10 Mg                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2010              | 7371975       | DIRECT           | N                  | DS, LT, OT      |                      |                      | 18 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Amenorrhoea; Amnesia;<br>Arthralgia; Arthropathy;<br>Asthenia; Back Pain; Bone<br>Disorder; Decreased<br>Appetite; Depression;<br>Disturbance In Attention;<br>Dizziness; Educational<br>Problem; Headache;<br>Hyperaesthesia;<br>Hypoaesthesia; Impaired<br>Work Ability; Loss Of<br>Personal Independence In<br>Daily Activities;<br>Musculoskeletal Pain;<br>Nausea; Neck Pain;<br>Photophobia; Suicide<br>Attempt; Thyroid Disorder;<br>Thyroid Neoplasm;<br>Unevaluable Event | Lupron Depot   |              |            | S           |              | 11.25 Mg Lupron Depot 1<br>(3mo. Dose) |                 | Abbott       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro        |              |            | S           |              |                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2010              | 7376996       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013211           |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                |                                                                                 |                                |      |                                  |              |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------|------|----------------------------------|--------------|
| Arthropod Bite; Deafness;<br>Dysarthria; Eye Movement<br>Disorder; Infected Bite;<br>Paraesthesia; Sudden<br>Onset Of Sleep; Vision<br>Blurred | Lexapro<br><br>Toprol XL<br>Lyrica<br>Valium<br>Oxycodone (Tablets)<br>Celebrex | S<br><br>C<br>C<br>C<br>C<br>C | Oral | 20 Mg (10 Mg, 2 In 1<br>D), Oral | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2010              | 7382987       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012960           |                      | 20 YR      | Male       | FRA            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Hypersensitivity; Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Apr-2010              | 7287879       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011556           |                      | 80 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------------------|-----------------|--------------|
| Pleurothotonus        | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral                               |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral                               |                 |              |
|                       | Risperdal            |              |            | S           | Oral         | 3 Mg (3 Mg, 1 In 1 D), Oral                                                                    |                 | Not Reported |
|                       | Risperdal            |              |            | S           | Oral         | 4 Mg (4 Mg, 1 In 1 D),<br>Oral, 3 Mg (3 Mg, 1 In 1<br>D), Oral, 2 Mg (2 Mg, 1 In<br>1 D), Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 4 Mg (4 Mg, 1 In 1 D),<br>Oral, 3 Mg (3 Mg, 1 In 1<br>D), Oral, 2 Mg (2 Mg, 1 In<br>1 D), Oral |                 |              |
|                       |                      |              |            |             | Oral         | 4 Mg (4 Mg, 1 In 1 D),<br>Oral, 3 Mg (3 Mg, 1 In 1<br>D), Oral, 2 Mg (2 Mg, 1 In<br>1 D), Oral |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |                            |                         |                    |                 |                            | 1 D), Oral                                                   |                 |              |                |
|-------------------------------|----------------------------|-------------------------|--------------------|-----------------|----------------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
|                               |                            | Trazodone Hydrochloride |                    | C               |                            |                                                              |                 |              | Not Reported   |
|                               |                            | Distraneurin            |                    | C               |                            |                                                              |                 |              | Not Reported   |
|                               |                            | Lorazepam               |                    | C               |                            |                                                              |                 |              | Not Reported   |
| <u>FDA Received Date</u>      | <u>Case #</u>              | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2010                   | 7367891                    | EXPEDITED (15-DAY)      | Y                  | HO, OT          | AU-WATSON-2010-05601       |                                                              |                 | Unknown      | AUS            |
| <u>Preferred Term</u>         | <u>Product</u>             | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma Scale Abnormal; Overdose | Promethazine Hydrochloride |                         |                    | S               |                            | 250 Mg, Unk                                                  |                 | Watson       |                |
|                               | Escitalopram Oxalate       |                         |                    | S               |                            | Unk                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>              | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2010                   | 7377123                    | EXPEDITED (15-DAY)      | Y                  | OT              | 1000013366                 |                                                              | 38 YR           | Female       | FRA            |
| <u>Preferred Term</u>         | <u>Product</u>             | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Metrorrhagia  | Escitalopram Oxalate       |                         |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
|                               | Tranxene T-Tab             |                         |                    | C               |                            |                                                              |                 | Not Reported |                |
|                               | Stresam                    |                         |                    | C               |                            |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>      | <u>Case #</u>              | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2010                   | 7256520                    | EXPEDITED (15-DAY)      | Y                  | HO              | FR-ASTRAZENECA-2010SE02552 |                                                              | 59 YR           | Female       | FRA            |
| <u>Preferred Term</u>         | <u>Product</u>             | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Fibrosis; Hepatitis   | Crestor                    |                         |                    | S               | Oral                       |                                                              | 4 MTH           | Not Reported |                |
|                               | Nitrofurantoin             |                         |                    | S               | Oral                       |                                                              | 3 YR            | Not Reported |                |
|                               | Ibuprofen                  |                         |                    | S               | Oral                       |                                                              |                 | Not Reported |                |
|                               | Acetaminophen              |                         |                    | S               | Oral                       | As Required (Regular Intakes Estimated At 15 Days Per Month) |                 | Not Reported |                |
|                               |                            |                         |                    |                 |                            | As Required (Regular Intakes Estimated At 15 Days Per Month) |                 |              |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                             |                                              | Escitalopram Oxalate | S                  | Oral            |                      | 4 MTH                         | Not Reported    |            |                |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------|----------------|
|                                                                                                             |                                              | Caffeine             | C                  |                 |                      |                               | Not Reported    |            |                |
|                                                                                                             |                                              | Hydrocortisone       | C                  |                 |                      | 10 YR                         | Not Reported    |            |                |
|                                                                                                             |                                              | Hydrocortisone       | C                  |                 |                      |                               | Not Reported    |            |                |
|                                                                                                             |                                              | Hydrocortisone       | C                  |                 |                      |                               | Not Reported    |            |                |
|                                                                                                             |                                              | Hydrocortisone       | C                  |                 |                      |                               | Not Reported    |            |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2010                                                                                                 | 7385697                                      | DIRECT               | Y                  |                 |                      |                               |                 | Male       | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Sexual Dysfunction                                                                                          | Lexapro                                      |                      |                    | S               |                      |                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Apr-2010                                                                                                 | 7234236                                      | EXPEDITED (15-DAY)   | Y                  | DE              | 1000010624           |                               | 34 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Asphyxia; Intentional Self-Injury                                                                           | Escitalopram Oxalate                         |                      |                    | S               |                      | 15mg (15 Mg, 1 In 1 D)        |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Apr-2010                                                                                                 | 7364035                                      | EXPEDITED (15-DAY)   | Y                  | OT              | 1000013035           |                               | 37 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                               | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Aggression; Agitation; Anxiety; Feeling Abnormal; Muscle Tightness; Pain; Paraesthesia; Withdrawal Syndrome | Escitalopram Oxalate                         |                      |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                                                                                             | Escitalopram Oxalate                         |                      |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                                                                                             | Atarax                                       |                      |                    | C               |                      |                               |                 |            | Not Reported   |
|                                                                                                             | Lorazepam                                    |                      |                    | C               |                      |                               |                 |            | Not Reported   |
|                                                                                                             | Zolpidem                                     |                      |                    | C               |                      |                               |                 |            | Not Reported   |
|                                                                                                             | Havlane                                      |                      |                    | C               |                      |                               |                 |            | Not Reported   |
|                                                                                                             | Propoxyphene Hydrochloride And Acetaminophen |                      |                    | C               |                      |                               |                 |            | Not Reported   |
|                                                                                                             | Avlocardyl                                   |                      |                    | C               |                      |                               |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2010              | 7376806       | DIRECT           | Y                  | OT              |                      |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Affect Lability;<br>Bradycardia; Chest Injury;<br>Cognitive Disorder;<br>Dizziness;<br>Electrocardiogram<br>Abnormal;<br>Electroencephalogram<br>Abnormal; Fatigue;<br>Feeling Of Body<br>Temperature Change;<br>Generalised Tonic-Clonic<br>Seizure; Haemorrhage;<br>Head Injury; Headache;<br>Loss Of Consciousness;<br>Post Concussion<br>Syndrome; Presyncope;<br>Seizure; Skin Laceration | Lexapro        |              |            | S           | Oral         | 10 Mg Qd Po        |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2010              | 7387779       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013411           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Anxiety; Disturbance In<br>Attention; Restlessness;<br>Somnolence | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D) Oral      |                 | Not Reported |
|                                                                   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2010              | 7334085       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012321           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Aggression; Physical  | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Assault D),Oral

| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 30-Apr-2010                                    | 7372551              | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2010SE08150 |                               | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenopia; Burning Sensation                  | Nexium               |                    |                    | S               | Oral                       |                               |                 | Astrazeneca  |                |
|                                                | Lexapro              |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
|                                                | Lexapro              |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2010                                    | 7370845              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013207                 |                               | 24 YR           | Male         | DNK            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Overdose; Polydipsia; Polyuria  | Escitalopram Oxalate |                    |                    | S               | Oral                       | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                | Seroquel             |                    |                    | C               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2010                                    | 7367249              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013161                 |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intraocular Pressure Increased                 | Escitalopram Oxalate |                    |                    | S               |                            | 10 Mg (10 Mg, 1 In 1 D)       |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2010                                    | 7374622              | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2009UW05839 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Dysgeusia; Feeling Abnormal; | Nexium               |                    |                    | S               | Oral                       |                               |                 | Astrazeneca  |                |
|                                                | Lexapro              |                    |                    | S               |                            |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastroesophageal Reflux  
Disease; Insomnia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2010              | 7381519       | DIRECT           | N                  | RI, OT          |                      |                      | 35 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anaesthesia; Anorgasmia;<br>Diarrhoea; Dizziness;<br>Euphoric Mood;<br>Paraesthesia; Sexual<br>Dysfunction; Urogenital<br>Disorder | Lexapro        |              |            | S           | Oral         | 20mg Once Daily Po |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2010              | 7382754       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013496           |                      | 29 YR      | Male       | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Neutropenia; White Blood<br>Cell Count Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2010              | 7383461       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013495           |                      | 82 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                           | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Loss Of<br>Consciousness; Malaise;<br>Orthostatic Hypotension | Escitalopram Oxalate                        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           |              |                    |                 | Not Reported |
|                                                                                 | Corvasal (Molsidomine)                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                 | Tareg                                       |              |            | S           | Oral         | (80 Mg), Oral      |                 | Not Reported |
|                                                                                 | Lasix                                       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                 | Tahor                                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Diffu K                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Levothyrox                                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                 | Mopral                                      |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 04-May-2010                                                               | 7376020                                  | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2010FR25016      |                              | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Loss of Consciousness; Malaise; Orthostatic Hypotension | Lasix                                    |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate                     |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                           | Tahor                                    |                    |                    | C               |                      | 10 Mg                        |                 | Not Reported |                |
|                                                                           | Diffu K                                  |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                           | Levothyrox                               |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                           | Omeprazole                               |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                           | Tareg                                    |                    |                    | S               | Oral                 | 80 Mg                        |                 | Novartis     |                |
|                                                                           | Corvasal (Molsidomine)                   |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                           | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2010                                                               | 7382982                                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000013518           |                              |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Off Label Use                                                 | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 20 Mg (20mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                           | Cokenzen                                 |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2010                                                               | 7382985                                  | EXPEDITED (15-DAY) | Y                  | DS              | 1000013497           |                              | 81 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Gait Disturbance; Gastrointestinal Motility Disorder; Muscle Spasticity   | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg (10mg, 1 In 1 D), Oral |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------|-----------------|------------------------------|----------------|
| 04-May-2010                                                                                                                                                                                                                                                              | 7383004                           | DIRECT             | N                  | HO, LT, RI, OT  |                      |                                                    | 86 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Abnormal Behaviour;<br>Abnormal Weight Gain;<br>Atrial Fibrillation;<br>Cerebrovascular Accident;<br>Dizziness; Dysarthria;<br>Dyspnoea; Fall; Feeling<br>Abnormal; Fluid Retention;<br>Gait Disturbance;<br>Haemorrhage;<br>Paraesthesia; Transient<br>Ischaemic Attack | Lexapro                           |                    |                    | S               | Oral                 | 10 Mg Once Daily Po                                |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-May-2010                                                                                                                                                                                                                                                              | 7311836                           | EXPEDITED (15-DAY) | Y                  | DS              | 1000011619           |                                                    | 44 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Aggression; Diarrhoea;<br>Hyperacusis; Libido<br>Increased; Nausea;<br>Overdose; Photophobia;<br>Self-Injurious Ideation;<br>Speech Disorder; Suicidal<br>Ideation; Tinnitus; Visual<br>Impairment                                                                       | Escitalopram Oxalate<br>Lithionit |                    |                    | S<br>C          | Oral                 | 10-30 Mg (1 In 1 D),Oral                           |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-May-2010                                                                                                                                                                                                                                                              | 7319624                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000011973           |                                                    | 22 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Food Allergy                                                                                                                                                                                                                                                             | Lexapro                           |                    |                    | S               | Oral<br>Oral         | 10mg, Oral; 15 Mg, Oral<br>10mg, Oral; 15 Mg, Oral |                 | Not Reported                 |                |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 05-May-2010                                                    | 7351932        | EXPEDITED (15-DAY) | Y                  | OT              | 1000012612           |                                                                                                                  | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract; Night Blindness;<br>Optic Neuropathy;<br>Photophobia | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10mg, 1 In 1d),<br>Oral, 5mg (5mg, 1 In1d),<br>Oral 10mg (10mg 1 In 1d<br>Oral) 5 Mg (5mg 1 In1d)<br>Oral |                 | Not Reported |                |
|                                                                |                |                    |                    |                 | Oral                 | 10 Mg (10mg, 1 In 1d),<br>Oral, 5mg (5mg, 1 In1d),<br>Oral 10mg (10mg 1 In 1d<br>Oral) 5 Mg (5mg 1 In1d)<br>Oral |                 |              |                |
|                                                                |                |                    |                    |                 | Oral                 | 10 Mg (10mg, 1 In 1d),<br>Oral, 5mg (5mg, 1 In1d),<br>Oral 10mg (10mg 1 In 1d<br>Oral) 5 Mg (5mg 1 In1d)<br>Oral |                 |              |                |
|                                                                | Fentanyl       |                    |                    | C               |                      |                                                                                                                  |                 | Not Reported |                |
|                                                                | Lortab         |                    |                    | C               |                      |                                                                                                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 05-May-2010                                                                                                                                                                                                                                                     | 7385628        | DIRECT           | Y                  | DS, RI          |                      |                                    | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Balance<br>Disorder; Blood<br>Cholesterol Abnormal;<br>Breast Mass; Diabetes<br>Mellitus; Heart Rate<br>Irregular; Hypertension;<br>Muscular Weakness;<br>Musculoskeletal Stiffness;<br>Oedema Peripheral;<br>Periorbital Oedema;<br>Weight Increased | Risperdal      |                  |                    | S               | Oral                 | Risperadol Twice A Day<br>Oral Tab |                 | Janssen      |                |
|                                                                                                                                                                                                                                                                 | Lexapro        |                  |                    | S               | Oral                 | Lexapro Once A Day Oral<br>Tab     |                 | Forest       |                |
|                                                                                                                                                                                                                                                                 | Benzopropine   |                  |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                 | Cogentin       |                  |                    | C               |                      |                                    |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| 05-May-2010                                                                                              | 7386860                  | EXPEDITED (15-DAY) | N                  | OT              | 1000013405           |                                                        | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Euphoric Mood; Seizure                                                          | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg (10 Mg), Oral                                    |                 | Not Reported |                |
|                                                                                                          | Depakote Er              |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2010                                                                                              | 7158926                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000009248           |                                                        |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Obsessive<br>Thoughts; Psychotic<br>Disorder; Sleep Disorder;<br>Violence-Related<br>Symptom | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 20 Mg (1 In 1 D) Oral |                 | Not Reported |                |
|                                                                                                          | Xanax                    |                    |                    | C               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 20 Mg (1 In 1 D) Oral |                 | Not Reported |                |
|                                                                                                          | Norset                   |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2010                                                                                              | 7381231                  | EXPEDITED (15-DAY) | Y                  | DS              | US-WYE-H14853710     |                                                        | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Energy<br>Increased; Headache;<br>Irritability; Nervousness                            | Pristiq Extended Release |                    |                    | S               | Oral                 |                                                        |                 | Wyeth        |                |
|                                                                                                          | Valium                   |                    |                    | C               |                      | Unknown                                                |                 | Roche        |                |
|                                                                                                          | Lexapro                  |                    |                    | S               | Oral                 |                                                        |                 | Lundbeck     |                |
|                                                                                                          | Lexapro                  |                    |                    | S               | Oral                 |                                                        |                 | Lundbeck     |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-May-2010                                                                                              | 7388880                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000013550           |                                                        |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                                |                      |   |      |                               |              |
|------------------------------------------------|----------------------|---|------|-------------------------------|--------------|
| Aggression; Alcohol Interaction; Disinhibition | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|------------------------------------------------|----------------------|---|------|-------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2010              | 7389400       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013678           |                      | 46 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Overdose              | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-May-2010              | 7233425       | EXPEDITED (15-DAY) | Y                  | HO              | 1000010625           |                      | 60 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Amnesia; Extrapyrimalal Disorder; Fall; Off Label Use; Variant Creutzfeldt-Jakob Disease | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                          | Venlafaxine          |              |            | S           |              |                               |                 | Not Reported |
|                                                                                          | Clonazepam           |              |            | S           |              |                               |                 | Not Reported |
|                                                                                          | Stilnox              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                          | Stresam              |              |            | C           |              |                               |                 | Not Reported |
|                                                                                          | Tareg                |              |            | C           |              |                               |                 | Not Reported |
| Lipanthyl                                                                                |                      |              | C          |             |              |                               | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-May-2010              | 7381776       | EXPEDITED (15-DAY) | Y                  | HO, OT          | IN-JNJFOC-20100501137 |                      | 19 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradykinesia; Cognitive Disorder; Drug Interaction; Muscle Rigidity; Reduced Facial Expression; Tremor | Risperidone          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                        | Amitriptyline        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                        | Amitriptyline        |              |            | S           | Unknown      | At Night           |                 | Not Reported |
|                                                                                                        | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 10-May-2010                                                                                                                                                   | 7390522              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013560           |                                                                                | 91 DAY          | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Maternal Drugs Affecting Foetus; Maternal Exposure During Breast Feeding; Neonatal Disorder; Rapid Eye Movements Sleep Abnormal; Restlessness         | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1) D, Transplacental; 20 Mg (20 Mg, 1 In 1 D), Transmammary |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-May-2010                                                                                                                                                   | 7397945              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013696           |                                                                                | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Pressure Fluctuation; Cerebral Microangiopathy; Headache; Hypertensive Crisis | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                                                  |                 | Not Reported |                |
|                                                                                                                                                               | Abilify              |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Athymil              |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Omeprazole           |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Carbol               |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
|                                                                                                                                                               | Paracetamol          |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2010                                                                                                                                                   | 7390280              | EXPEDITED (15-DAY) | Y                  | CA              | 1000013702           |                                                                                |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Atresia; Choanal Atresia; Maternal Drugs Affecting Foetus                                                                                                | Escitalopram Oxalate |                    |                    | S               | Transplacental       | Transplacental                                                                 |                 | Not Reported |                |
|                                                                                                                                                               | Folic Acid           |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2010                                                                                                                                                   | 7391982              | EXPEDITED (15-DAY) | Y                  | LT              | 1000013712           |                                                                                | 63 YR           | Male         | DNK            |

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| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------|-----------------|--------------|----------------|
| Homicide                                                                       | Lexapro              |                    |                    | S               | Oral                 | 10 Mg, Oral                                             |                 | Not Reported |                |
|                                                                                | Keppra               |                    |                    | S               | Oral                 | 250 Mg, Oral                                            |                 | Not Reported |                |
|                                                                                | Cyress Capsule       |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2010                                                                    | 7392582              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013738           |                                                         | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 15 Mg, 1 In 1 D, Oral |                 | Not Reported |                |
|                                                                                | Omeprazole           |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
|                                                                                | Aggrenox (Tablets)   |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2010                                                                    | 7392592              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013703           |                                                         | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Device Intolerance; Drug Ineffective; Lichenoid Keratosis; Toxic Skin Eruption | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                             |                 | Not Reported |                |
|                                                                                | Zolpidem             |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                        |                 | Not Reported |                |
|                                                                                | Zithromax            |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
|                                                                                | Levothyros (Tablets) |                    |                    | C               |                      |                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2010                                                                    | 7392912              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013488           |                                                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                        | Lexapro              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------------|-----------------|--------------|----------------|
| 12-May-2010                                               | 7385241                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2010SA025602        |                               | 94 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Hypochromic Anaemia; Myelodysplastic Syndrome; | Plavix                   |                    |                    | S               | Oral                                  |                               |                 | Not Reported |                |
| Thrombocytopenic Purpura                                  | Equanil                  |                    |                    | S               | Oral                                  |                               |                 | Not Reported |                |
|                                                           | Escitalopram Oxalate     |                    |                    | S               | Oral                                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2010                                               | 7385421                  | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-10P-163-0643069-00          |                               | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Euphoric Mood; Seizure              | Depakote Er              |                    |                    | S               |                                       | Increased To An Unknown Dose  |                 | Not Reported |                |
|                                                           | Lexapro                  |                    |                    | S               | Oral                                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2010                                               | 7385544                  | EXPEDITED (15-DAY) | Y                  | LT              | DE-PFIZER INC-2010055676              |                               | 45 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Epidermal Necrolysis                                | Ampicillin And Sulbactam |                    |                    | S               | Intravenous (not otherwise specified) | 3 G, 3x/Day                   | 5 DAY           | Pfizer       |                |
|                                                           | Sulbactam Sodium         |                    |                    | S               | Intravenous (not otherwise specified) | 0.5 G, 3x/Day                 | 7 DAY           | Not Reported |                |
|                                                           | Norvasc                  |                    |                    | S               | Oral                                  | 10 Mg, 1x/Day                 |                 | Pfizer       |                |
|                                                           | Norvasc                  |                    |                    | S               | Oral                                  | 20 Mg, 1x/Day                 |                 | Pfizer       |                |
|                                                           | Hydrochlorothiazide      |                    |                    | S               | Oral                                  | 12.5 Mg, 1x/Day               | 5 DAY           | Not Reported |                |
|                                                           | Hydrochlorothiazide      |                    |                    | S               | Oral                                  | 12.5 Mg, 2x/Day               |                 | Not Reported |                |
|                                                           | Metamizole Sodium        |                    |                    | S               | Intravenous (not otherwise specified) | 1 G, 2x/Day (Morning,Evening) | 4 DAY           | Not Reported |                |

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|                                                                                |   |                                       |                             |        |              |
|--------------------------------------------------------------------------------|---|---------------------------------------|-----------------------------|--------|--------------|
| Metamizole Sodium                                                              | S | Intravenous (not otherwise specified) | 1 G, 1x/Day (Morning)       | 5 DAY  | Not Reported |
| Metamizole Sodium                                                              | S | Intravenous (not otherwise specified) | 1 G, 2x/Day (Morning, Noon) | 1 DAY  | Not Reported |
| Potassium Chloride                                                             | S | Intravenous (not otherwise specified) | Unk                         | 16 DAY | Not Reported |
| Paracetamol                                                                    | S | Intravenous (not otherwise specified) | Unk                         | 5 DAY  | Not Reported |
| Paracetamol                                                                    | S | Intravenous (not otherwise specified) | Unk                         | 4 DAY  | Not Reported |
| Paracetamol                                                                    | S | Intravenous (not otherwise specified) | Unk                         | 6 DAY  | Not Reported |
| Beloc-Zok                                                                      | S | Oral                                  | Unk                         | 5 DAY  | Not Reported |
| Beloc-Zok                                                                      | S | Oral                                  | Unk                         | 8 DAY  | Not Reported |
| Beloc-Zok                                                                      | S |                                       | Unk                         |        | Not Reported |
| Norepinephrine                                                                 | S | Intravenous (not otherwise specified) | Unk                         | 8 DAY  | Not Reported |
| Embolex                                                                        | S | Subcutaneous                          | Unk                         | 13 DAY | Not Reported |
| Zocor                                                                          | S | Oral                                  | 20 Mg, 1x/Day               | 13 DAY | Not Reported |
| Sorbitol\Xylitol                                                               | S | Intravenous (not otherwise specified) | 3.5 %, Unk                  | 1 DAY  | Not Reported |
| Sorbitol\Xylitol                                                               | S | Intravenous (not otherwise specified) | 3.5 %, Unk                  | 5 DAY  | Not Reported |
| Sorbitol\Xylitol                                                               | S | Intravenous (not otherwise specified) | 3.5 %, Unk                  | 2 DAY  | Not Reported |
| Potassium                                                                      | S | Oral                                  | 40 Mmol, Unk                | 3 DAY  | Not Reported |
| Potassium                                                                      | S | Oral                                  | 40 Mmol, Unk                | 5 DAY  | Not Reported |
| Potassium                                                                      | S | Oral                                  | 40 Mmol, Unk                | 4 DAY  | Not Reported |
| Fresubin                                                                       | S | Oral                                  | Unk                         | 13 DAY | Not Reported |
| Magnesium Chloride Anhydrous\Potassium Chloride\Sodium Acetate\Sodium Chloride | S | Intravenous (not otherwise specified) | Unk                         | 13 DAY | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |   |                                       |                |        |              |
|------------------------------------|---|---------------------------------------|----------------|--------|--------------|
| Bifiteral                          | S | Oral                                  | 10 MI, 3x/Day  |        | Not Reported |
| Nexium                             | S | Oral                                  | 20 Mg, 1x/Day  |        | Not Reported |
| Ramipril                           | S | Oral                                  | 5 Mg, 1x/Day   | 3 DAY  | Not Reported |
| Ramipril                           | S | Oral                                  | 2.5 Mg, 1x/Day |        | Not Reported |
| Cipralex                           | S | Oral                                  | 10 Mg, 1x/Day  |        | Not Reported |
| Midazolam                          | S | Intravenous (not otherwise specified) | 100 Mg, Unk    | 11 DAY | Not Reported |
| Propofol                           | S | Intravenous (not otherwise specified) | 2 %, Unk       | 11 DAY | Not Reported |
| Insulin Nos                        | S | Intravenous (not otherwise specified) | Unk            | 16 DAY | Not Reported |
| Sufentanil                         | S | Intravenous (not otherwise specified) | 500 Ug, Unk    | 16 DAY | Not Reported |
| Erythromycin                       | S | Intravenous (not otherwise specified) | 200 Mg, 3x/Day | 5 DAY  | Not Reported |
| Erythromycin                       | S | Intravenous (not otherwise specified) | 200 Mg, 3x/Day | 3 DAY  | Not Reported |
| Mucosolvan                         | S | Respiratory (inhalation)              | Unk            | 9 DAY  | Not Reported |
| Metoclopramide Hydrochloride       | S | Intravenous (not otherwise specified) | 10 Mg, 2x/Day  | 11 DAY | Not Reported |
| Domperidone                        | S | Oral                                  | 10 Mg, 1x/Day  | 12 DAY | Not Reported |
| Ipratropium                        | S | Oral                                  | 5 Gtt, 4x/Day  | 8 DAY  | Not Reported |
| Albuterol Sulfate                  | S |                                       | 5 Gtt, 4x/Day  | 8 DAY  | Not Reported |
| Levothyroxine Sodium               | S | Oral                                  | Unk            | 14 DAY | Not Reported |
| Piperacillin                       | S | Intravenous (not otherwise specified) | 4 G, 3x/Day    | 7 DAY  | Not Reported |
| Haloperidol                        | S | Intravenous (not otherwise specified) | 5 Mg, Unk      | 1 DAY  | Not Reported |
| Solutions For Parenteral Nutrition | S | Intravenous (not otherwise specified) | Unk            | 4 DAY  | Not Reported |
| Clonidine                          | S | Intravenous (not otherwise specified) | 750 Ug, Unk    | 7 DAY  | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |   |                                       |                                            |          |              |
|----------------------------------|---|---------------------------------------|--------------------------------------------|----------|--------------|
| Enoxaparin Sodium                | S | Subcutaneous                          | 0.4 MI, Unk                                |          | Not Reported |
| Urapidil                         | S | Intravenous (not otherwise specified) | Unk                                        | 5 DAY    | Not Reported |
| Gastrozepin                      | S | Oral                                  | 25 Mg, 3x/Day                              | 4 DAY    | Not Reported |
| Tavanic                          | S | Oral                                  | 500 Mg, 3x/Day                             |          | Not Reported |
| Paracetamol                      | S | Rectal                                | Unk                                        |          | Not Reported |
| Atacand                          | S | Oral                                  | Unk                                        |          | Not Reported |
| Levothyroxine Sodium             | S | Oral                                  | 75 Mg, 1x/Day                              |          | Not Reported |
| Scopolamine                      | S | Transdermal                           | Unk                                        |          | Not Reported |
| Beloc Zok (Metoprolol Succinate) | C | Oral                                  | Unk Df, 1x/Day                             | 2923 DAY | Not Reported |
| Ezetimibe/Simvastatin            | C | Oral                                  | 1df 1x/D, 10 Mg Ezetimibe/20mg Simvastatin | 2923 DAY | Not Reported |
| Allopurinol                      | C | Oral                                  | 300 Mg, 1x/Day                             | 1468 DAY | Not Reported |
| Metronidazole                    | C | Intravenous (not otherwise specified) | 500 Mg, 3x/Day                             | 4 DAY    | Not Reported |
| Claforan                         | C | Intravenous (not otherwise specified) | 2 G, 3x/Day                                | 4 DAY    | Not Reported |
| Mannitol                         | C | Intravenous (not otherwise specified) | 20%, 125 MI                                | 1 DAY    | Not Reported |
| Fentanyl                         | C | Intravenous (not otherwise specified) | Unk                                        | 2 DAY    | Not Reported |
| Furosemide                       | C | Intravenous (not otherwise specified) | 5 Mg, Unk                                  | 1 DAY    | Not Reported |
| Dobutamine                       | C | Intravenous (not otherwise specified) | 250 Mg, Unk                                | 3 DAY    | Not Reported |
| Acetylcysteine                   | C | Oral                                  | 600 Mg, Unk                                |          | Not Reported |
| Ceruletide Diethylamine          | C | Intravenous (not otherwise specified) | Unk                                        | 1 DAY    | Not Reported |
| Milax                            | C | Rectal                                | Unk                                        | 1 DAY    | Not Reported |
| Bisacodyl                        | C | Rectal                                | Unk                                        | 1 DAY    | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 12-May-2010                                                                                                                                                                                                                  | 7388173              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013521           |                                | 61 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Blood Albumin Decreased; Blood Sodium Decreased; Confusional State; Dehydration; Depression; Diarrhoea; Disease Recurrence; Dizziness; Hypophagia; Malnutrition; Myoclonus; Tachycardia; Tremor; Withdrawal Syndrome | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D), 20 Mg |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Citalopram           |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Venlafaxine          |                    |                    | S               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Omeprazole           |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2010                                                                                                                                                                                                                  | 7400875              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013757           |                                | 88 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hallucination; Muscular Weakness; Off Label Use                                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Allopurinol          |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Cozaar               |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Betolvidon (Tablets) |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Aspirin              |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-May-2010                                                                                                                                                                                                                  | 7405084              | EXPEDITED (15-DAY) | N                  | OT              | 1000013761           |                                | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Burning Sensation; Drug Ineffective; Insomnia; Off Label Use; Overdose; Vomiting                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 30 Mg (30 Mg,1 In 1 D),Oral    |                 | Not Reported |                |



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|                      |   |      |                                                                      |              |
|----------------------|---|------|----------------------------------------------------------------------|--------------|
| Escitalopram Oxalate | S | Oral | D),Oral<br>20 Mg (20 Mg,1 In 1 D),Oral ; 40 Mg (40 Mg,1 In 1 D),Oral | Not Reported |
| Escitalopram Oxalate | S | Oral | Oral                                                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2010              | 6985993       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005843           |                      | 76 YR      | Male       | ITA            |

| <u>Preferred Term</u>       | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Agitation; Amyotrophy;      | Nebivolol Hydrochloride           |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D), Oral     |                 | Not Reported |
| Balance Disorder; Biliary   | Nebivolol Hydrochloride           |              |            | S           | Oral         | (1 In 1 D), Oral               |                 | Not Reported |
| Dilatation; Bradycardia;    | Escitalopram Oxalate              |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D), Oral   |                 | Not Reported |
| Cholelithiasis; Decreased   | Furosemide                        |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D), Oral   |                 | Not Reported |
| Appetite; Dehydration;      | Trandolapril                      |              |            | S           | Oral         | 2 Mg (2 Mg, 1 In 1 D), Oral    |                 | Not Reported |
| Delusion; Disease           | Topalgic [Tramadol Hydrochloride] |              |            | S           | Oral         | 200 Mg (200 Mg,1 In 1 D), Oral |                 | Not Reported |
| Complication; Drug          | Diffu K                           |              |            | C           |              |                                |                 | Not Reported |
| Interaction; Dysuria; Fall; | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              |                                |                 | Not Reported |
| General Physical Health     | Crestor                           |              |            | C           |              |                                |                 | Not Reported |
| Deterioration; Humerus      | Previscan (Fluindione)            |              |            | C           |              |                                |                 | Not Reported |
| Fracture; Memory            | Forlax                            |              |            | C           |              |                                |                 | Not Reported |
| Impairment; Nervous         |                                   |              |            |             |              |                                |                 |              |
| System Disorder;            |                                   |              |            |             |              |                                |                 |              |
| Orthostatic Hypotension;    |                                   |              |            |             |              |                                |                 |              |
| Therapy Non-Responder;      |                                   |              |            |             |              |                                |                 |              |
| Tremor; Urinary             |                                   |              |            |             |              |                                |                 |              |
| Incontinence; Urinary       |                                   |              |            |             |              |                                |                 |              |
| Retention                   |                                   |              |            |             |              |                                |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2010              | 7386677       | NON-EXPEDITED    | N                  |                 | A0850509A            |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Chest Discomfort; Chest | Treximet       |              |            | S           | Oral         |                    | 1 DAY           | Glaxosmithkline |
| Pain; Drug Interaction; | Lexapro        |              |            | S           | Unknown      |                    | 5 YR            | Not Reported    |
| Nausea; Vomiting        |                |              |            |             |              |                    |                 |                 |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 6970657       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-09P-056-0568066-00 |                      | 76 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                         | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Amnestic Disorder; Amyotrophy; Asthenia; Biliary Dilatation; Bradycardia; Cholelithiasis; Decreased Appetite; Dehydration; Drug Interaction; Dysuria; Fall; General Physical Health Deterioration; Humerus Fracture; Hypotension; Jugular Vein Distension; Malaise; Orthostatic Hypotension; Persecutory Delusion; Tremor; Urinary Incontinence; Urinary Retention | Trandolapril                      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Topalgic (France)                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Diffu K                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Aspegic [Acetylsalicylate Lysine] |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Crestor                           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Forlax                            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Previscan (Fluindione)            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Escitalopram Oxalate              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Furosemide                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                               | Temerit                           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7299860       | EXPEDITED (15-DAY) | Y                  |                 | 1000011579           |                      | 53 YR      | Male       | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Hypertension; Tremor; Ulcer | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                      | Protedine            |              |            | C           |              |                    |                 | Not Reported |
|                                      | Selomax              |              |            | C           |              |                    |                 | Not Reported |
|                                      | Losar                |              |            | C           |              |                    |                 | Not Reported |
|                                      | Neurobion            |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7388151       | EXPEDITED (15-DAY) | Y                  | OT              | AT-JNJFOC-20100501916 |                      | 48 YR      | Female     | AUT            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                            |   |         |           |              |
|------------------------------------|----------------------------|---|---------|-----------|--------------|
| Headache;<br>Hyponatraemia; Nausea | Risperdal                  | S | Unknown |           | Not Reported |
|                                    | Risperdal                  | S | Unknown |           | Not Reported |
|                                    | Mianserin Hydrochloride    | S | Unknown | 0-0-0-2   | Not Reported |
|                                    | Neurontin                  | S | Unknown |           | Not Reported |
|                                    | Neurontin                  | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown | 25-100 Mg | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Seroquel                   | S | Unknown |           | Not Reported |
|                                    | Prothipendyl Hydrochloride | S | Unknown |           | Not Reported |
|                                    | Prothipendyl Hydrochloride | S | Unknown | 0-0-0-1   | Not Reported |
|                                    | Atarax                     | S | Unknown | 1-1-0-1   | Not Reported |
|                                    | Metformin Hydrochloride    | S | Unknown | 1-0-1-0   | Not Reported |
|                                    | Aspirin                    | S | Unknown | 1-0-0-0   | Not Reported |
|                                    | Nexium                     | S | Unknown | 0-0-0-1   | Not Reported |
|                                    | Ferrous Sulfate            | S | Unknown | 1-0-0-0   | Not Reported |
|                                    | Neurontin                  | S | Unknown |           | Not Reported |
|                                    | Neurontin                  | S | Unknown | 0-1-0-0   | Not Reported |
|                                    | Akineton                   | S | Unknown |           | Not Reported |
|                                    | Akineton                   | S | Unknown |           | Not Reported |
|                                    | Cipralext                  | S | Unknown |           | Not Reported |
|                                    | Depakene                   | S | Oral    |           | Not Reported |
|                                    | Depakene                   | S | Oral    |           | Not Reported |
|                                    | Nexium                     | S | Unknown |           | Not Reported |
|                                    | Ferrous Sulfate            | S | Unknown |           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |                                       |              |
|--------------------------------|---|---------------------------------------|--------------|
| Depakene                       | C | Intravenous (not otherwise specified) | Not Reported |
| Depakene                       | C | Intravenous (not otherwise specified) | Not Reported |
| Lorazepam                      | C | Unknown 2.5 - 11.25 Mg                | Not Reported |
| Lorazepam                      | C | Unknown                               | Not Reported |
| Lorazepam                      | C | Unknown                               | Not Reported |
| Lorazepam                      | C | Unknown                               | Not Reported |
| Lorazepam                      | C | Unknown                               | Not Reported |
| Lorazepam                      | C | Unknown                               | Not Reported |
| Tenoretic                      | C | Unknown                               | Not Reported |
| Mirtazapine                    | C | Unknown                               | Not Reported |
| Mirtazapine                    | C | Unknown                               | Not Reported |
| Phenoxybenzamine Hydrochloride | C | Unknown                               | Not Reported |
| Dexibuprofen                   | C | Unknown                               | Not Reported |
| Dexibuprofen                   | C | Unknown                               | Not Reported |
| Augmentin                      | C | Unknown                               | Not Reported |
| Augmentin                      | C | Unknown                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 14-May-2010              | 7392549              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013707           |                               | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness    | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg ( 5mg, 1 In 1 D),Oral    |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Alprazolam           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                          | Lisinopril           |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7395478       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013726           |                      | 97 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                             | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation; Blood Magnesium Decreased; Blood Potassium Decreased; Blood Pressure Increased; Fall; Inappropriate Antidiuretic Hormone Secretion; Spinal Fracture; Urinary Tract Infection | Lexapro                          |              |            | S           | Oral         | 5 Mg, Oral         |                 | Not Reported |
|                                                                                                                                                                                                   | Long Acting Tolterodine Tartrate |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Atenolol                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Furosemide                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Lisinopril                       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Lorazepam                        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Docusate                         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Ciprofloxacin                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Methylcellulose                  |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                   | Multi-Vitamin                    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7397017       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013818           |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Bile Duct Obstruction; Yellow Skin | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                    |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7397130       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013800           |                      | 63 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cerebral Infarction   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Baklofen             |              |            | C           |              |                               |                 | Not Reported |
|                       | Ibuprofen            |              |            | C           |              |                               |                 | Not Reported |
|                       | Alvedon              |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2010              | 7398087       | EXPEDITED (15-DAY) | Y                  | DE              | 1000013794           |                      | 52 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Intentional Overdose;<br>Pneumonia Aspiration;<br>Toxicity To Various Agents | Escitalopram Oxalate |                    |                    | S               | Oral                           | 10 Mg (10 Mg,1 In 1 D),<br>Oral; (400 Mg,Once), Oral |                 | Not Reported |                |
|                                                                                                    |                      |                    |                    |                 | Oral                           | 10 Mg (10 Mg,1 In 1 D),<br>Oral; (400 Mg,Once), Oral |                 |              |                |
|                                                                                                    | Lamotrigine          |                    |                    | C               |                                |                                                      |                 | Not Reported |                |
|                                                                                                    | Clonazepam           |                    |                    | C               |                                |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2010                                                                                        | 7325717              | EXPEDITED (15-DAY) | Y                  | CA              | IE-ASTRAZENECA-<br>2010SE11012 |                                                      | < 1 DAY         | Female       | IRL            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertonia Neonatal;<br>Hypotonia; Poor Sucking<br>Reflex; Talipes                                 | Quetiapine           |                    |                    | S               | Transplacental                 |                                                      | 5 WEEK          | Not Reported |                |
|                                                                                                    | Quetiapine           |                    |                    | S               | Transplacental                 |                                                      | 5 WEEK          | Not Reported |                |
|                                                                                                    | Escitalopram Oxalate |                    |                    | S               | Transplacental                 |                                                      | 5 WEEK          | Not Reported |                |
|                                                                                                    | Amoxil               |                    |                    | S               | Transplacental                 |                                                      |                 | Not Reported |                |
|                                                                                                    | Augmentin            |                    |                    | S               | Transplacental                 |                                                      |                 | Not Reported |                |
|                                                                                                    | Ranitidine           |                    |                    | S               | Transplacental                 |                                                      |                 | Not Reported |                |
|                                                                                                    | Cyanocobalamin       |                    |                    | S               | Transplacental                 |                                                      |                 | Not Reported |                |
|                                                                                                    | Lexapro              |                    |                    | C               | Transplacental                 |                                                      |                 | Not Reported |                |
|                                                                                                    | Antibiotics          |                    |                    | C               | Transplacental                 |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-May-2010                                                                                        | 7397018              | DIRECT             | Y                  | DS              |                                |                                                      | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Erectile Dysfunction; Loss<br>Of Libido                                                            | Lexapro              |                    |                    | S               | Oral                           | 10 Mg 1/Day P/O                                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2010                                                                                        | 7177793              | EXPEDITED (15-DAY) | Y                  | OT              | 1000009635                     |                                                      | 51 YR           | Male         | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Aggression; Alcohol Interaction; Amnesia | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                          | Alcohol                       |              |            | S           | Oral         |                               |                 | Not Reported |
|                                          | Hydrochlorothiazide/Valsartan |              |            | C           |              |                               |                 | Not Reported |
|                                          | Chronadalate                  |              |            | C           |              |                               |                 | Not Reported |
|                                          | Simvastatin                   |              |            | C           |              |                               |                 | Not Reported |
|                                          | Inipomp                       |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2010              | 7361774       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012932           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anaphylactic Reaction; Mobility Decreased; Oedema; Oedema Peripheral; Pruritus Generalised; Rash Generalised | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                              | Depakene             |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2010              | 7364041       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013117           |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Deep Vein Thrombosis; Muscle Haemorrhage; Sciatica | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral                   |                 | Not Reported |
|                                                    | Fluindione           |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral                   |                 | Not Reported |
|                                                    | Arixtra              |              |            | S           | Subcutaneous | 1 Dosage Forms, Subcutaneous                    |                 | Not Reported |
|                                                    | Levothyrox           |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2010              | 7398668       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013789           |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Cerebrovascular Accident;<br>Drug Interaction | Lexapro                                |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                               | Plavix                                 |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                               | Lasix (40 Milligram, Tablets)          |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Glucophage Xr (500 Milligram, Tablets) |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Potassium                              |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Toprol XL                              |              |            | C           |              |                                  |                 | Not Reported |
|                                               | Proventil (Inhalant)                   |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2010              | 7399128       | EXPEDITED (15-DAY) | N                  | OT              | 1000013840           |                      | 31 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|--------------|
| Dizziness; Drug<br>Withdrawal Syndrome;<br>Paraesthesia Oral;<br>Ventricular Extrasystoles | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                                                            |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2010              | 7399145       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013850           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Haematochezia         | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Trankimazin          |              |            | C           |              |                                  |                 | Not Reported |



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| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------|-----------------|--------------|----------------|
| 19-May-2010                                                                                                                  | 7399151                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000013847           |                                                 | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| C-Reactive Protein Increased; Clumsiness; Fall; Hyperosmolar State; Hyponatraemia; Rib Fracture; Spinal Compression Fracture | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                   |                 | Not Reported |                |
|                                                                                                                              | Omeprazole              |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D)                         |                 | Not Reported |                |
|                                                                                                                              | Norset                  |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Seresta                 |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Noctamide               |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Theralene               |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2010                                                                                                                  | 7399170                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000013819           |                                                 | 77 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Central Nervous System Vasculitis; Confusional State; Depression; Hypokalaemia; Hyponatraemia; Vomiting                      | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                              | Fludex (Indapamide)     |                    |                    | S               | Oral                 | 1.5 Mg (1.5 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
|                                                                                                                              | Mono Tildiem (Capsules) |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Olmotec (Tablets)       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Azopt (Eye Drops)       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Xalatan                 |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Lexomil (Tablets)       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Inexium (Tablets)       |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
|                                                                                                                              | Cardiocalm (Tablets)    |                    |                    | C               |                      |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-May-2010                                                                                                                  | 7399387                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000013821           |                                                 | 94 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematoma; Hypochromic                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D),                        |                 | Not Reported |                |

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|                                         |         |  |   |      |                                            |              |
|-----------------------------------------|---------|--|---|------|--------------------------------------------|--------------|
| Anaemia;<br>Thrombocytopenic<br>Purpura | Equanil |  | S | Oral | Oral<br>800 Mg (400 Mg, 2 In 1 D),<br>Oral | Not Reported |
|                                         | Plavix  |  | S | Oral | 75 Mg (75 Mg, 1 In 1 D),<br>Oral           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 19-May-2010              | 7407483        | EXPEDITED (15-DAY) | Y                  | OT              | 1000013732           |                                 | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Retinal Injury           | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 19-May-2010              | 11950598                             | EXPEDITED (15-DAY) | Y                  | OT              | 011437U              |                                      | 63 YR           | Male         | NLD            |
| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicide                 | Keppra (Keppra)                      |                    |                    | S               |                      | (5 Mg, 10mg Tablet Times<br>Per 5mg) |                 | Not Reported |                |
|                          | Lexapro (Lexapro) (Not<br>Specified) |                    |                    | S               |                      |                                      |                 | Not Reported |                |
|                          | Cyress                               |                    |                    | C               |                      |                                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 21-May-2010                                                                                              | 7360410              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012912           |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blunted Affect;<br>Dissociation; Drug<br>Interaction; Fatigue;<br>Psychomotor Retardation;<br>Somnolence | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                          | Artane               |                    |                    | S               |                      | 6 Mg (2 Mg, 3 In 1 D)            |                 | Not Reported |                |
|                                                                                                          | Artane               |                    |                    | S               |                      | 4 Mg (2 Mg, 2 In 1 D)            |                 | Not Reported |                |

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| Nebilox                                                         |                      | C                  |                    | Not Reported    |                              |                                            |                 |              |                |
|-----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2010                                                     | 7375526              | EXPEDITED (15-DAY) | Y                  | CA              | 1000013312                   |                                            | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Disease Congenital;<br>Maternal Drugs Affecting<br>Foetus | Escitalopram Oxalate |                    |                    | S               | Transplacental               | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2010                                                     | 7376555              | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2010039102 |                                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;                                           | Arthrotec            |                    |                    | S               |                              | Unk                                        |                 | Pfizer       |                |
| Anxiety; Dizziness;                                             | Lyrica               |                    |                    | S               | Oral                         | 25 Mg, 1x/Day                              |                 | Pfizer       |                |
| Haematocrit Increased;                                          | Lyrica               |                    |                    | S               |                              |                                            |                 | Pfizer       |                |
| Haemoglobin Increased;                                          | Lyrica               |                    |                    | S               |                              |                                            |                 | Pfizer       |                |
| Hot Flush; Memory                                               | Lyrica               |                    |                    | S               |                              |                                            |                 | Pfizer       |                |
| Impairment; Nausea;                                             | Neurontin            |                    |                    | S               |                              | Unk                                        |                 | Pfizer       |                |
| Vision Blurred                                                  | Lexapro              |                    |                    | S               |                              | Unk                                        |                 | Not Reported |                |
|                                                                 | Estrace              |                    |                    | C               |                              | Unk                                        |                 | Not Reported |                |
|                                                                 | Fexofenadine         |                    |                    | C               |                              | Unk                                        |                 | Not Reported |                |
|                                                                 | Avapro               |                    |                    | C               |                              | 300 Mg, Unk                                |                 | Not Reported |                |
|                                                                 | Avapro               |                    |                    | C               |                              |                                            |                 | Not Reported |                |
|                                                                 | Synthroid            |                    |                    | C               |                              | 0.1 Mg, 1x/Day                             |                 | Not Reported |                |
|                                                                 | Synthroid            |                    |                    | C               |                              |                                            |                 | Not Reported |                |
|                                                                 | Morphine Sulfate     |                    |                    | C               |                              | Unk                                        |                 | Not Reported |                |
|                                                                 | Ms Contin            |                    |                    | C               |                              | 15 Mg, 2x/Day                              |                 | Not Reported |                |
|                                                                 | Estradiol            |                    |                    | C               |                              | 1 Mg, 1x/Day                               |                 | Not Reported |                |
|                                                                 | Allegra              |                    |                    | C               |                              | 180 Mg, As Needed                          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|--------------------------------|---------------------------------|-----------------|--------------|----------------|
| 21-May-2010                                                            | 7396125                            | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2010SA027745 |                                 | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hypokalaemia;<br>Hyponatraemia                   | Fludex (Indapamide)                |                    |                    | S               | Oral                           |                                 |                 | Not Reported |                |
|                                                                        | Mono-Tildiem                       |                    |                    | S               | Oral                           |                                 |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate               |                    |                    | S               | Oral                           | 1 Df Qd Dose:1 Unit(S)          |                 | Not Reported |                |
|                                                                        | Olmotec                            |                    |                    | S               | Oral                           | 1 Df Qd Dose:1 Unit(S)          |                 | Not Reported |                |
|                                                                        | Azopt                              |                    |                    | S               | Ophthalmic                     |                                 |                 | Not Reported |                |
|                                                                        | Xalatan                            |                    |                    | S               | Ophthalmic                     |                                 |                 | Not Reported |                |
|                                                                        | Bromazepam                         |                    |                    | S               | Oral                           | 0.25 Df Qd Dose:0.25 Unit(S)    |                 | Not Reported |                |
|                                                                        | Esomeprazole                       |                    |                    | S               | Oral                           |                                 |                 | Not Reported |                |
|                                                                        | Phenobarbital\Quinine Hydrobromide |                    |                    | S               | Oral                           | Two To Three Df Daily           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2010                                                            | 7402359                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000013882                     |                                 | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Jaundice; Left Ventricular Failure; Urinary Tract Infection | Escitalopram Oxalate               |                    |                    | S               | Oral                           | 20 Mg (10 Mg, 2 In 1 D), Oral   |                 | Not Reported |                |
|                                                                        | Memantine Hydrochloride            |                    |                    | S               | Oral                           | 20 Mg (10 Mg, 2 In 1 D), Oral   |                 | Not Reported |                |
|                                                                        | Memantine Hydrochloride            |                    |                    | S               | Oral                           | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                        | Equanil                            |                    |                    | S               | Oral                           | 250 Mg (250 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                        | Kardegic                           |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                        | Cordarone                          |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                        | Aricept                            |                    |                    | C               |                                |                                 |                 | Not Reported |                |
|                                                                        | Cardensiel                         |                    |                    | C               |                                |                                 |                 | Not Reported |                |

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|                                                                                    | Inexium                     |                    |                    | C               |                            |                                  |                 |              | Not Reported   |
|------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                                    | Lasix                       |                    |                    | C               |                            |                                  |                 |              | Not Reported   |
|                                                                                    | Tianeptine                  |                    |                    | C               |                            |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2010                                                                        | 7396727                     | EXPEDITED (15-DAY) | N                  | OT              | NL-ASTRAZENECA-2010SE22555 |                                  |                 | Female       | NLD            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dental Caries;<br>Depression; Dry Mouth;<br>Thinking Abnormal;<br>Weight Increased | Seroquel Xr                 |                    |                    | S               | Oral                       |                                  |                 | Astrazeneca  |                |
|                                                                                    | Citalopram                  |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
|                                                                                    | Lexapro                     |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
|                                                                                    | Nortriptyline Hydrochloride |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
|                                                                                    | Paroxetine Hydrochloride    |                    |                    | S               | Unknown                    |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                                                        | 5807234                     | EXPEDITED (15-DAY) | Y                  | OT              | S05-USA-01283-01           |                                  | 27 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                            | Lexapro                     |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                                                        | 7404639                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000013548                 |                                  | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Inflammation; Leukopenia;<br>Neutropenia                                           | Escitalopram Oxalate        |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                    | Zopiclone                   |                    |                    | C               |                            |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                                                        | 7404817                     | EXPEDITED (15-DAY) |                    | OT              | BCN-AS-2010-RR-085         |                                  | 21 YR           | Female       | AUS            |

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| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| Overdose; Serotonin Syndrome; Somnolence    | Tramadol Hydrochloride    |                    |                    | S               | Oral                 | 3 Gram (S), Oral                                          |                 | Not Reported |                |
|                                             | Quetiapine                |                    |                    | S               | Oral                 | 15 Gram (S), Oral                                         |                 | Not Reported |                |
|                                             | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 560 Milligram Oral.                                       |                 | Not Reported |                |
|                                             | Mirtazapine (Mirtazapine) |                    |                    | S               | Oral                 | 315 Milligram (S), Oral                                   |                 | Not Reported |                |
|                                             | Fluoxetine                |                    |                    | S               | Oral                 | 1.1 Gram (S), Oral                                        |                 | Not Reported |                |
|                                             | Risperidone (Risperidone) |                    |                    | S               | Oral                 | 120 Milligram (S), Oral                                   |                 | Not Reported |                |
|                                             | Lithium                   |                    |                    | S               | Oral                 | 13 Gram (S), Oral                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                 | 7405053                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000013985           |                                                           | 24 YR           | Female       | ESP            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Oculogyric Crisis                           | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 20 Milligram/Milliliters (20 Milligram/Milliliters), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                 | 7405055                   | EXPEDITED (15-DAY) | N                  | OT              | 1000013983           |                                                           | 57 YR           | Female       | CAN            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Pharyngeal Oedema; Throat Irritation | Escitalopram Oxalate      |                    |                    | S               |                      |                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2010                                 | 7406602                   | DIRECT             |                    |                 |                      |                                                           |                 | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                            | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg Daily P.O.                                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------|----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 24-May-2010                                   | 7406603                    | DIRECT                    | Y                           |                          |                               |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Weight Increased                              | Lexapro                    |                           |                             | S                        | Oral                          | 20mg Daily Po                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-May-2010                                   | 7406604                    | DIRECT                    | Y                           |                          |                               |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Weight Increased                              | Lexapro                    |                           |                             | S                        | Oral                          | 20 Mg Daily P.O.              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-May-2010                                   | 7398968                    | EXPEDITED (15-DAY)        | Y                           | HO                       | AU-MYLANLABS-2010S1008237     |                               | 21 YR                    | Female              | AUS                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Serotonin Syndrome                  | Mirtazapine                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Tramadol Hydrochloride     |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Escitalopram Oxalate       |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Fluoxetine                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Lithium                    |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Quetiapine                 |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                               | Risperidone                |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-May-2010                                   | 7399042                    | EXPEDITED (15-DAY)        | N                           | OT                       | US-WATSON-2010-06562          |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a>    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Aphasia; Asthenia; Blepharospasm; | Hydroxychloroquine Sulfate |                           |                             | S                        | Oral                          | 200 Mg, Daily                 | 91 DAY                   | Watson              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |         |   |              |              |       |              |
|----------------------------|---------|---|--------------|--------------|-------|--------------|
| Blood Ketone Body;         | Lexapro | S | Oral         | 10 Mg, Daily | 3 DAY | Not Reported |
| Decreased Appetite;        | Lexapro | S |              |              |       | Not Reported |
| Dehydration; Depressed     | Mobic   | C | Oral         | Unk          |       | Not Reported |
| Level Of Consciousness;    | Xopenex | C | Respiratory  | Unk          |       | Not Reported |
| Depressed Mood;            |         |   | (inhalation) |              |       |              |
| Dizziness; Drug            |         |   |              |              |       |              |
| Interaction; Fall; Feeling |         |   |              |              |       |              |
| Abnormal; Headache;        |         |   |              |              |       |              |
| Heart Rate Irregular;      |         |   |              |              |       |              |
| Hypokalaemia; Mental       |         |   |              |              |       |              |
| Disorder; Mood Altered;    |         |   |              |              |       |              |
| Muscle Spasms; Muscle      |         |   |              |              |       |              |
| Twitching; Myalgia;        |         |   |              |              |       |              |
| Nausea; Paraesthesia;      |         |   |              |              |       |              |
| Personality Change;        |         |   |              |              |       |              |
| Syncope; Tremor; White     |         |   |              |              |       |              |
| Blood Cell Count           |         |   |              |              |       |              |
| Increased                  |         |   |              |              |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2010              | 7406623       | DIRECT           | Y                  | OT              |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dry Eye; Retinal Tear;<br>Vision Blurred | Lexapro        |              |            | S           | Oral         | 10 Md Qd Po        |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2010              | 7406632       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013922           |                      | 52 YR      | Male       | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Heart Rate Irregular;<br>Nausea; Restlessness | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 B) ,Oral |                 | Not Reported |
|                                               | Lorasifar            |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2010              | 7407946       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013988           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                  |                                                           |   |                                |              |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---|--------------------------------|--------------|
| Abdominal Pain Upper;<br>Drug Ineffective; Meniscus<br>Injury; Nausea; Poor<br>Quality Sleep; Spinal<br>Fracture | Lexapro                                                   | S | 20 Mg (20 Mg, 1 In 1 D)        | Not Reported |
|                                                                                                                  | Celebrex                                                  | S | (3 In 1 D)                     | Not Reported |
|                                                                                                                  | Seroquel                                                  | S | 600 Mg (600 Mg, At<br>Bedtime) | Not Reported |
|                                                                                                                  | Tegretol                                                  | C |                                | Not Reported |
|                                                                                                                  | Lopresor                                                  | C |                                | Not Reported |
|                                                                                                                  | Glucophage                                                | C |                                | Not Reported |
|                                                                                                                  | Prilosec                                                  | C |                                | Not Reported |
|                                                                                                                  | Dichloralphenazone/Isomethepte<br>ne Mucate/Acetaminophen | C |                                | Not Reported |
|                                                                                                                  | Synthroid                                                 | C |                                | Not Reported |
|                                                                                                                  | Klonopin                                                  | C |                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2010              | 7407947       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013969           |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------|-----------------|--------------|
| Mental Status Changes | Lexapro         |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (200 Mg, 1 In<br>1 D), Oral |                 | Not Reported |
|                       |                 |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (200 Mg, 1 In<br>1 D), Oral |                 |              |
|                       | Lexapro         |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral    |                 | Not Reported |
|                       |                 |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral    |                 |              |
|                       | Tacrolimus      |              |            | S           | Oral         | Oral                                                                |                 | Not Reported |
|                       | Acyclovir       |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Fludrocortisone |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Trimethoprim    |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Magnesium       |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Lasix           |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Metoprolol      |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Omeprazole      |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Nystatin        |              |            | C           |              |                                                                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                  | Multivitamins        |                    |                    | C               |                      |                               |                 |              | Not Reported   |
|----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                                  | Aspirin              |                    |                    | C               |                      |                               |                 |              | Not Reported   |
|                                                                                  | Oxycodone            |                    |                    | C               |                      |                               |                 |              | Not Reported   |
|                                                                                  | Cyclobenzaprine      |                    |                    | C               |                      |                               |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2010                                                                      | 7410435              | DIRECT             | N                  | DS              |                      |                               |                 | Male         | USA            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Impaired Work Ability                                                | Risperidone Odt      |                    |                    | S               |                      | 1 Tablet Once Bedtime         |                 | Not Reported |                |
|                                                                                  | Lexapro              |                    |                    | S               |                      | 1 Tablet Once Morning         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2010                                                                      | 7319687              | EXPEDITED (15-DAY) | Y                  | DE              | 1000011867           |                               | 62 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed Suicide                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2010                                                                      | 7365625              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013054           |                               | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Dysphonia; Dysuria; Erythema; Headache; Mouth Ulceration; Vasculitis | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                  | Abilify              |                    |                    | S               |                      | 15 Mg (15 Mg, 1 In 1 D)       |                 | Not Reported |                |
|                                                                                  | Xanax                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                  | Mopral               |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-May-2010                                                                      | 7409080              | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000014090           |                               | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                      |                             |   |               |                                          |              |
|------------------------------------------------------------------------------------------------------|-----------------------------|---|---------------|------------------------------------------|--------------|
| Asthenia; Chest Pain;<br>Diplopia; Gaze Palsy;<br>Musculoskeletal Stiffness;<br>Tolosa-Hunt Syndrome | Escitalopram Oxalate        | S | Oral          | Oral                                     | Not Reported |
|                                                                                                      | Influenza Virus Vaccine Nos | S | Intramuscular | (1 Dosage Forms, Once),<br>Intramuscular | Not Reported |

| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 28-May-2010                                        | 7410918              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014089           |                          | 15 YR           | Female       | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Off<br>Label Use; Somnolence | Escitalopram Oxalate |                    |                    | S               |                      | One Blister (Once), Oral |                 | Not Reported |                |
|                                                    | Zolpidem             |                    |                    | S               | Oral                 | One Blister (Once), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 28-May-2010                                                                                                                                      | 7440815                                                | EXPEDITED (15-DAY) | Y                  | HO              | 2010AP001032         |                      | 21 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram T Wave<br>Inversion; Intentional<br>Overdose; Serotonin<br>Syndrome | Escitalopram Oxalate<br>(Escitalopram Oxalate)         |                    |                    | S               |                      | 560 Mg               |                 | Not Reported |                |
|                                                                                                                                                  | Tramadol Hydrochloride                                 |                    |                    | S               |                      | 3 Gm                 |                 | Not Reported |                |
|                                                                                                                                                  | Mirtazapine (Mirtazapine)                              |                    |                    | S               |                      | 315 Mg               |                 | Not Reported |                |
|                                                                                                                                                  | Fluoxetine Hydrochloride<br>(Fluoxetine Hydrochloride) |                    |                    | S               |                      | 1.1 Gm               |                 | Not Reported |                |
|                                                                                                                                                  | Risperidone (Risperidone)                              |                    |                    | S               |                      | 120 Mg               |                 | Not Reported |                |
|                                                                                                                                                  | Quetiapine                                             |                    |                    | S               |                      | 15 Gm                |                 | Not Reported |                |
|                                                                                                                                                  | Lithium (Lithium)                                      |                    |                    | S               |                      | 13 Gm                |                 | Not Reported |                |

| <u>FDA Received Date</u>                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 01-Jun-2010                                                     | 7383394              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013228           |                                  | 33 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Ejaculation Delayed;<br>Insomnia; Libido | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, In 1 D),Oral         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                      |   |      |                               |              |
|---------------------------------------------------------------------|----------------------|---|------|-------------------------------|--------------|
| Decreased; Poor Quality Sleep; Therapeutic Product Effect Decreased | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|---------------------------------------------------------------------|----------------------|---|------|-------------------------------|--------------|

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 01-Jun-2010                                                                                                                                     | 7405693                                 | EXPEDITED (15-DAY) | N                  | OT              | US-ASTRAZENECA-2010SE23095 |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper; Anxiety; Drug Ineffective; Insomnia; Meniscus Injury; Nausea; Panic Attack; Thoracic Vertebral Fracture; Thyroid Disorder | Seroquel                                |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                                                                 | Celebrex                                |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                                                 | Effexor                                 |                    |                    | S               | Oral                       |                      | 0 YR            | Not Reported |                |
|                                                                                                                                                 | Lexapro                                 |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                                                 | Cymbalta                                |                    |                    | S               | Oral                       |                      | 0 MTH           | Not Reported |                |
|                                                                                                                                                 | Neurontin                               |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                 | Glucophage                              |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                 | Prilosec                                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                 | Dichloralphenazone\Isometheptene Mucate |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                                                                                 | Lorcet                                  |                    |                    | C               |                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 01-Jun-2010                                                | 7405738        | EXPEDITED (15-DAY) | N                  | OT              | A0860846A            |                      | 74 YR           | Male            | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anger; Confusional State; Hallucination; Suicidal Ideation | Lamictal       |                    |                    | S               | Oral                 | 175mg Twice Per Day  |                 | Glaxosmithkline |                |
|                                                            | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported    |                |
|                                                            | Digoxin        |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                            | Coumadin       |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                            | Vimpat         |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                            | Seroquel       |                    |                    | C               |                      |                      |                 | Not Reported    |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 01-Jun-2010              | 7410379        | EXPEDITED (15-DAY) | Y                  | HO              | DSA_43183_2010       |                      | 77 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                                    |   |            |                                         |              |
|-------------------------|------------------------------------|---|------------|-----------------------------------------|--------------|
| Central Nervous System  | Mono-Tildiem                       | S | Oral       | 300 Mg Qd Oral                          | Not Reported |
| Vasculitis; Depression; | Fludex /00340101/                  | S | Oral       | 1.5 Mg Qd Oral                          | Not Reported |
| Hypokalaemia;           | Escitalopram Oxalate               | S | Oral       | Dose: 1 Unit Daily Oral                 | Not Reported |
| Hyponatraemia; Vomiting | Olmetec                            | S | Oral       | Dose: 1 Unit Daily Oral                 | Not Reported |
|                         | Azopt                              | S | Ophthalmic | 1 Gtt Qd Ophthalmic                     | Not Reported |
|                         | Xalatan                            | S | Ophthalmic | 1 Gtt Qd Ophthalmic                     | Not Reported |
|                         | Bromazepam                         | S | Oral       | 0.25 Df Qd, Dose: 0.25 Units Daily Oral | Not Reported |
|                         | Esomeprazole (Esomeprazole)        | S | Oral       | 20 Mg Qd Oral                           | Not Reported |
|                         | Phenobarbital\Quinine Hydrobromide | S | Oral       | Dose: Daily Oral                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2010              | 7412458       | EXPEDITED (15-DAY) | N                  | OT              | 1000014091           |                      | 46 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------------|-----------------|--------------|
| Anosmia; Anxiety;                                                                        | Escitalopram Oxalate |              |            | S           | Oral         | Oral                                                                      |                 | Not Reported |
| Depression; Hepatic Steatosis;                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral |                 | Not Reported |
| Hypersensitivity; Impaired Work Ability; Influenza;                                      |                      |              |            |             | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral |                 |              |
| Lower Respiratory Tract Infection; Memory Impairment; Oedema                             |                      |              |            |             | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral ; (1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral |                 |              |
| Peripheral; Swelling Face; Tinnitus; Upper Respiratory Tract Infection; Weight Increased | Phenylpropanolamine  |              |            | S           | Oral         | 50 Mg (50 Mg,1 In 1 D),Oral                                               |                 | Not Reported |
|                                                                                          | Champix              |              |            | S           | Oral         | 0.5 Mg (0.5 Mg,1 In 1 D),Oral                                             |                 | Not Reported |
|                                                                                          | Amoxin               |              |            | S           | Oral         | Oral                                                                      |                 | Not Reported |
|                                                                                          | Oxazepam             |              |            | C           |              |                                                                           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 01-Jun-2010                                                                                               | 7412480        | DIRECT             | N                  | RI              |                      |                               | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Discomfort; Dry Mouth; Lip Dry; Muscle Contractions Involuntary; Salivary Hypersecretion; Speech Disorder | Lexapro        |                    |                    | S               | Oral                 | 1 1/2 Tablets Daily Po        |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2010                                                                                               | 7413099        | EXPEDITED (15-DAY) | Y                  | OT              | 1000014040           |                               | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Inappropriate Schedule Of Product Administration; Seizure; Treatment Noncompliance                        | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                           | Xanax          |                    |                    | S               | Oral                 | 0.5 Mg, Prn, Oral             |                 | Not Reported |                |
|                                                                                                           | Ativan         |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2010                                                                                               | 7413407        | DIRECT             |                    |                 |                      |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                          | Lexapro        |                    |                    | S               | Oral                 | 10mg Daily P.O.               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2010                                                                                               | 7413475        | DIRECT             | Y                  |                 |                      |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                          | Lexapro        |                    |                    | S               | Oral                 | 20mg Daily Po                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 02-Jun-2010                                                  | 7413484                   | DIRECT             | Y                  |                 |                      |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                             | Lexapro                   |                    |                    | S               | Oral                 | 20mg Daily P.O.         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2010                                                  | 7413569                   | EXPEDITED (15-DAY) | Y                  | HO, LT          | USA/AUS/10/0013240   |                         | 21 YR           | Unknown      | AUS            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Ileus; Overdose; Serotonin Syndrome                          | Risperidone               |                    |                    | S               | Oral                 | 120 Mg, Per Oral        |                 | Not Reported |                |
|                                                              | Fluoxetine                |                    |                    | S               | Oral                 | 1.1 Gm, Per Oral        |                 | Not Reported |                |
|                                                              | Tramadol Hydrochloride    |                    |                    | S               | Oral                 | 3 Gm, Per Oral          |                 | Not Reported |                |
|                                                              | Quetiapine                |                    |                    | S               | Oral                 | 15 Gm, Per Oral         |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 560 Mg, Per Oral        |                 | Not Reported |                |
|                                                              | Mirtazapine (Mirtazapine) |                    |                    | S               | Oral                 | 315 Mg, Per Oral        |                 | Not Reported |                |
|                                                              | Lithium                   |                    |                    | S               | Oral                 | 13 Gm, Per Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2010                                                  | 7011298                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000005786           |                         | 29 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Pregnancy; Toxoplasmosis | Escitalopram Oxalate      |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate      |                    |                    | S               |                      | 5 Mg (5 Mg, 1 In 1 D)   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2010                                                  | 7320246                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000011889           |                         | 40 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                        | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                          |                             |                    |                    |                                  |                      |                            |                 |            |                 |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|----------------------------------|----------------------|----------------------------|-----------------|------------|-----------------|
| Chorea                                                                                                                                   | Escitalopram Oxalate        | S                  | Oral               | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported         |                            |                 |            |                 |
|                                                                                                                                          | Trazolan                    | C                  |                    |                                  | Not Reported         |                            |                 |            |                 |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 03-Jun-2010                                                                                                                              | 7416700                     | EXPEDITED (15-DAY) | Y                  | OT                               | 1000014098           |                            |                 | Unknown    | DNK             |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                 |
| Maternal Exposure During Breast Feeding;<br>Neutropenia                                                                                  | Escitalopram Oxalate        |                    |                    | S                                | Transmammary         | Transmammary               |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 03-Jun-2010                                                                                                                              | 7416701                     | EXPEDITED (15-DAY) |                    | OT                               | 1000014125           |                            |                 | Female     | GBR             |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                 |
| Anger; Feeling Abnormal                                                                                                                  | Escitalopram Oxalate        |                    |                    | S                                | Oral                 | Oral                       |                 |            | Not Reported    |
| <u>FDA Received Date</u>                                                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u> | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u>  |
| 03-Jun-2010                                                                                                                              | 7994731                     | EXPEDITED (15-DAY) | N                  | OT                               | B0657267A            |                            | 40 YR           | Female     | FRA             |
| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>         | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                 |
| Blood Pressure Increased;<br>Foetal Death; Hellp<br>Syndrome; Maternal<br>Exposure During<br>Pregnancy; Proteinuria;<br>Thrombocytopenia | Clamoxyl (Amoxicillin)      |                    |                    | S                                | Oral                 | 1g Three Times Per Day     |                 |            | Glaxosmithkline |
|                                                                                                                                          | Amitriptyline Hydrochloride |                    |                    | S                                | Oral                 |                            |                 |            | Unknown         |
|                                                                                                                                          | Bromazepam                  |                    |                    | S                                | Oral                 | 48mg Per Day               | 1 DAY           |            | Unknown         |
|                                                                                                                                          | Rivotril                    |                    |                    | S                                | Oral                 | 2unit Per Day              |                 |            | Unknown         |
|                                                                                                                                          | Prazepam                    |                    |                    | S                                | Oral                 |                            |                 |            | Unknown         |
|                                                                                                                                          | Topiramate                  |                    |                    | S                                | Oral                 |                            |                 |            | Unknown         |
|                                                                                                                                          | Zyprexa                     |                    |                    | S                                | Oral                 |                            |                 |            | Unknown         |
|                                                                                                                                          | Zopiclone                   |                    |                    | S                                | Oral                 | 7.5mg Per Day              | 3 MTH           |            | Unknown         |
|                                                                                                                                          | Chlorpromazine              |                    |                    | S                                | Oral                 | 20drop Three Times Per Day |                 |            | Unknown         |



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|                       |   |         |                     |        |         |
|-----------------------|---|---------|---------------------|--------|---------|
| Oxazepam              | S | Oral    | 10mg Twice Per Day  |        | Unknown |
| Spasfon Lyoc          | S | Oral    | 80mg Twice Per Day  |        | Unknown |
| Effexor               | S | Oral    | 37.5mg Per Day      |        | Unknown |
| Stilnox               | S | Oral    | 10mg Per Day        | 1 MTH  | Unknown |
| Trimeprazine Tartrate | S | Oral    | 100drop Per Day     |        | Unknown |
| Escitalopram Oxalate  | S | Oral    | 10mg Per Day        | 16 DAY | Unknown |
| Akineton              | S | Oral    | 4mg Twice Per Day   |        | Unknown |
| Periciazine           | S | Oral    | 50drop Per Day      |        | Unknown |
| Econazole Nitrate     | C | Vaginal |                     | 6 DAY  | Unknown |
| Flagyl                | C | Oral    | 500mg Twice Per Day | 6 DAY  | Unknown |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7399722       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013845           |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Hyperreflexia; Nervous System Disorder; Seizure; Tremor | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7410310       | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | DE-ABBOTT-10P-062-0648697-00 |                      | 68 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Akineton       |              |            | S           |              |                    |                 | Not Reported |
|                       | Cipralelex     |              |            | S           |              | 15-20mg            |                 | Not Reported |
|                       | Risperdal      |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7417969       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014254           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Localised Infection;  | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                            |   |              |
|----------------------------------------------------------------------|----------------------------|---|--------------|
| Localised Oedema;<br>Nausea; Nodule; Pain;<br>Pyrexia; Swelling Face | Benzodiazepine Derivatives | C | Not Reported |
|----------------------------------------------------------------------|----------------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7417970       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012225           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Anal Incontinence; Fall;<br>Hot Flush; Paraesthesia;<br>Serotonin Syndrome;<br>Vertigo | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |
|                                                                                        | Analgesics           |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7418428       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014234           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Crying; Impulsive<br>Behaviour; Intentional<br>Self-Injury | Citalopram Hydrobromide |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1<br>D),Oral                                   |                 | Not Reported |
|                                                                     | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1<br>D),Oral ; 15 Mg (15 Mg, 1<br>In 1 D),Oral |                 | Not Reported |
|                                                                     |                         |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1<br>D),Oral ; 15 Mg (15 Mg, 1<br>In 1 D),Oral |                 |              |
|                                                                     | Hydroxyzine (Tablets)   |              |            | C           |              |                                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Jun-2010              | 7418438       | EXPEDITED (15-DAY) | Y                  | HO              | DSM-2010-00772       |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Central Nervous System<br>Vasculitis; Confusional<br>State; Depression;<br>Hypokalaemia;<br>Hyponatraemia; Vomiting | Olmotec             |              |            | S           | Oral         | (1 In 1 D),Oral                    |                 | Not Reported |
|                                                                                                                     | Fludex (Indapamide) |              |            | S           | Oral         | 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |   |            |                                    |              |
|--------------------------------------|---|------------|------------------------------------|--------------|
| Mono-Tildiem                         | S | Oral       | 300 Mg (300 Mg,1 In 1 D),Oral      | Not Reported |
| Escitalopram Oxalate                 | S | Oral       | (1 In 1 D), Oral                   | Not Reported |
| Azopt                                | S | Ophthalmic | 1 Get (1 Gtt,1 In 1 D), Ophthalmic | Not Reported |
| Xalatan                              | S | Ophthalmic | 1 Get (1 Gtt,1 In 1 D), Ophthalmic | Not Reported |
| Lexomil (Bromazepam)<br>(Bromazepam) | S | Oral       | 0.25 Units (1 In 1 D), Oral        | Not Reported |
| Esomeprazole                         | S | Oral       | 20 Mg (20 Mg,1 In 1 D), Oral       | Not Reported |
| Crataegus                            | S | Oral       | (1 In 1 D), Oral                   | Not Reported |

| <u>FDA Received Date</u>     | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|-------------------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------|-----------------|--------------|----------------|
| 04-Jun-2010                  | 7418944                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000013442                   |                               | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate                    | Escitalopram Oxalate                |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| Aminotransferase             | Escitalopram Oxalate                |                    |                    | S               | Oral                         | Oral                          |                 | Not Reported |                |
| Increased; Blood             | Votum (Tablets)                     |                    |                    | C               |                              |                               |                 | Not Reported |                |
| Creatinine Increased;        | Ass(100 Milligram, Tablets)         |                    |                    | C               |                              |                               |                 | Not Reported |                |
| Blood Pressure Increased;    | Pantoprazol (40 Milligram, Tablets) |                    |                    | C               |                              |                               |                 | Not Reported |                |
| Blood Urea Increased;        | Metformin (500 Milligram, Tablets)  |                    |                    | C               |                              |                               |                 | Not Reported |                |
| Bradycardia; Cardiac         | Lyrica                              |                    |                    | C               |                              |                               |                 | Not Reported |                |
| Arrest; Fall; Fibrin D Dimer |                                     |                    |                    |                 |                              |                               |                 |              |                |
| Increased; Long Qt           |                                     |                    |                    |                 |                              |                               |                 |              |                |
| Syndrome; Torsade De         |                                     |                    |                    |                 |                              |                               |                 |              |                |
| Pointes; Vascular            |                                     |                    |                    |                 |                              |                               |                 |              |                |
| Encephalopathy               |                                     |                    |                    |                 |                              |                               |                 |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2010                  | 7345199                             | EXPEDITED (15-DAY) | Y                  | HO, OT          | IT-ABBOTT-10P-083-0634308-00 |                               | 40 YR           | Male         | ITA            |
| <u>Preferred Term</u>        | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation;                   | Akineton                            |                    |                    | S               | Oral                         | Overdose: 10 Df               |                 | Not Reported |                |
| Electrocardiogram            |                                     |                    |                    |                 |                              |                               |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                        |   |      |                 |              |
|--------------------------|------------------------|---|------|-----------------|--------------|
| Repolarisation           | Unspecified Ingredient | S | Oral | Overdose: 20 Df | Not Reported |
| Abnormality; Intentional | Escitalopram Oxalate   | S | Oral | Overdose: 14 Df | Not Reported |
| Overdose; Overdose;      | Lithium Carbonate      | S | Oral | Overdose: 10 Df | Not Reported |
| Sinus Bradycardia        | Risperdal              | C |      | 2.6786 Mg       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jun-2010              | 7411681              | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2010SE24728 |                      | 24 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                | Inexium              |                    |                    | S               | Oral                       |                      | 2 MTH           | Astrazeneca  |                |
|                          | Bromazepam           |                    |                    | S               | Oral                       |                      | 7 DAY           | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                          | Efferalgan Codeine   |                    |                    | S               | Oral                       | 500 Mg As Requested  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 08-Jun-2010                                                                                                                                                                                                                                                                                                                                                       | 7005978              | EXPEDITED (15-DAY) | Y                  | HO              | 1000006235           |                                 | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Activated Partial Thromboplastin Time Prolonged; Ascites; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Condition Aggravated; Gastrooesophageal Reflux Disease; Hepatic Cirrhosis; Hepatic Fibrosis; Hepatic Steatosis; Hepatomegaly; Liver Disorder; Ocular Icterus; Red Blood Cell Count Decreased; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Zopiclone            |                    |                    | S               | Oral                 | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                   | Dolotmin             |                    |                    | C               |                      |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Splenomegaly; Waist  
Circumference Increased;  
White Blood Cell Count  
Increased; Yellow Skin

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|------------------------------|----------------|
| 08-Jun-2010                                                                                                             | 7360456                   | EXPEDITED (15-DAY) | Y                  | DS              | 1000012909           |                                         | 58 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Back Pain; Drug<br>Interaction; Impaired Work<br>Ability; Musculoskeletal<br>Pain; Oedema Peripheral;<br>Polyneuropathy | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral         |                 | Not Reported                 |                |
|                                                                                                                         | Terbinafine Hydrochloride |                    |                    | S               | Oral                 | 250 Mg (250 Mg, 1 In 1<br>D),Oral       |                 | Not Reported                 |                |
|                                                                                                                         | Sertraline Hydrochloride  |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D),<br>Oral        |                 | Not Reported                 |                |
|                                                                                                                         | Zovirax<br>Symbicort      |                    |                    | C<br>C          |                      |                                         |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 08-Jun-2010                                                                                                             | 7418536                   | DIRECT             | Y                  | DE              |                      |                                         | 44 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Akathisia; Completed<br>Suicide; Impaired Work<br>Ability; Insomnia                                                     | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Daily Po                          |                 | Not Reported                 |                |
|                                                                                                                         | Xanax                     |                    |                    | S               | Oral                 | Decreased From 4mg TO<br>.5 Mg Daily Po |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 08-Jun-2010                                                                                                             | 7420404                   | EXPEDITED (15-DAY) | Y                  | LT              | 1000014265           |                                         | 71 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>                   |                |
| Drug Interaction;<br>Hyponatraemia                                                                                      | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral             |                 | Not Reported                 |                |
|                                                                                                                         | Potassium Chloride        |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported                 |                |
|                                                                                                                         | Mirtazapine               |                    |                    | S               | Oral                 | 15 Mg, Oral                             |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                               |                         |                    |                    |                 |                              |                      |                 |              |                |
|---------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Seroquel                                                                                                      |                         |                    | C                  |                 |                              | Not Reported         |                 |              |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2010                                                                                                   | 7252348                 | EXPEDITED (15-DAY) | Y                  | DE, LT          | PHHY2010FR02745              |                      | 48 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Insomnia;<br>Myalgia; Persistent<br>Depressive Disorder;<br>Suicide Attempt | Glivec                  |                    |                    | S               | Oral                         | 400 Mg, Qd           |                 | Novartis     |                |
|                                                                                                               | Baraclude               |                    |                    | S               | Oral                         | 0.5 Mg, Qd           |                 | Not Reported |                |
|                                                                                                               | Zopiclone               |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate    |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                               | Zyprexa                 |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2010                                                                                                   | 7255775                 | EXPEDITED (15-DAY) | Y                  | DE, LT          | PHHY2010FR03314              |                      | 48 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Persistent Depressive<br>Disorder; Suicide Attempt                                      | Glivec                  |                    |                    | S               | Oral                         | 400 Mg, Qd           |                 | Novartis     |                |
|                                                                                                               | Baraclude               |                    |                    | S               |                              | 0.05 Mg/Day          |                 | Not Reported |                |
|                                                                                                               | Zyprexa                 |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate    |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                                               | Zopiclone               |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jun-2010                                                                                                   | 7409341                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2010064874 |                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hypokalaemia;<br>Hyponatraemia                                                          | Xalatan                 |                    |                    | S               | Ophthalmic                   | 1 Drop(S);Daily      |                 | Pfizer       |                |
|                                                                                                               | Diltiazem Hydrochloride |                    |                    | S               | Oral                         | 300 Mg, Daily        | 38 DAY          | Not Reported |                |
|                                                                                                               | Olmotec                 |                    |                    | S               | Oral                         | 1 Unit Daily         | 38 DAY          | Not Reported |                |
|                                                                                                               | Fludex (Indapamide)     |                    |                    | S               | Oral                         | Unk                  | 9 DAY           | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                        |   |            |           |              |
|--------------------------------------------------------|---|------------|-----------|--------------|
| Escitalopram Oxalate                                   | S | Oral       | Unk       | Not Reported |
| Azopt                                                  | S | Ophthalmic | Unk       | Not Reported |
| Bromazepam                                             | S | Oral       | Unk       | Not Reported |
| Esomeprazole                                           | S | Oral       | Unk       | Not Reported |
| Phenobarbital\Quinine<br>Hydrobromide\Valerian Extract | S | Oral       | Unk;Daily | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 09-Jun-2010              | 7414258       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-<br>2010SA030905 |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Foetal Death; Hellp<br>Syndrome | Stilnox                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Zopiclone                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Chlorpromazine              |              |            | S           | Oral         | Dose:60 Unit(S)    |                 | Not Reported |
|                                 | Periciazine                 |              |            | S           | Oral         | Dose:50 Unit(S)    |                 | Not Reported |
|                                 | Amitriptyline Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Amitriptyline Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Bromazepam                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Bromazepam                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Rivotril                    |              |            | S           | Oral         | Dose:2 Unit(S)     |                 | Not Reported |
|                                 | Prazepam                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Topiramate                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                 | Zyprexa                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Zyprexa                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Oxazepam                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Spasfon-Lyoc                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Effexor                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Theralene                   |              |            | S           | Oral         | Dose:100 Unit(S)   |                 | Not Reported |
|                                 | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                 | Biperiden Hydrochloride     |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |              |
|-------------------|---|---------|--------------|
| Amoxicillin       | S | Oral    | Not Reported |
| Econazole Nitrate | C | Unknown | Not Reported |
| Flagyl            | C | Oral    | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 09-Jun-2010                       | 7416706                | EXPEDITED (15-DAY)        | N                           | OT                       | 1000014124                    |                               | 48 YR               | Female              | NLD                     |

| <a href="#">Preferred Term</a>                                                                                      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>                                      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|------------------------------------------------------------------|--------------------------|---------------------|
| Crying; Depression;<br>Dizziness; Feeling<br>Abnormal; Hyperhidrosis;<br>Restlessness; Suicidal<br>Ideation; Tremor | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                          | Not Reported        |
|                                                                                                                     | Remeron                 |                       |                     | C                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                          | Not Reported        |
|                                                                                                                     | Foster                  |                       |                     | C                    |                       |                                                                  |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 09-Jun-2010                       | 7419521                | DIRECT                    | N                           | HO, LT, RI, OT           |                               |                               | 86 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Product Quality Issue;<br>Rectal Haemorrhage;<br>Transfusion | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg 2 X Daily Po           |                          | Forest              |
|                                                              | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg 2 X Daily Po           |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Jun-2010                       | 7367166                | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | 1000013141                    |                               | < 1 DAY             | Male                | DNK                     |

| <a href="#">Preferred Term</a>                                                                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>                | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|--------------------------------------------|--------------------------|---------------------|
| Apgar Score Low;<br>Caesarean Section; Drug<br>Withdrawal Syndrome<br>Neonatal;<br>Hyperglycaemia; | Escitalopram Oxalate    |                       |                     | S                    | Transplacental        | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental |                          | Not Reported        |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypertonia Neonatal;  
Hypopnoea; Maternal  
Drugs Affecting Foetus;  
Selective Eating Disorder;  
Yawning

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jun-2010                                                                                                                | 7399719                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000013871                                          |                      | 36 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Diplopia;<br>Dyspnoea; Fear; Frontal<br>Lobe Epilepsy; Loss Of<br>Libido; Muscle Spasms;<br>Paraesthesia; Rash | Escitalopram Oxalate        |                    |                    | S               | Oral                                                | (20 Mg),Oral         |                 | Not Reported |                |
|                                                                                                                            | Escitalopram Oxalate        |                    |                    | S               | Oral                                                | (60 Mg),Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2010                                                                                                                | 7415524                     | EXPEDITED (15-DAY) | N                  | OT              | NL-ASTRAZENECA-<br>2010SE22548                      |                      |                 | Male         | NLD            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Homicidal<br>Ideation; Libido<br>Decreased; Suicidal<br>Ideation; Tooth Disorder;<br>Weight Increased              | Seroquel                    |                    |                    | S               | Oral                                                |                      |                 | Zeneca       |                |
|                                                                                                                            | Amitriptyline Hydrochloride |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                                            | Lexapro                     |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                                            | Trazodone Hydrochloride     |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                                            | Prothiaden                  |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                                            | Oxazepam                    |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2010                                                                                                                | 7415950                     | NON-EXPEDITED      | N                  |                 | US-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-00694RO |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Hypomania;<br>Increased Appetite;<br>Weight Increased                                                            | Lithium Carbonate           |                    |                    | S               | Oral                                                | 600 Mg               |                 | Roxane       |                |
|                                                                                                                            | Lithium Carbonate           |                    |                    | S               |                                                     | 750 Mg               |                 | Roxane       |                |
|                                                                                                                            | Lexapro                     |                    |                    | S               | Oral                                                | 20 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                              | Lexapro                |                    | S                  | Oral            | 10 Mg                |                             | Not Reported    |              |                |
|------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
|                              | Lexapro                |                    | S                  | Oral            | 5 Mg                 |                             | Not Reported    |              |                |
|                              | Tegretol               |                    | C                  | Oral            | 600 Mg               |                             | Not Reported    |              |                |
|                              | Ativan                 |                    | C                  | Oral            | 1.5 Mg               |                             | Not Reported    |              |                |
|                              | Vitamin D2             |                    | C                  |                 |                      |                             | Not Reported    |              |                |
|                              | Haldol                 |                    | C                  | Oral            |                      |                             | Not Reported    |              |                |
| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jun-2010                  | 7423926                | EXPEDITED (15-DAY) | Y                  | OT              | 1000014375           |                             | 65 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Movement Disorder            | Lexapro                |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                              | Lexapro                |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2010                  | 7402287                | EXPEDITED (15-DAY) | Y                  | HO              | AU-WATSON-2010-06800 |                             | 21 YR           | Female       | AUS            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Serotonin Syndrome | Mirtazapine            |                    |                    | S               |                      | 315 Mg Single               |                 | Watson       |                |
|                              | Risperidone            |                    |                    | S               |                      | 120 Mg                      |                 | Watson       |                |
|                              | Fluoxetine             |                    |                    | S               |                      | 1.1 G Single                |                 | Watson       |                |
|                              | Tramadol Hydrochloride |                    |                    | S               |                      | 3 G Single                  |                 | Watson       |                |
|                              | Quetiapine             |                    |                    | S               |                      | 15 G Single                 |                 | Not Reported |                |
|                              | Escitalopram Oxalate   |                    |                    | S               |                      | 560 Mg Single               |                 | Not Reported |                |
|                              | Lithium                |                    |                    | S               |                      | 13 G Single                 |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jun-2010                  | 7424492                | EXPEDITED (15-DAY) | Y                  | HO              | 1000014376           |                             | 57 YR           | Female       | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Condition          | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                             |   |              |
|------------------------|-----------------------------|---|--------------|
| Aggravated; Creatinine | Glucor                      | C | Not Reported |
| Renal Clearance        | Gliclazide                  | C | Not Reported |
| Decreased; Dizziness;  | Beclomethasone Dipropionate | C | Not Reported |
| Headache;              | Ramipril                    | C | Not Reported |
| Hyperkalaemia;         | Prazosin Hydrochloride      | C | Not Reported |
| Hyponatraemia; Visual  | Lantus                      | C | Not Reported |
| Impairment             | Previscan (Fluindione)      | C | Not Reported |
|                        | Alteis                      | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2010              | 7424519       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014378           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Vasculitis            | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Xanax                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jun-2010              | 7427249       | EXPEDITED (15-DAY) | Y                  | HO              | 2010US001864         |                      | 55 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Drug Interaction; Mental | Prograf                 |              |            | S           | Oral         | Oral                                                         |                 | Not Reported |
| Status Changes           | Lexapro                 |              |            | S           | Oral         | 10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral |                 | Not Reported |
|                          |                         |              |            |             | Oral         | 10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral |                 |              |
|                          |                         |              |            |             | Oral         | 10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral |                 |              |
|                          |                         |              |            |             | Oral         | 10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral |                 |              |
|                          |                         |              |            |             | Oral         | 10 Mg, Uid/Qd, Oral; 5 Mg, Uid/Qd, Oral; 20 Mg, Uid/Qd, Oral |                 |              |
|                          | Acyclovir               |              |            | C           |              |                                                              |                 | Not Reported |
|                          | Fludrocortisone Acetate |              |            | C           |              |                                                              |                 | Not Reported |
|                          | Omeprazole              |              |            | C           |              |                                                              |                 | Not Reported |
|                          | Nystatin                |              |            | C           |              |                                                              |                 | Not Reported |
|                          | Multi-Vitamin           |              |            | C           |              |                                                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |              |
|--------------------------------|---|--------------|
| Aspirin (Acetylsalicylic Acid) | C | Not Reported |
| Oxycodone (Oxycodone)          | C | Not Reported |
| Cyclobenzaprine                | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2010              | 7407509       | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2010FR33477      |                      | 50 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Loss Of<br>Personal Independence In<br>Daily Activities;<br>Somnolence | Aliskiren            |              |            | S           |              | 300 Mg             |                 | Novartis     |
|                                                                                  | Aliskiren            |              |            | S           |              | 150 Mg             |                 | Novartis     |
|                                                                                  | Escitalopram Oxalate |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Jun-2010              | 7419044       | EXPEDITED (15-DAY) | N                  | OT              | NL-ASTRAZENECA-2010SE22612 |                      |            | Male       | NLD            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Homicidal<br>Ideation; Insomnia;<br>Irritability; Libido<br>Decreased; Nausea;<br>Suicidal Ideation; Weight<br>Increased | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                                                    | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                                                    | Citalopram     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Effexor        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                    | Remeron        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2010              | 5833301       | EXPEDITED (15-DAY) | N                  | DE, OT          | HQWYE547320JUN05     |                      | 53 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Completed<br>Suicide; Condition<br>Aggravated; Drug<br>Ineffective; Glycosylated<br>Haemoglobin Increased;<br>Gun Shot Wound;<br>Hypoglycaemia; Impaired | Effexor        |              |            | S           |              |                    |                 | Wyeth        |
|                                                                                                                                                                   | Effexor        |              |            | S           |              |                    |                 | Wyeth        |
|                                                                                                                                                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Work Ability; Insomnia;  
Mental Impairment;  
Nervousness;  
Restlessness; Suicidal  
Ideation; Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2010              | 7419997       | EXPEDITED (15-DAY) | Y                  | OT              | FR-JNJFOC-20100604288 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension;<br>Speech Disorder; Syncope | Tramadol Hydrochloride      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Morphine                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Oxazepam                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Meprobamate                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Escitalopram Oxalate        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Amitriptyline               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Nortriptyline Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Phenobarbital               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Clonazepam                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Sertraline Hydrochloride    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                      | Tiaprider                   |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 15-Jun-2010              | 7420004       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-2010074215 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension;<br>Speech Disorder; Syncope | Sertraline Hydrochloride |              |            | S           |              |                    |                 | Pfizer       |
|                                                      | Morphine Sulfate         |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Tramadol                 |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Clonazepam               |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Amitriptyline            |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Oxazepam                 |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Meprobamate              |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |              |
|---------------|---|--------------|
| Nortriptyline | S | Not Reported |
| Phenobarbital | S | Not Reported |
| Tiapride      | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7071246       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007682           |                      | 74 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Blood Creatine<br>Phosphokinase Increased;<br>Dehydration; Disturbance<br>In Attention; Myoglobin<br>Blood Increased; Urinary<br>Tract Infection | Escitalopram Oxalate                  |              |            | S           | Oral         | 10 Mg (10mg, 1 In 1 D) ,<br>Oral        |                 | Not Reported |
|                                                                                                                                                                           | Pipamperone                           |              |            | S           |              | 3 Dosage Forms (3<br>Dosage Forms, 1 In |                 | Not Reported |
|                                                                                                                                                                           | Tiapride                              |              |            | S           | Oral         | 300mg (100mg, 3 In 1 D),<br>Oral        |                 | Not Reported |
|                                                                                                                                                                           | Risperdal                             |              |            | S           |              | 1 Mg (0.5 Mg, 2 In 1 D)                 |                 | Not Reported |
|                                                                                                                                                                           | Clexane (0.8 Milligram, Injection)    |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                                           | Concor (2.5 Milligram, Tablets)       |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                                           | Ferro Sanol (40milligram,<br>Tablets) |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                                           | Folsan (0.4 Milligram, Tablets)       |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                                           | Lisinopril (5milligram, Tablets)      |              |            | C           |              |                                         |                 | Not Reported |
|                                                                                                                                                                           | Metformin (500milligram,<br>Tablets)  |              |            | C           |              |                                         |                 | Not Reported |
| Vitamin B (1 Dosage Forms,<br>Tablets)                                                                                                                                    |                                       |              | C          |             |              |                                         | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7420743       | EXPEDITED (15-DAY) | Y                  | OT              | AU-RANBAXY-2010RR-<br>34452 |                      | 21 YR      | Female     | AUS            |

| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Serotonin<br>Syndrome | Fluoxetine Hcl         |              |            | S           | Oral         | 1.1 G, Unk         |                 | Ranbaxy      |
|                                 | Tramadol Hydrochloride |              |            | S           | Oral         | 3 G, Unk           |                 | Not Reported |
|                                 | Quetiapine             |              |            | S           | Oral         | 15 G, Unk          |                 | Not Reported |
|                                 | Escitalopram Oxalate   |              |            | S           | Oral         | 560 Mg, Unk        |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                 | Mirtazapine                 | S                  | Oral               | 315 Mg, Unk     |                            |                                        |                 | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                 | Risperidone                 | S                  | Oral               | 120 Mg, Unk     |                            |                                        |                 | Ranbaxy      |                |
|                                                                                                                                 | Lithium                     | S                  | Oral               | 13 G, Unk       |                            |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2010                                                                                                                     | 7420844                     | EXPEDITED (15-DAY) | N                  | OT              | NL-ASTRAZENECA-2010SE22837 |                                        |                 | Female       | NLD            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Headache; Homicidal Ideation; Insomnia; Irritability; Libido Decreased; Nausea; Suicidal Ideation; Weight Increased | Seroquel                    |                    |                    | S               | Oral                       |                                        |                 | Zeneca       |                |
|                                                                                                                                 | Prozac                      |                    |                    | S               |                            |                                        |                 | Not Reported |                |
|                                                                                                                                 | Lexapro                     |                    |                    | S               |                            |                                        |                 | Not Reported |                |
|                                                                                                                                 | Amitriptyline Hydrochloride |                    |                    | S               |                            |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2010                                                                                                                     | 7427780                     | DIRECT             | N                  | OT              |                            |                                        | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Urticaria                                                                                                             | Lexapro                     |                    |                    | S               | Oral                       | 10mg Once A Day Po , Approx 6-8 Months | 6 MTH           | Forest       |                |
| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2010                                                                                                                     | 7429729                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000014441                 |                                        | 24 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Disease Recurrence; Haemorrhage; Hepatitis                                                                                      | Escitalopram Oxalate        |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
|                                                                                                                                 | Inexium                     |                    |                    | S               | Oral                       | 40 Mg (40 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
|                                                                                                                                 | Bromazepam                  |                    |                    | S               | Oral                       | 6 Mg (6 Mg, 1 In 1 D), Oral            |                 | Not Reported |                |
|                                                                                                                                 | Efferalgan Codeine          |                    |                    | S               | Oral                       | 500 Mg, As Required, Oral              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7429882       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014442           |                      | 79 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Gastrooesophageal Reflux Disease; Hepatitis Acute; Melaena; Oropharyngeal Pain | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral                       |                 | Not Reported |
|                                                                                | Lercanidipine        |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral     |                 | Not Reported |
|                                                                                | Tanakan              |              |            | S           | Oral         | 3 Dosage Forms (3 Dosage Forms, 1 In 1 D), Oral     |                 | Not Reported |
|                                                                                | Ezetimibe            |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral     |                 | Not Reported |
|                                                                                | Zolpidem             |              |            | S           | Oral         | 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                | Plavix               |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), Oral     |                 | Not Reported |
|                                                                                | Sotalol              |              |            | C           |              |                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7431749       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014447           |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Unevaluable Event     | Lexapro              |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7431939       | EXPEDITED (15-DAY) | N                  | OT              | 1000011550           |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                  |                        |   |      |                                                                                             |              |
|--------------------------------------------------------------------------------------------------|------------------------|---|------|---------------------------------------------------------------------------------------------|--------------|
| Amnesia; Disturbance In Attention; Fatigue; Headache; Hyperhidrosis; Nervousness; Sleep Disorder | Escitalopram Oxalate   | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                  |                        |   | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |              |
|                                                                                                  | Lormetazepam (Tablets) | C |      |                                                                                             | Not Reported |
|                                                                                                  | Aceclofenac            | C |      |                                                                                             | Not Reported |
|                                                                                                  | Zaldiar                | C |      |                                                                                             | Not Reported |
|                                                                                                  | Adolonta (Tablets)     | C |      |                                                                                             | Not Reported |
|                                                                                                  | Paracetamol            | C |      |                                                                                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7453600       | EXPEDITED (15-DAY) | Y                  | HO              | 2010SP032445         |                      | 21 YR      | Female     | AUS            |

| <u>Preferred Term</u>                          | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Overdose; Serotonin Syndrome | Mirtazapine                                         |              |            | S           | Oral         | 315 Mg; Po         |                 | Not Reported |
|                                                | Tramadol Hydrochloride                              |              |            | S           | Oral         | 3000 Mg; Po        |                 | Not Reported |
|                                                | Escitalopram Oxalate                                |              |            | S           | Oral         | 560 Mg; Po         |                 | Not Reported |
|                                                | Fluoxetine Hydrochloride (Fluoxetine Hydrochloride) |              |            | S           | Oral         | 1100 Mg; Po        |                 | Not Reported |
|                                                | Risperidone (Risperidone)                           |              |            | S           | Oral         | 120 Mg; Po         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7453639       | EXPEDITED (15-DAY) | Y                  | HO              | 2010SP031915         |                      | 67 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Abnormal Behaviour; Agitation; Delirium; Disorientation; Mental Disorder; Unresponsive To Stimuli | Mirtazapine    |              |            | S           | Oral         | 45 Mg;Qd;Po; 60 Mg;Qd;Po                   |                 | Not Reported |
|                                                                                                   |                |              |            |             | Oral         | 45 Mg;Qd;Po; 60 Mg;Qd;Po                   |                 |              |
|                                                                                                   | Cipralext      |              |            | S           | Oral         | 10 Mg;Qd;Po; 20 Mg; Qd; Po; 30 Mg;Qd;Po 15 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |      |                                                                       |              |
|-------------------|---|------|-----------------------------------------------------------------------|--------------|
| Lithium Carbonate | S | Oral | Mg;Qd;Po<br>10 Mg;Qd;Po; 20 Mg; Qd;<br>Po; 30 Mg;Qd;Po 15<br>Mg;Qd;Po | Not Reported |
|                   |   | Oral | 10 Mg;Qd;Po; 20 Mg; Qd;<br>Po; 30 Mg;Qd;Po 15<br>Mg;Qd;Po             |              |
|                   |   | Oral | 10 Mg;Qd;Po; 20 Mg; Qd;<br>Po; 30 Mg;Qd;Po 15<br>Mg;Qd;Po             |              |
| Lyrica            | S | Oral | 225 Mg;Qd;Po; 450<br>Mg;Qd;Po                                         | Not Reported |
|                   |   | Oral | 225 Mg;Qd;Po; 450<br>Mg;Qd;Po                                         |              |
|                   |   | Oral | 50 Mg;Qd;Po; 75<br>Mg;Qd;Po; 50 Mg;Qd;Po;<br>25 Mg;Qd;Po              |              |
|                   |   | Oral | 50 Mg;Qd;Po; 75<br>Mg;Qd;Po; 50 Mg;Qd;Po;<br>25 Mg;Qd;Po              |              |
|                   |   | Oral | 50 Mg;Qd;Po; 75<br>Mg;Qd;Po; 50 Mg;Qd;Po;<br>25 Mg;Qd;Po              |              |
| Allopurinol       | C |      | 50 Mg;Qd;Po; 75<br>Mg;Qd;Po; 50 Mg;Qd;Po;<br>25 Mg;Qd;Po              | Not Reported |
| Disalunil         | C |      |                                                                       | Not Reported |
| Lisinopril        | C |      |                                                                       | Not Reported |
| Pantozol          | C |      |                                                                       | Not Reported |
| Tavor (Lorazepam) | C |      |                                                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2010              | 7752483       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014437           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abortion Induced; Blood Pressure Increased; Fall; Fatigue; Foetal Death; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10mg, 1 In 1d, Oral) |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                     |                             |                    |                    |                                                 |                       |                      |                 |              |                |
|-----------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-------------------------------------------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Hellp Syndrome; Maternal Exposure During Pregnancy; Overdose; Pregnancy; Sleep Disorder; Somnolence | Amitriptyline Hydrochloride | S                  | Oral               | One Bottle (Once) Oral                          | Not Reported          |                      |                 |              |                |
|                                                                                                     | Bromazepam                  | S                  | Oral               | 48 Mg (Once), Oral                              | Not Reported          |                      |                 |              |                |
|                                                                                                     | Rivotril                    | S                  | Oral               | 2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral | Not Reported          |                      |                 |              |                |
|                                                                                                     |                             |                    | Oral               | 2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral |                       |                      |                 |              |                |
|                                                                                                     | Prazepam                    | S                  | Oral               | Oral                                            | Not Reported          |                      |                 |              |                |
|                                                                                                     | Topiramate                  | S                  | Oral               | Oral                                            | Not Reported          |                      |                 |              |                |
|                                                                                                     | Zyprexa                     | S                  | Oral               | 5mg (5mg, 1 In 1d), Oral                        | Not Reported          |                      |                 |              |                |
|                                                                                                     | Zopiclone                   | S                  | Oral               | 7.5 Mg (7.5 Mg, 1 In 1 D) Oral                  | Not Reported          |                      |                 |              |                |
|                                                                                                     | Chlorpromazine              | S                  | Oral               | 60 Gtt (Gtt, 1 In 1 D), Oral                    | Not Reported          |                      |                 |              |                |
|                                                                                                     | Oxazepam                    | S                  | Oral               | 20mg (20mg, 1 In 1d), Oral                      | Not Reported          |                      |                 |              |                |
|                                                                                                     | Spasfon Lyoc                | S                  | Oral               | 160 Mg (160 Mg, 1 In 1d) Oral                   | Not Reported          |                      |                 |              |                |
|                                                                                                     | Effexor                     | S                  | Oral               | 37.5 Mg, (37.5 Mg, 1 In 1d) Oral                | Not Reported          |                      |                 |              |                |
|                                                                                                     | Stilnox                     | S                  | Oral               | 10mg (10mg, 1 In 1d) Oral                       | Not Reported          |                      |                 |              |                |
|                                                                                                     | Theralene                   | S                  |                    | 100 Gtt (100 Gtt, 1 In 1                        | Not Reported          |                      |                 |              |                |
|                                                                                                     | Akineton                    | S                  | Oral               | 8mg (8mg, 1 In 1 D), Oral                       | Not Reported          |                      |                 |              |                |
|                                                                                                     | Periciazine                 | S                  | Oral               | 50gtt (50gtt, 1 In 1d), Oral                    | Not Reported          |                      |                 |              |                |
|                                                                                                     | Clamoxyl (Amoxicillin)      | S                  | Oral               | 3gm (3gm, 1 In 1d) Oral                         | Not Reported          |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                 | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jun-2010                                                                                         | 7423108                     | EXPEDITED (15-DAY) | Y                  | OT                                              | IT-JNJFOC-20100603797 |                      | 32 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Self-Injury; Miosis; Sopor                                                              | Haldol                      |                    |                    | S                                               | Oral                  |                      |                 | Not Reported |                |
|                                                                                                     | Depakene                    |                    |                    | S                                               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |              |
|-------------|---|------|--------------|
| Delorazepam | S | Oral | Not Reported |
| Ciprallex   | S | Oral | Not Reported |
| Seroquel    | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 17-Jun-2010              | 7423501                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>BP-06 |                      | 56 YR           | Male                 | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Hepatitis                | Tamsulosin Hydrochloride |                    |                    | S               | Oral                                                          |                      |                 | Boehringer Ingelheim |                |
|                          | Tamsulosin Hydrochloride |                    |                    | S               | Oral                                                          |                      |                 | Boehringer Ingelheim |                |
|                          | Escitalopram Oxalate     |                    |                    | S               | Oral                                                          |                      |                 | Not Reported         |                |
|                          | Rythmol                  |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |
|                          | Seloken                  |                    |                    | C               |                                                               |                      |                 | Not Reported         |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|------------|----------------|
| 17-Jun-2010                                                                              | 7428361              | DIRECT           | Y                  | DS, HO          |                      |                             | 65 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Enterococcal Infection;<br>Foaming At Mouth;<br>Serotonin Syndrome;<br>Somnolence; Wound | Linezolid            |                  |                    | S               | Oral                 | 600 Mg Every 12 Hours<br>Po |                 | Pfizer     |                |
|                                                                                          | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20 Mg Daily Po              |                 | Forest     |                |

| <a href="#">FDA Received Date</a>                               | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 17-Jun-2010                                                     | 7450812                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 2010SP032472                  |                               | 30 YR                    | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Coma Scale Abnormal;<br>Drug Interaction;<br>Serotonin Syndrome | Remeron                 |                           |                             | S                        | Oral                          | 30 Mg;Qd;Po                   |                          | Not Reported        |                         |
|                                                                 | Ciprallex               |                           |                             | S                        | Oral                          | 20 Mg;Qd;Po                   |                          | Not Reported        |                         |
|                                                                 | Zyprexa                 |                           |                             | S                        | Oral                          | 10 Mg;Qd;Po                   |                          | Not Reported        |                         |
|                                                                 | Stilnox                 |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2010              | 7454281       | EXPEDITED (15-DAY) | Y                  | HO              | 612608               |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|---------------------------------------|----------------------------------|-----------------|--------------|
| Blood Pressure Diastolic Decreased; Drug Interaction; Hypoxia; Respiratory Acidosis; Serotonin Syndrome | Fentanyl Citrate                          |              |            | S           | Intravenous (not otherwise specified) | 250 Mg Microgram(S), Intravenous |                 | Not Reported |
|                                                                                                         | Escitalopram Oxalate                      |              |            | S           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Insulin Nos                               |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Trazodone Hydrochloride (Gabapentin)      |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Lasoprazole                               |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Lorazepam                                 |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Oxycodone Hydrochloride                   |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Cetirizine Hydrochloride                  |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Etomidate                                 |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Vecuronium Bromide                        |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Morphine Sulfate                          |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Cefazolin                                 |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Ipratropium Bromide And Albuterol Sulfate |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Enoxaparin Sodium                         |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Famotidine                                |              |            | C           |                                       |                                  |                 | Not Reported |
|                                                                                                         | Midazolam                                 |              |            | C           |                                       |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2010              | 7455526       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014444           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|---------------------------------------------------------------------|-----------------|--------------|
| Maternal Drugs Affecting Foetus; Respiratory Disorder Neonatal | Escitalopram Oxalate |              |            | S           | Oral           | 10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                | Buspar               |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D), Transplacental; 5 Mg (5mg, 1 In 1 D), Oral |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |                |                                            |              |
|-------------------------|---|----------------|--------------------------------------------|--------------|
| Effexor                 | S | Transplacental | 75 Mg (75 Mg, 1 In 1 D),<br>Transplacental | Not Reported |
| Oxazepam                | S | Transplacental | 15 Mg (15 Mg, 1 In 1 D),<br>Transplacental | Not Reported |
| Trazodone Hydrochloride | S | Transplacental | 50 Mg, Transplacental                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2010              | 7355641       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012709           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Aggression; Crying;<br>Delirium; Dementia;<br>Dysarthria; Parkinsonism;<br>Therapeutic Product Effect<br>Decreased; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Jun-2010              | 7383623       | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-<br>20100500532 |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|---------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Bradyphrenia;            | Fentanyl                  |              |            | S           | Transdermal                              |                    |                 | Not Reported |
| Pseudomonas Infection;   | Haloperidol               |              |            | S           | Unknown                                  |                    |                 | Not Reported |
| Pyrexia; Somnolence;     | Unspecified Ingredient    |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
| Staphylococcal Infection | Doxorubicin Hydrochloride |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                          | Lorazepam                 |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                          | Fluoxetine Hydrochloride  |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                          | Morphine                  |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                          | Trazodone Hydrochloride   |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                          | Ondansetron               |              |            | S           | Unknown                                  |                    |                 | Not Reported |
|                          | Escitalopram Oxalate      |              |            | S           | Unknown                                  |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |                                       |              |
|--------------------------|---|---------------------------------------|--------------|
| Diazepam                 | S | Unknown                               | Not Reported |
| Paroxetine Hydrochloride | C | Unknown                               | Not Reported |
| Movicol                  | C | Unknown                               | Not Reported |
| Enoxaparin Sodium        | C | Unknown                               | Not Reported |
| Co Trimoxazole           | C | Unknown                               | Not Reported |
| Hydrocortisone           | C | Unknown                               | Not Reported |
| Dexamethasone            | C | Unknown                               | Not Reported |
| Omeprazole               | C | Unknown                               | Not Reported |
| Paracetamol              | C | Unknown                               | Not Reported |
| Augmentine               | C | Unknown                               | Not Reported |
| Urokinase                | C | Unknown                               | Not Reported |
| Blood Transfusion        | C | Intravenous (not otherwise specified) | Not Reported |
| Metoclopramide           | C | Unknown                               | Not Reported |
| Domperidone              | C | Unknown                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2010              | 7437127       | EXPEDITED (15-DAY) | Y                  | DE              | 1000014486           |                      | 51 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Cerebellar Haematoma;<br>International Normalised<br>Ratio Increased | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                      | Sintrom              |              |            | S           | Oral         | Oral                        |                 | Not Reported |
|                                                                      | Dexamethasone        |              |            | S           | Oral         | 1 Mg (1 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                      | Lormetazepam         |              |            | S           | Oral         | 1 Mg (1 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                      | Serc (Tablets)       |              |            | C           |              |                             |                 | Not Reported |
|                                                                      | Omeprazol (Tablets)  |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2010              | 7437144       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014519           |                      | 67 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |                      |   |      |                                                                    |              |
|-----------------------------------------|----------------------|---|------|--------------------------------------------------------------------|--------------|
| Delirium; Drug Interaction;<br>Overdose | Escitalopram Oxalate | S | Oral | 30 Mg (30 Mg, 1 In 1 D),<br>Oral                                   | Not Reported |
|                                         | Escitalopram Oxalate | S | Oral | 15 Mg (15 Mg, 1 In 1 D,<br>Oral)                                   | Not Reported |
|                                         | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral | Not Reported |
|                                         |                      |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |              |
|                                         | Remergil             | S | Oral | 60 Mg ( 60 Mg, 1 In 1 D),<br>Oral                                  | Not Reported |
|                                         | Remergil             | S | Oral | 45 Mg ( 45 Mg, 1 In 1 D),<br>Oral; 30 Mg (30 Mg, 1 In1<br>D), Oral | Not Reported |
|                                         | Lithium              | S | Oral | 225 Mg (225 Mg, 1 In 1 D),<br>Oral                                 | Not Reported |
|                                         | Lithium              | S | Oral | 450 Mg (450 Mg, 1 In 1 D),<br>Oral                                 | Not Reported |
|                                         | Lyrica               | S | Oral | 75 Mg (75 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1<br>D), Oral | Not Reported |
|                                         |                      |   | Oral | 75 Mg (75 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1<br>D), Oral |              |
|                                         | Lyrica               | S | Oral | 25 Mg (25 Mg, 1 In 1 D),<br>Oral                                   | Not Reported |
|                                         | Lyrica               | S | Oral | 50 Mg (50 Mg, 1 In 1 D),<br>Oral                                   | Not Reported |
|                                         | Allopurinol          | C |      |                                                                    | Not Reported |
|                                         | Disalunil            | C |      |                                                                    | Not Reported |
|                                         | Lisinopril           | C |      |                                                                    | Not Reported |
|                                         | Pantozol             | C |      |                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jun-2010              | 7465312       | EXPEDITED (15-DAY) | Y                  | HO              | 2010SP032784         |                      | 60 YR      | Female     | FRA            |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression;                | Mirtazapine          |              |            | S           | Oral         | 15 Mg; Qd; Po      |                 | Not Reported |
| Hypokalaemia;              | Prozac               |              |            | S           | Oral         | Po                 |                 | Not Reported |
| Inappropriate Antidiuretic | Aldactazine          |              |            | S           | Oral         | 25 Mg; Bid; Po     |                 | Not Reported |
| Hormone Secretion;         | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg; Qd; Po      |                 | Not Reported |
| Malaise; Oedema            | Levothyrox           |              |            | C           |              |                    |                 | Not Reported |
| Peripheral; Weight         | Cymbalta             |              |            | C           |              |                    |                 | Not Reported |
| Decreased                  |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2010              | 7382984       | EXPEDITED (15-DAY) | N                  | OT              | 1000013348           |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Asthenia; Condition       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
| Aggravated; Depression;   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
| Drug Ineffective; Fear;   | Xanax                |              |            | C           |              |                                  |                 | Not Reported |
| Feeling Abnormal; Mood    |                      |              |            |             |              |                                  |                 |              |
| Altered; Nervousness;     |                      |              |            |             |              |                                  |                 |              |
| Palpitations; Psychiatric |                      |              |            |             |              |                                  |                 |              |
| Symptom; Self-Injurious   |                      |              |            |             |              |                                  |                 |              |
| Ideation; Sleep Disorder; |                      |              |            |             |              |                                  |                 |              |
| Social Avoidant           |                      |              |            |             |              |                                  |                 |              |
| Behaviour; Suicidal       |                      |              |            |             |              |                                  |                 |              |
| Ideation; Tremor          |                      |              |            |             |              |                                  |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2010              | 7427102       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ABBOTT-10P-056-<br>0650779-00 |                      | 51 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jun-2010              | 7435734       | DIRECT           | N                  | DE              |                      |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                         |                    |                    |                 |                                                 |                                                   |                 |            |                |
|----------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------|-----------------|------------|----------------|
| Completed Suicide                                              | Lexapro                 |                    |                    | S               |                                                 |                                                   |                 |            | Forest         |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jun-2010                                                    | 7436289                 | DIRECT             | N                  | HO, RI          |                                                 |                                                   | 20 YR           | Female     | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Bipolar Disorder; Mania                                        | Lexapro                 |                    |                    | S               | Oral                                            | 20 Mg Twice/ Day Po                               |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2010                                                    | 7281514                 | EXPEDITED (15-DAY) | Y                  |                 | GB-TEVA-224097ISR                               |                                                   |                 | Female     | GBR            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Trazodone Hydrochloride |                    |                    | S               | Unknown                                         | The Suspect Medication<br>Was Taken By The Father |                 |            | Barr           |
|                                                                | Escitalopram Oxalate    |                    |                    | S               | Oral                                            |                                                   |                 |            | Not Reported   |
|                                                                | Escitalopram Oxalate    |                    |                    | S               |                                                 |                                                   |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2010                                                    | 7427873                 | EXPEDITED (15-DAY) | Y                  | HO              | GXKR2010DE06697                                 |                                                   | 77 YR           | Female     | DEU            |
| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Interaction; Epistaxis                                    | Aspirin                 |                    |                    | S               | Oral                                            | 100 Mg, Qd                                        |                 |            | Not Reported   |
|                                                                | Remergil                |                    |                    | C               |                                                 |                                                   |                 |            | Not Reported   |
|                                                                | Fragmin                 |                    |                    | C               |                                                 |                                                   |                 |            | Not Reported   |
|                                                                | Simvastatin             |                    |                    | C               |                                                 |                                                   |                 |            | Not Reported   |
|                                                                | Metoprolol              |                    |                    | C               |                                                 |                                                   |                 |            | Not Reported   |
|                                                                | Plavix                  |                    |                    | S               | Oral                                            | 75 Mg, Qd                                         |                 |            | Not Reported   |
|                                                                | Cipraxel                |                    |                    | S               |                                                 | 30 Mg, Qd                                         | 5 DAY           |            | Not Reported   |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2010                                                    | 7427945                 | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15155708 |                                                   | 28 YR           | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------|-----------------|--------------|----------------|
| Depression; Emotional Disorder; Product Dose Omission; Psychotic Disorder                                     | Abilify                |                    |                    | S               |                              | Pills                                 |                 | Not Reported |                |
|                                                                                                               | Lexapro                |                    |                    | S               |                              |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2010                                                                                                   | 7428201                | EXPEDITED (15-DAY) |                    | OT              | FR-ABBOTT-10P-056-0650481-00 |                                       | 40 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced; Blood Pressure Increased; Fatigue; Foetal Death; HELLp Syndrome; Sleep Disorder; Somnolence | Akineton               |                    |                    | S               | Oral                         | Controlled Release Coated Tablet      |                 | Not Reported |                |
|                                                                                                               | Seroplex               |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Clamoxyl (Amoxicillin) |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Laroxyl                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Laroxyl                |                    |                    | S               | Oral                         | Overdose: 1 Bottle (Unspecified Dose) |                 | Not Reported |                |
|                                                                                                               | Lexomil                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Lexomil                |                    |                    | S               | Oral                         | Overdose; 4 Tablets On 16 Nov 2008    |                 | Not Reported |                |
|                                                                                                               | Rivotril               |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Rivotril               |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Lysanxia               |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Epitomax               |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Zyprexa                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Zyprexa                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Zyprexa                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
|                                                                                                               | Imovane                |                    |                    | S               | Oral                         |                                       |                 | Not Reported |                |
| Largactil                                                                                                     |                        |                    | S                  | Oral            | 60 Gtt Drops                 |                                       | Not Reported    |              |                |
| Seresta                                                                                                       |                        |                    | S                  | Oral            |                              |                                       | Not Reported    |              |                |
| Spasfon Lyoc                                                                                                  |                        |                    | S                  | Oral            | Oral Lyophilized             |                                       | Not Reported    |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |              |   |         |               |  |              |
|--|--------------|---|---------|---------------|--|--------------|
|  | Effexor      | S | Oral    |               |  | Not Reported |
|  | Stilnox      | S | Oral    |               |  | Not Reported |
|  | Theralene    | S | Oral    | 100 Gtt Drops |  | Not Reported |
|  | Neuleptil    | S | Oral    | 50 Gtt Drops  |  | Not Reported |
|  | Gyno Pevaryl | C | Vaginal |               |  | Not Reported |
|  | Flagyl       | C | Oral    |               |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 23-Jun-2010              | 7349042              | EXPEDITED (15-DAY) | Y                  | DS              | 1000012568           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Enteritis                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Lysanxia             |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 23-Jun-2010                      | 7383396              | EXPEDITED (15-DAY) | Y                  | DS              | 1000013490           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Rigidity;<br>Diarrhoea | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                  | Lysanxia             |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 23-Jun-2010                             | 7417605                 | EXPEDITED (15-DAY) | Y                  | OT              | FR-PURDUE-USA-<br>2010-0044363 |                      | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome | Oxycodone Hydrochloride |                    |                    | S               | Oral                           | 120 Mg, Daily        |                 | Purdue       |                |
|                                         | Fentanyl                |                    |                    | S               | Nasal                          | 200 Mcg, See Text    |                 | Not Reported |                |
|                                         | Escitalopram Oxalate    |                    |                    | S               |                                | 5 Mg, Daily          |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2010              | 7428702       | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-           |                      | 66 YR      | Male       | ITA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

20100605115

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|--------------|----------------|
| Intentional Self-Injury;<br>Sluggishness;<br>Tachypnoea                                                                  | Risperdal            |                    |                    | S               | Oral                     | Unspecified Dose Of 2 Mg  |                 | Not Reported |                |
|                                                                                                                          | Lorazepam            |                    |                    | S               | Oral                     |                           |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                     |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2010                                                                                                              | 7430691              | NON-EXPEDITED      | Y                  | HO              | US-PFIZER INC-2008015742 |                           | 39 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                                       | Geodon               |                    |                    | S               | Oral                     | Q Hs                      |                 | Pfizer       |                |
|                                                                                                                          | Lexapro              |                    |                    | S               |                          |                           |                 | Not Reported |                |
|                                                                                                                          | Klonopin             |                    |                    | C               |                          |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2010                                                                                                              | 7430881              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2008028856 |                           |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Metrorrhagia                                                                                        | Depo-Provera         |                    |                    | S               |                          |                           |                 | Pfizer       |                |
|                                                                                                                          | Lexapro              |                    |                    | S               |                          |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2010                                                                                                              | 7458969              | EXPEDITED (15-DAY) | N                  | OT              | DSA_43296-2010           |                           | 28 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Anxiety;<br>Fatigue; Feelings Of<br>Worthlessness; Mood<br>Swings; Obsessive<br>Thoughts; Poor Quality | Wellbutrin XI        |                    |                    | S               | Oral                     | Df Oral                   | 2 MTH           | Not Reported |                |
|                                                                                                                          | Ciprallex            |                    |                    | S               | Oral                     | Df, Oral, (20 Mg Qd Oral) |                 | Not Reported |                |
|                                                                                                                          | Hydrocortisone       |                    |                    | C               |                          |                           |                 | Not Reported |                |
|                                                                                                                          | Ortho Tri Cyclen     |                    |                    | C               |                          |                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sleep

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jun-2010              | 7452900       | EXPEDITED (15-DAY) | N                  | OT              | DSA_43299_2010       |                      | 56 YR      | Male       | CAN            |

| <u>Preferred Term</u>       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Depression;   | Wellbutrin XI          |              |            | S           | Oral         | 300 Mg Qd Oral     | 3 YR            | Not Reported |
| Dizziness; Dry Mouth;       | Ciprallex              |              |            | S           | Oral         | 10 Mg Qd Oral      |                 | Not Reported |
| Erection Increased;         | Clonazepam             |              |            | S           | Oral         | 1 Mg Qd Oral       | 2 YR            | Not Reported |
| Fatigue; Increased          | Seroquel               |              |            | S           | Oral         | 200 Mg Qd Oral     | 2 YR            | Not Reported |
| Appetite; Muscular          | Echinacea              |              |            | C           |              |                    |                 | Not Reported |
| Weakness; Nausea;           | Horse Chestnut Extract |              |            | C           |              |                    |                 | Not Reported |
| Somnolence; Suicidal        | Silybum Marianum       |              |            | C           |              |                    |                 | Not Reported |
| Ideation; Tinnitus; Tremor; |                        |              |            |             |              |                    |                 | Not Reported |
| Weight Increased            |                        |              |            |             |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 25-Jun-2010              | 7417683       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PURDUE-USA-2010-0044495 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Abuse; Hypotension; | Tramadol Hydrochloride   |              |            | S           |              |                    |                 | Purdue       |
| Speech Disorder; Syncope | Morphine Sulfate         |              |            | S           |              |                    |                 | Purdue       |
|                          | Oxazepam                 |              |            | S           |              |                    |                 | Not Reported |
|                          | Meprobamate              |              |            | S           |              |                    |                 | Not Reported |
|                          | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                          | Amitriptyline            |              |            | S           |              |                    |                 | Not Reported |
|                          | Nortriptyline            |              |            | S           |              |                    |                 | Not Reported |
|                          | Phenobarbital            |              |            | S           |              |                    |                 | Not Reported |
|                          | Clonazepam               |              |            | S           |              |                    |                 | Not Reported |
|                          | Sertraline Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                          | Tiaprider                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2010              | 7451649       | EXPEDITED (15-DAY) | N                  | HO              | 1000014566           |                      | 78 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                           |             |   |      |                               |              |
|-----------------------------------------------------------------------------------------------------------|-------------|---|------|-------------------------------|--------------|
| Asthenia; Blood Pressure Diastolic Decreased; Dizziness; Lethargy; Loss Of Consciousness; Skin Laceration | Lexapro     | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                           | Geodon      | C |      |                               | Not Reported |
|                                                                                                           | Simvastatin | C |      |                               | Not Reported |
|                                                                                                           | Trilipix    | C |      |                               | Not Reported |
|                                                                                                           | Remeron     | C |      |                               | Not Reported |
|                                                                                                           | Clonazepam  | C |      |                               | Not Reported |
|                                                                                                           | Azor        | C |      |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jun-2010              | 7454270       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000014616           |                      | 30 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress Syndrome; Aspiration; Coma; Intentional Overdose | Escitalopram Oxalate |              |            | S           | Oral         | Once, Oral         |                 | Not Reported |
|                                                                             | Alprazolam           |              |            | S           | Oral         | Once, Oral         |                 | Not Reported |
|                                                                             | Alcohol              |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2010              | 7400874       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013739           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Asthenia; Condition Aggravated; Decreased Appetite; Suicidal Ideation; Weight Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                  | Xanax                |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jun-2010              | 7442747       | EXPEDITED (15-DAY) | Y                  | LT              | GXKR2010DK05980      |                      | 71 YR      | Female     | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased; Drug Interaction | Mirtazapine    |              |            | S           | Oral         |                    |                 | Novartis     |
|                                          | Seroquel       |              |            | C           | Oral         | 25 Milligram(S)    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               | Bendroflumethiazide            |                  | S                  | Oral            |                          | Unk                  |                 | 1241 DAY     | Not Reported   |
|-----------------------------------------------|--------------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                               | Escitalopram Oxalate           |                  | S                  | Oral            |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                      | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2010                                   | 7443773                        | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2007036940 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Level Decreased                          | Geodon                         |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                               | Lexapro                        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | All Other Therapeutic Products |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                               | Avodart                        |                  |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2010                                   | 7444399                        | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-2007090114 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation; Muscle Twitching; Pruritus | Geodon                         |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                               | Lexapro                        |                  |                    | S               | Oral                     | Daily                |                 | Not Reported |                |
|                                               | Xanax                          |                  |                    | C               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2010                                   | 7444692                        | NON-EXPEDITED    | Y                  | OT              | US-PFIZER INC-2007091513 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lacunar Infarction                            | Geodon                         |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                               | Geodon                         |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                               | Lexapro                        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                               | Celebrex                       |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                               | Synthroid                      |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                               | Asa                            |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                               | Lyrica                         |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                               | Oxycontin                      |                  |                    | C               |                          |                      |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|--------------------|--------------------|------------------|--------------------------|---------------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 28-Jun-2010                                                                                                                       | 7444703                                                      | NON-EXPEDITED      | Y                  |                  | US-PFIZER INC-2007083863 |                                                                                             | 13 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Anxiety;<br>Electrocardiogram Qt<br>Prolonged; Panic<br>Reaction; Sinus<br>Arrhythmia; Tic; Wolff-<br>Parkinson-White<br>Syndrome | Geodon<br>Paliperidone<br>Lexapro<br>Trazodone Hydrochloride |                    |                    | S<br>S<br>S<br>C | Oral                     |                                                                                             |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported       |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 28-Jun-2010                                                                                                                       | 7450075                                                      | DIRECT             | Y                  |                  |                          |                                                                                             | 36 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Cough                                                                                                                             | Lisinopril And<br>Hydrochlorothiazide<br>Lexapro             |                    |                    | S<br>S           | Oral<br>Oral             | 1 Tab Daily Po<br>1 Tab Daily Po                                                            |                 | Lupin<br>Forest                                              |                |
| <u>FDA Received Date</u>                                                                                                          | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 28-Jun-2010                                                                                                                       | 7455403                                                      | EXPEDITED (15-DAY) | Y                  | HO               | 1000014615               |                                                                                             | 56 YR           | Male                                                         | DNK            |
| <u>Preferred Term</u>                                                                                                             | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Effusion; General Physical<br>Health Deterioration;<br>Hepatic Steatosis;<br>Hepatitis; Hepatomegaly                              | Escitalopram Oxalate<br>Tamsulosin<br>Rythmol<br>Seloken     |                    |                    | S<br>S<br>C<br>C | Oral<br>Oral             | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral<br>0.4 Mg (0.4 Mg, 1 In 1 D),<br>Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|------------------------------|----------------|
| 28-Jun-2010                                                                                                          | 7455426                                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000014623           |                                       | 45 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                   |                |
| Agitation; Anxiety;<br>Irritability; Tension                                                                         | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral      |                 | Not Reported                 |                |
|                                                                                                                      | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 1 W |                 | Not Reported                 |                |
|                                                                                                                      |                                            |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 1 W | 1 WEEK          |                              |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Jun-2010                                                                                                          | 7455463                                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000014634           |                                       | 27 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anal Incontinence;<br>Disorientation; Intentional<br>Overdose; Suicide<br>Attempt; Urinary<br>Incontinence; Vomiting | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | (140 Mg,Once), Oral                   |                 | Not Reported                 |                |
|                                                                                                                      | Amitriptyline                              |                    |                    | S               | Oral                 | (2550 Mg,Once), Oral                  |                 | Not Reported                 |                |
|                                                                                                                      | Desogestrel\Ethinyl Estradiol              |                    |                    | S               |                      | 44 Tablets At Most (Once)             |                 | Not Reported                 |                |
|                                                                                                                      | Voltaren                                   |                    |                    | S               | Oral                 | (500 Mg,Once), Oral                   |                 | Not Reported                 |                |
|                                                                                                                      | Ibuprofen                                  |                    |                    | S               | Oral                 | (1200 Mg,Once), Oral                  |                 | Not Reported                 |                |
|                                                                                                                      | Acetaminophen\Butylscopolamin<br>e Bromide |                    |                    | S               | Oral                 | 20 Tablets At Most (Once),<br>Oral    |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 28-Jun-2010                                                                                                          | 7455560                                    | EXPEDITED (15-DAY) | N                  | HO              | 1000014698           |                                       | 56 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>                   |                |
| Loss Of Consciousness;<br>Skin Laceration                                                                            | Lexapro                                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral      |                 | Not Reported                 |                |
|                                                                                                                      | Ativan<br>Amlodipine                       |                    |                    | C<br>C          |                      |                                       |                 | Not Reported<br>Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010                                                                                                                 | 7445082              | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2007079588 |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Asthenia; Drug Ineffective; Drug Interaction; Drug Tolerance; Fatigue; Incorrect Dose Administered; Nausea; Pain | Xanax                |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                             | Zolpidem Tartrate    |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Klonopin             |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Hyoscyamine Sulfate  |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Hyoscyamine Sulfate  |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Ultram               |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Xanax                |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                             | Lexapro              |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Lexapro              |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Valium               |                  |                    | S               |                          | Frequency: Prn       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                                                                                 | 7445512              | NON-EXPEDITED    | Y                  | LT, OT          | US-PFIZER INC-2008026143 |                      | 83 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Ventricular Tachycardia                                                                                   | Tikosyn              |                  |                    | S               |                          | Every Day            |                 | Pfizer       |                |
|                                                                                                                             | Atenolol             |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Acetylsalicylic Acid |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Lasix                |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Spironolactone       |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Glucosamine          |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Lexapro              |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                             | Barium               |                  |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                                                                                 | 7445958              | NON-EXPEDITED    | Y                  | OT              | US-PFIZER INC-2008052204 |                      | 70 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mental Status Changes; Muscle Rigidity; Pyrexia; Serotonin Syndrome                                                         | Zyvox                |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                             | Lexapro              |                  |                    | S               |                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010              | 7445994              | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2008052576 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Somnolence               | Alprazolam           |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                          | Benadryl             |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Alcohol              |                  |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010                              | 7446456        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2008088248 |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Fatigue; Hyperhidrosis | Xanax          |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                          | Prevacid       |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                          | Zetia          |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                          | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010                                                                                                                                                                                                                                                 | 7446509             | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2008085946 |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Apathy; Constipation; Depression; Diarrhoea; Drug Interaction; Fatigue; Hypoaesthesia; Impatience; Increased Appetite; Insomnia; Irritability; Restlessness; Rhinorrhoea; Sexual Dysfunction; Urinary Tract Infection; Weight Increased | Xanax               |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                             | Uroxatral           |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Bentyl              |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Bentyl              |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Librax              |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Librax              |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Hyoscyamine Sulfate |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Hyoscyamine Sulfate |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Mesalazine          |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Mesalazine          |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                             | Ultram              |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |

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|            |   |      |                |              |
|------------|---|------|----------------|--------------|
| Ambien     | C |      | Unk            | Not Reported |
| Alprazolam | C |      | Unk            | Not Reported |
| Lexapro    | S | Oral | 2.5 Mg, 1x/Day | Not Reported |
| Lexapro    | S | Oral | 1.5 Mg, 1x/Day | Not Reported |
| Lexapro    | S | Oral | 2 Mg, 1x/Day   | Not Reported |
| Lexapro    | S | Oral | 3 Mg, 1x/Day   | Not Reported |
| Lexapro    | S | Oral | 3.5 Mg, 1x/Day | Not Reported |
| Lexapro    | S | Oral | 4 Mg, 1x/Day   | Not Reported |
| Lexapro    | S | Oral | 4.5 Mg, 1x/Day | Not Reported |
| Lexapro    | S | Oral | 5 Mg, 1x/Day   | Not Reported |
| Valium     | S |      | Unk            | Not Reported |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010                       | 7446543        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2008088016 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Panic Attack; Somnolence | Xanax          |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                   | Xanax Xr       |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                   | Prolixin       |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                   | Imipramine     |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                   | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                   | Elavil         |                  |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Jun-2010                                           | 7446617        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2008092147 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dry Eye; Mydriasis; Ocular Hyperaemia; Vision Blurred | Xanax          |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                       | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                       | Effexor        |                  |                    | S               |                          |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 29-Jun-2010                                                       | 7446642        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2009154057 |                                                  | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia                                                          | Xanax          |                  |                    | S               |                          | 0.25mg 1/2 Tablet At 2:30pm And 1 Tablet At 10pm |                 | Pfizer       |                |
|                                                                   | Alprazolam     |                  |                    | S               |                          |                                                  |                 | Pfizer       |                |
|                                                                   | Lexapro        |                  |                    | S               |                          |                                                  |                 | Not Reported |                |
|                                                                   | Lumigan        |                  |                    | C               |                          |                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                       | 7446731        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2008156744 |                                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Visual Impairment                               | Zyvox          |                  |                    | S               |                          | Unk                                              |                 | Pfizer       |                |
|                                                                   | Lexapro        |                  |                    | S               |                          | Unk                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                       | 7446805        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2008157256 |                                                  | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Drug Interaction; Vision Blurred; Visual Acuity Reduced | Procrit        |                  |                    | S               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Fosamax        |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Zocor          |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Levaquin       |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Restoril       |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Valtrex        |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Lasix          |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Potassium      |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |
|                                                                   | Amaryl         |                  |                    | C               |                          | Unk                                              |                 | Not Reported |                |

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|                                   | Tricor                        |                  | C                  |                 |                          | Unk                      |                 |            | Not Reported   |
|-----------------------------------|-------------------------------|------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|------------|----------------|
|                                   | Mucinex                       |                  | C                  |                 |                          | Unk                      |                 |            | Not Reported   |
|                                   | Zyvox                         |                  | S                  | Oral            |                          | 600 Mg, 2x/Day           | 3 DAY           |            | Pfizer         |
|                                   | Lexapro                       |                  | S                  |                 |                          | 20 Mg, 1x/Day            |                 |            | Not Reported   |
| <u>FDA Received Date</u>          | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jun-2010                       | 7446892                       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2009177597 |                          | 65 YR           | Female     | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Erythema; Somnolence              | Xanax                         |                  |                    | S               | Oral                     | Unk                      |                 |            | Pfizer         |
|                                   | Lexapro                       |                  |                    | S               | Oral                     | 5 Mg, 1x/Day             |                 |            | Not Reported   |
| <u>FDA Received Date</u>          | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jun-2010                       | 7447371                       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2009224169 |                          | 56 YR           | Male       | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Interaction; Night Sweats    | Xanax                         |                  |                    | S               |                          | 1 Caplet 2-3 Times A Day |                 |            | Pfizer         |
|                                   | Diphenhydramine Hydrochloride |                  |                    | S               | Oral                     | 50 Mg, 1x/Day            |                 |            | Not Reported   |
|                                   | Lexapro                       |                  |                    | S               |                          | 10 Mg, 1x/Day            |                 |            | Not Reported   |
| <u>FDA Received Date</u>          | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jun-2010                       | 7447442                       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2009225427 |                          | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>             | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Disturbance In Attention; Fatigue | Xanax                         |                  |                    | S               | Oral                     | Unk                      |                 |            | Pfizer         |
|                                   | Lexapro                       |                  |                    | S               | Oral                     | 10 Mg, 1x/Day            |                 |            | Not Reported   |
|                                   | Omeprazole                    |                  |                    | C               |                          | Unk                      |                 |            | Not Reported   |
|                                   | Claritin                      |                  |                    | C               |                          | Unk                      |                 |            | Not Reported   |
|                                   | Advil                         |                  |                    | C               |                          | Unk                      |                 |            | Not Reported   |
|                                   | Diphenhydramine               |                  |                    | C               |                          | Unk                      |                 |            | Not Reported   |

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|                                                                                                                                                                                 |                          |                    |                    |                 |                      |                                  |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Vitamins Nos                                                                                                                                                                    |                          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                                                                                                                                     | 7509541                  | NON-EXPEDITED      | Y                  | OT              | US-WYE-H14644910     |                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Serotonin Syndrome                                                                                                                                 | Pristiq Extended Release |                    |                    | S               |                      | 50 Mg 1x Per 1 Day               |                 | Not Reported |                |
|                                                                                                                                                                                 | Lexapro                  |                    |                    | S               |                      | Unspecified Dose Increased       |                 | Not Reported |                |
|                                                                                                                                                                                 |                          |                    |                    |                 |                      | Unspecified Dose Increased       |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2010                                                                                                                                                                     | 7529715                  | NON-EXPEDITED      | Y                  |                 | US-WYE-H14057310     |                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Libido                                                                                                                                                                  | Pristiq Extended Release |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                 | Lexapro                  |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                                                                                                                                                                     | 7388881                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000013554           |                                  | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Balance Disorder;<br>Carotid Artery Aneurysm;<br>Cerebellar Syndrome;<br>Feeling Drunk; No<br>Reaction On Previous<br>Exposure To Drug;<br>Tremor; Weight<br>Decreased | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                 | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                 | Lysanxia                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                                                                                                                                                                     | 7464121                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000014751           |                                  | 47 YR           | Female       | DNK            |



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| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| Insomnia; Mania; Mood Altered       | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                     | Lexomil              |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                         | 7465582              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014784           |                              | 59 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Extrasystoles; Tachycardia | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)      |                 | Not Reported |                |
|                                     | Xanax                |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                         | 7465628              | EXPEDITED (15-DAY) | Y                  | OT              | 1000014753           |                              | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Lymphadenopathy                     | Escitalopram Oxalate |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                     | Mini Pill            |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                         | 7469284              | EXPEDITED (15-DAY) | N                  | OT              | 1000014745           |                              | 59 YR           | Male         | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Gangrene                            | Escitalopram Oxalate |                    |                    | S               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jun-2010                         | 7472295              | EXPEDITED (15-DAY) | Y                  | OT              | 1000014707           |                              | 18 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Cold; Paralysis; Seizure    | Lexapro              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| 02-Jul-2010                                                                                                                                                           | 7367130              | EXPEDITED (15-DAY) | Y                  | HO              | 1000013181                                    |                               | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage; Immune Thrombocytopenic Purpura; Splenectomy                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                                          | 10 Mg (10 Mg, 1 In 1d), Oral  |                 | Not Reported |                |
|                                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                       | Lexomil              |                    |                    | C               |                                               |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jul-2010                                                                                                                                                           | 7452228              | EXPEDITED (15-DAY) |                    | HO, OT          | IT-ROXANE LABORATORIES, INC.- 2010-RO-00776RO |                               | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Human Herpesvirus 6 Infection; Relapsing Fever | Lamotrigine          |                    |                    | S               |                                               |                               | 34 DAY          | Roxane       |                |
|                                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               |                                               |                               | 34 DAY          | Not Reported |                |
|                                                                                                                                                                       | Cefixime             |                    |                    | S               |                                               | 800 Mg                        |                 | Not Reported |                |
|                                                                                                                                                                       | Cefixime             |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Cefixime             |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Cefixime             |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Cefixime             |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Betamethasone        |                    |                    | S               |                                               | 1 Mg                          |                 | Not Reported |                |
|                                                                                                                                                                       | Betamethasone        |                    |                    | S               | Intravenous (not otherwise specified)         |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Betamethasone        |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Betamethasone        |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Fexofenadine         |                    |                    | S               |                                               | 120 Mg                        |                 | Not Reported |                |
|                                                                                                                                                                       | Fexofenadine         |                    |                    | S               |                                               |                               |                 | Not Reported |                |
|                                                                                                                                                                       | Azithromycin         |                    |                    | S               |                                               | 500 Mg                        | 3 DAY           | Not Reported |                |
|                                                                                                                                                                       | Acyclovir            |                    |                    | S               | Intravenous (not otherwise specified)         |                               | 8 DAY           | Not Reported |                |
|                                                                                                                                                                       | Acyclovir            |                    |                    | S               |                                               |                               | 8 DAY           | Not Reported |                |

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### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------------------|-----------------|------------------------------|----------------|
| 02-Jul-2010                                           | 7457618                          | DIRECT             | N                  | OT              |                         |                                  | 48 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Economic Problem;<br>Impulsive Behaviour;<br>Migraine | Lexapro                          |                    |                    | S               |                         |                                  |                 | Forest                       |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-Jul-2010                                           | 7475923                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000014740              |                                  | 90 YR           | Unknown                      | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hallucination; Seizure                                | Lexapro<br>Multiple Ssri'S (Nos) |                    |                    | S<br>C          |                         |                                  |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 05-Jul-2010                                           | 7453255                          | EXPEDITED (15-DAY) | Y                  | OT              | TR-RANBAXY-2010RR-34335 |                                  | 31 YR           | Female                       | TUR            |
| <u>Preferred Term</u>                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bruxism                                               | Fluoxetine                       |                    |                    | S               |                         | 20 Mg, Unk                       |                 | Ranbaxy                      |                |
|                                                       | Venlafaxine                      |                    |                    | S               |                         | 150 Mg, Unk                      |                 | Not Reported                 |                |
|                                                       | Venlafaxine                      |                    |                    | S               |                         | Unk                              |                 | Not Reported                 |                |
|                                                       | Escitalopram Oxalate             |                    |                    | S               |                         | 10 Mg, Unk                       |                 | Not Reported                 |                |
|                                                       | Venlafaxine                      |                    |                    | C               |                         | 37.5 Mg, Unk                     |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 06-Jul-2010                                           | 7196237                          | EXPEDITED (15-DAY) | Y                  | DS, OT          | 1000010044              |                                  | 39 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |                |
| Chorea; Overdose                                      | Escitalopram Oxalate             |                    |                    | S               | Oral                    | 30 Mg (30 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |                |

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|                      |   |      |                                  |              |
|----------------------|---|------|----------------------------------|--------------|
| Escitalopram Oxalate | S | Oral | 50 Mg (50 Mg, 1 In 1 D),<br>Oral | Not Reported |
|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2010              | 7326996       | EXPEDITED (15-DAY) | Y                  | OT              | IE-ROCHE-629222      |                      |            | Female     | IRL            |

| <u>Preferred Term</u>        | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                                                                                    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|------------------|--------------|------------|-------------|------------------------------------------|-------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Complication Of<br>Pregnancy | Trastuzumab      |              |            | S           | Intravenous (not<br>otherwise specified) | Loading Dose. Frequency:<br>One Time Per Odos.<br>Actual Dose: 732 Mg.                                |                 | Roche        |
|                              | Trastuzumab      |              |            | S           | Intravenous (not<br>otherwise specified) | Maintenance Dose, Actual<br>Dose Given 549 Mg On 03<br>Jan, 25 Jan, 13 Feb, 3 Mar<br>And 24 Mar 2006. |                 | Roche        |
|                              | Lexapro          |              |            | S           | Oral                                     |                                                                                                       |                 | Not Reported |
|                              | Levothyroxine    |              |            | S           | Oral                                     |                                                                                                       |                 | Not Reported |
|                              | Doxorubicin      |              |            | C           |                                          |                                                                                                       |                 | Not Reported |
|                              | Cyclophosphamide |              |            | C           |                                          |                                                                                                       |                 | Not Reported |
|                              | Docetaxel        |              |            | C           |                                          | Taken Once.                                                                                           |                 | Not Reported |
|                              | Citalopram       |              |            | C           | Oral                                     |                                                                                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2010              | 7336573       | EXPEDITED (15-DAY) | Y                  | OT              | 1000012354           |                      | 44 YR      | Female     | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Eyelid Oedema; Face<br>Oedema; Hypersensitivity | Escitalopram Oxalate |              |            | S           | Oral         | 5mg (5mg, 1 In 1d), Oral      | 15 DAY          | Not Reported |
|                                                 | Escitalopram Oxalate |              |            | S           | Oral         | 10mg (10 Mg, 1 In 1d<br>Oral) |                 | Not Reported |
|                                                 | B12 Vitamin          |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2010              | 7413804       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014120           |                      | 36 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| Anxiety; Chest Discomfort;<br>Drug Ineffective; Muscle<br>Twitching; Panic Attack | Escitalopram Oxalate    |                    |                    | S               |                                          | (10mg)                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2010                                                                       | 7431940                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000014451                               |                                | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Infection;<br>Pancreatitis Acute                                        | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | 10mg (10mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2010                                                                       | 7453726                 | EXPEDITED (15-DAY) | Y                  | HO              | IT-TEVA-238720ISR                        |                                | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Reaction With<br>Eosinophilia And Systemic<br>Symptoms                       | Lamotrigine             |                    |                    | S               |                                          |                                |                 | Teva         |                |
|                                                                                   | Escitalopram Oxalate    |                    |                    | S               |                                          |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jul-2010                                                                       | 7454552                 | EXPEDITED (15-DAY) | Y                  | OT              | US-BAXTER-<br>2010BH017411               |                                | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                                           | Fentanyl Citrate        |                    |                    | S               | Intravenous (not<br>otherwise specified) |                                |                 | Not Reported |                |
|                                                                                   | Trazodone Hydrochloride |                    |                    | S               |                                          |                                | Not Reported    |              |                |
|                                                                                   | Escitalopram Oxalate    |                    |                    | S               |                                          |                                | Not Reported    |              |                |
|                                                                                   | Etomidate               |                    |                    | C               |                                          |                                | Not Reported    |              |                |
|                                                                                   | Vecuronium Bromide      |                    |                    | C               |                                          |                                | Not Reported    |              |                |
|                                                                                   | Morphine                |                    |                    | C               |                                          |                                | Not Reported    |              |                |
|                                                                                   | Cefazolin               |                    |                    | C               |                                          |                                | Not Reported    |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |         |              |
|--------------------------|---|---------|--------------|
| Insulin Nos              | C | Unknown | Not Reported |
| Gabapentin               | C | Unknown | Not Reported |
| Lansoprazole             | C | Unknown | Not Reported |
| Lorazepam                | C | Unknown | Not Reported |
| Oxycodone                | C | Unknown | Not Reported |
| Cetirizine Hydrochloride | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Jul-2010              | 7454586       | EXPEDITED (15-DAY) | Y                  | OT              | FR-TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T201001513 |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Affective Disorder;<br>Diarrhoea; Drug<br>Interaction; Hyperhidrosis;<br>Mydriasis; Night Sweats;<br>Panic Attack; Serotonin<br>Syndrome; Toxicity To<br>Various Agents; Tremor;<br>Vision Blurred; Visual<br>Impairment; Weight<br>Decreased | Oxycodone            |              |            | S           |              | 120 Mg, Qd For 6 Months |                 | Tyco         |
|                                                                                                                                                                                                                                               | Fentanyl             |              |            | S           | Nasal        | 4 Puffs Of 200 Ug/Puff  |                 | Not Reported |
|                                                                                                                                                                                                                                               | Escitalopram Oxalate |              |            | S           |              | 5 Mg, Qd                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2010              | 7475910       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014836           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Anal Incontinence;<br>Overdose; Urinary<br>Incontinence | Escitalopram Oxalate |              |            | S           |              | 110 Mg (110 Mg, 1 In 1 D) |                 | Not Reported |
|                                                         | Buspar               |              |            | S           |              |                           |                 | Not Reported |
|                                                         | Neurontin            |              |            | S           |              |                           |                 | Not Reported |
|                                                         | Lyrica               |              |            | S           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2010              | 7364029       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013013           |                      | 34 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| Headache; Immune Thrombocytopenic Purpura; Mucosal Haemorrhage; Skin Haemorrhage          | Escitalopram Oxalate    |                    |                    | S               | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                           | Cerazette (Desogestrel) |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2010                                                                               | 7389111                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000013450               |                               | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety Disorder; Fall; Generalised Tonic-Clonic Seizure; Refusal Of Treatment By Patient | Lexapro                 |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                           | Clonazepam              |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2010                                                                               | 7455686                 | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PFIZER INC-2010079804 |                               |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Drug Ineffective; Self-Medication                                      | Geodon                  |                    |                    | S               | Oral                     | 40 Mg, 2x/Day                 |                 | Pfizer       |                |
|                                                                                           | Lexapro                 |                    |                    | S               |                          | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jul-2010                                                                               | 7455747                 | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2010BR41874          |                               | 18 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Lavage; Intentional Overdose; Suicide Attempt                                     | Trileptal               |                    |                    | S               | Oral                     |                               |                 | Novartis     |                |
|                                                                                           | Hydrochlorothiazide     |                    |                    | S               |                          | 12 Tablets                    |                 | Not Reported |                |
|                                                                                           | Alprazolam              |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                                                           | Escitalopram Oxalate    |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                                                           | Omeprazole              |                    |                    | S               |                          | 20 Tablet                     |                 | Not Reported |                |
|                                                                                           | Methyldopa              |                    |                    | S               |                          | 10 Tablets                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |            |              |
|----------------------|---|------------|--------------|
| Orphenadrine Citrate | S |            | Not Reported |
| Caffeine             | S |            | Not Reported |
| Metamizole Sodium    | S |            | Not Reported |
| Dimenhydrinate       | S | 8 Tablets  | Not Reported |
| Norfloxacin          | S | 14 Tablets | Not Reported |
| Ketoprofen           | S | 20 Tablets | Not Reported |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2010                                           | 7456439              | EXPEDITED (15-DAY) | Y                  | HO              | IT-MYLANLABS-2010S1011176 |                      | 26 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Reaction With Eosinophilia And Systemic Symptoms | Escitalopram Oxalate |                    |                    | S               | Unknown                   |                      |                 | Alphapharm   |                |
|                                                       | Lamotrigine          |                    |                    | S               | Unknown                   |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 07-Jul-2010                                                                                                                               | 7456570                   | EXPEDITED (15-DAY) | N                  | DE, HO          | B0664190A            |                      | 18 YR           | Female          | CZE            |
| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Brain Oedema; Completed Suicide; Intentional Overdose; Intra-Abdominal Haemorrhage; Pulmonary Oedema; Shock Haemorrhagic; Traumatic Shock | Propafenone Hydrochloride |                    |                    | S               | Unknown              |                      |                 | Glaxosmithkline |                |
|                                                                                                                                           | Cipraxel                  |                    |                    | S               | Oral                 | 10mg Per Day         |                 | Not Reported    |                |
|                                                                                                                                           | Acetylsalicylic Acid      |                    |                    | S               | Unknown              |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jul-2010              | 7456861        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2007071087 |                      | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms            | Zolof          |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                          | Pancrelipase   |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                          | Reglan         |                  |                    | C               |                          |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Erythromycin | C | Not Reported |
| Vitamins     | C | Not Reported |
| Calcium      | C | Not Reported |
| Ambien       | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2010              | 7488336       | EXPEDITED (15-DAY) | Y                  | DE              | 1000014188           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Brain Oedema; Completed Suicide; Intentional Overdose; Pulmonary Oedema; Shock   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Haemorrhagic; Toxicity To Various Agents; Traumatic Haemorrhage; Traumatic Shock | Propafenone          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                  | Acetylsalicylic Acid |              |            | S           |              | Oral                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2010              | 7488339       | EXPEDITED (15-DAY) | Y                  |                 | 1000014597           |                      | 56 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Cyst; Scar            | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Effexor Xr           |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Concerta             |              |            | S           | Oral         | 72 Mg (72 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Seroquel             |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Abilify              |              |            | C           |              |                               |                 | Not Reported |
|                       | Adderall             |              |            | C           |              |                               |                 | Not Reported |
|                       | Vitamin B12          |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2010              | 7488412       | EXPEDITED (15-DAY) | Y                  | OT              | 1-23137813           |                      | 66 YR      | Male       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|--------------|----------------|
| Drug Interaction;<br>Serotonin Syndrome;<br>Vision Blurred                                              | Oxycodone Hydrochloride |                    | Y                  | S               | Oral                     | 120 Mg/Day, Oral       | 6 MTH           | Not Reported |                |
|                                                                                                         | Fentanyl                |                    |                    | S               | Nasal                    | 200 Mcg/Puff X4, Nasal |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate    |                    |                    | S               | Oral                     | 5mg/Day, Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                                                             | 6255636                 | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2007014646 |                        | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension;<br>Abdominal Pain; Bladder<br>Disorder; Visual<br>Impairment; Weight<br>Increased | Lyrica                  |                    |                    | S               |                          | 50 Mg, 3x/Day          |                 | Pfizer       |                |
|                                                                                                         | Lexapro                 |                    |                    | S               |                          | Unk                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                                                             | 7459403                 | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2006117679 |                        | 59 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Nausea                                                                                       | Chantix                 |                    |                    | S               |                          |                        |                 | Pfizer       |                |
|                                                                                                         | Lexapro                 |                    |                    | S               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Vytorin                 |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Zocor                   |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Lopresor                |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Cozaar                  |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Isosorbide              |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Pletal                  |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Fish Oil                |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Vitamin E               |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Acetylsalicylic Acid    |                    |                    | C               |                          |                        |                 | Not Reported |                |
|                                                                                                         | Vitamin C               |                    |                    | C               |                          |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                                                             | 7459443                 | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2006118392 |                        | 45 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Crying; Depression                                                        | Chantix                 |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                                           | Lexapro                 |                  |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                               | 7460110                 | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2006140548 |                      | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Nausea; Tobacco Withdrawal Symptoms                      | Chantix                 |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                           | Lexapro                 |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                           | Loratadine              |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Zocor                   |                  |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                               | 7460154                 | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2006142998 |                      | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Disturbance In Attention; Feeling Abnormal                     | Chantix                 |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                           | Lexapro                 |                  |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Jul-2010                                                               | 7461053                 | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2006140251 |                      | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Dysgeusia; Fatigue; Hot Flush; Paraesthesia; Somnolence | Chantix                 |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                                           | Verapamil Hydrochloride |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Benicar                 |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Ddavp                   |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Montelukast Sodium      |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Allegra                 |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Famotidine              |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Premarin                |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                           | Potassium               |                  |                    | C               |                          |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                    |   |                             |  |  |  |  |  |              |
|--|--------------------|---|-----------------------------|--|--|--|--|--|--------------|
|  | Theophylline       | C |                             |  |  |  |  |  | Not Reported |
|  | Tiotropium Bromide | C | Respiratory<br>(inhalation) |  |  |  |  |  | Not Reported |
|  | Chantix            | S |                             |  |  |  |  |  | Pfizer       |
|  | Lamictal           | S |                             |  |  |  |  |  | Not Reported |
|  | Lexapro            | S |                             |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2010              | 7466196       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | 5mg Everyday Po    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2010              | 7492641       | EXPEDITED (15-DAY) | N                  | DS              | DSA_43435_2010       |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Confusional State; Fall;<br>Fibromyalgia; Impaired<br>Work Ability; Loss Of<br>Employment; Unevaluable<br>Event; Weight Increased | Wellbutrin XI           |              |            | S           | Oral         | (100 Mg Qd Oral), (150<br>Mg Qd Oral) |                 | Not Reported |
|                                                                                                                                   |                         |              |            |             | Oral         | (100 Mg Qd Oral), (150<br>Mg Qd Oral) |                 |              |
|                                                                                                                                   | Lexapro                 |              |            | S           |              | (Df)                                  |                 | Not Reported |
|                                                                                                                                   | Percocet                |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                                                                   | Klonopin                |              |            | C           |              |                                       |                 | Not Reported |
|                                                                                                                                   | Trazodone Hydrochloride |              |            | C           |              |                                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 6268075       | NON-EXPEDITED    | Y                  | OT              | US-PFIZER INC-<br>2007010630 |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Body Temperature<br>Decreased; Dizziness;<br>Drug Interaction; Feeling<br>Hot; Heart Rate Increased;<br>Hyperhidrosis; | Chantix        |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                                                        | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypotension; Nausea;  
Serotonin Syndrome;  
Stress; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 6812957       | EXPEDITED (15-DAY) | Y                  | HO              | 1000001534           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Biliary Tract Disorder; Cholestasis; Gamma-Glutamyltransferase Increased; Hepatitis; Lithiasis; Toxoplasmosis; Visual Acuity Reduced; Visual Impairment | Escitalopram Oxalate          |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1d), Oral |                 | Not Reported |
|                                                                                                                                                                                             | Valproate Sodium              |              |            | S           | Oral         | 1000 Mg (500 Mg, 2 In 1 D), Oral               |                 | Not Reported |
|                                                                                                                                                                                             | Malocide                      |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                             | Adiazine                      |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                             | Claritin                      |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                             | Tercian (40 Milligram, Drops) |              |            | C           |              |                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7417995       | EXPEDITED (15-DAY) | N                  | OT              | US-SHIRE-SPV1-2010-01039 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Insomnia; Intentional Overdose; Vomiting | Vyvanse        |              |            | S           | Oral         | 20 - 70 Mg Capsules, One 1 DAY Dose |                 | Not Reported |
|                                          | Vyvanse        |              |            | S           |              | 70 Mg, 1x/Day:Qd In Am              | 332 DAY         | Not Reported |
|                                          | Lexapro        |              |            | S           |              | 20mg Daily                          | 2 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7420828       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014119           |                      | 47 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Blood Creatine Phosphokinase Increased; Bronchitis; Confusional | Escitalopram Oxalate |              |            | S           | Oral         | 14 Tablets Once, Oral 10 Mg (10 Mg, 1 In 1 D) Oral |                 | Not Reported |
|                                                                 | Truxol               |              |            | C           |              |                                                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

State; Drug Abuse;  
Intentional Overdose;  
Somnolence

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7424153       | EXPEDITED (15-DAY) | Y                  | DE              | 1000014405           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------|-----------------|--------------|
| Completed Suicide;<br>Decreased Appetite;<br>Dizziness; Erectile<br>Dysfunction; Fumbling;<br>Inappropriate Affect;<br>Insomnia; Negative<br>Thoughts | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D),<br>15 Mg, 1 In 1 D)<br>10 Mg (10 Mg, 1 In 1 D),<br>15 Mg, 1 In 1 D) |                 | Not Reported |
|                                                                                                                                                       | Adiro                |              |            | C           |              |                                                                                              |                 | Not Reported |
|                                                                                                                                                       | Enalapril Maleate    |              |            | C           |              |                                                                                              |                 | Not Reported |
|                                                                                                                                                       | Somnovit             |              |            | C           |              |                                                                                              |                 | Not Reported |
|                                                                                                                                                       | Trankimazin          |              |            | C           |              |                                                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7454283       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000014604           |                      | 16 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Fatigue; Hypotension;<br>Intentional Overdose;<br>Miosis; Respiratory<br>Failure; Seizure; Suicide<br>Attempt; Vomiting | Escitalopram Oxalate |              |            | S           | Oral         | (100 Mg, Once), Oral, Oral |                 | Not Reported |
|                                                                                                                         | Pipamperone          |              |            | S           | Oral         | (1600 Mg, Once), Oral      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7462294       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DK-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-00816RO |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Use; Ataxia; Blood<br>Albumin Decreased; Blood<br>Sodium Decreased;<br>Confusional State;<br>Dehydration; Depression; | Citalopram           |              |            | S           |              |                    |                 | Roxane       |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           |              | 10 Mg              |                 | Not Reported |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           |              | 20 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                              |                                                              |                  |       |                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------|-------|--------------------------------------------------------------|
| Diarrhoea; Dizziness;<br>Drug Withdrawal<br>Syndrome; Gait<br>Disturbance; Haemoglobin<br>Decreased; Lethargy;<br>Malnutrition; Myoclonus;<br>Sinus Tachycardia;<br>Therapy Cessation;<br>Treatment<br>Noncompliance; Tremor | Omeprazole<br>Venlafaxine<br>Vitamin B Complex<br>Disulfiram | S<br>S<br>S<br>S | 40 Mg | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------|-------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7463150       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2007010045 |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>                                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                     | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                             |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------|------------|---------------------------------|--------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------|
| Abnormal Dreams; Anger;<br>Anxiety; Headache;<br>Nervousness; Stress;<br>Withdrawal Syndrome | Chantix<br>Lexapro<br>Wellbutrin<br>Lipitor<br>Ambien<br>Zelnorm<br>Xanax |              |            | S<br>S<br>C<br>C<br>C<br>C<br>C |              |                    |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 09-Jul-2010              | 7464244       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2007020032 |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>                                                                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                          | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                             |
|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------------|--------------|--------------------|-----------------|------------------------------------------------------------------------------------------------------------------------|
| Abnormal Dreams; Drug<br>Interaction; Sleep Disorder | Chantix<br>Metformin Hydrochloride<br>Crestor<br>Acetylsalicylic Acid<br>Saw Palmetto<br>Omega-3 Triglycerides<br>Advil<br>Lexapro |              |            | S<br>C<br>C<br>C<br>C<br>C<br>C<br>S |              |                    |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|--------------|----------------|
| 09-Jul-2010                    | 7464284              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2007010277 |                          | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased       | Chantix              |                    |                    | S               |                          |                          |                 | Pfizer       |                |
|                                | Lexapro              |                    |                    | S               |                          |                          |                 | Not Reported |                |
|                                | Lexapro              |                    |                    | S               |                          |                          |                 | Not Reported |                |
|                                | Advair Diskus        |                    |                    | C               | Respiratory (inhalation) |                          |                 | Not Reported |                |
|                                | Albuterol            |                    |                    | C               | Respiratory (inhalation) |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jul-2010                    | 7498303              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014943               |                          |                 | Male         | DNK            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness; Malaise | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |                |
|                                |                      |                    |                    |                 | Oral                     | 10 Mg (10 Mg, 1 In 1 D), |                 |              |                |
|                                |                      |                    |                    |                 | Oral                     | 10 Mg (10 Mg, 1 In 1 D), | 2 YR            |              |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2010                    | 7454301              | EXPEDITED (15-DAY) | Y                  | OT              | NO-MERCK-1007NOR00003    |                          | 55 YR           | Male         | NOR            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrasystoles                  | Zocor                |                    |                    | S               | Oral                     |                          |                 | Merck        |                |
|                                | Escitalopram Oxalate |                    |                    | S               | Unknown                  |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2010                    | 7466470              | EXPEDITED (15-DAY) | Y                  | OT              | NO-WATSON-2010-09059     |                          | 55 YR           | Male         | NOR            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                         |        |            |                        |
|---------------------------------------------|-------------------------|--------|------------|------------------------|
| Anxiety; Chest Discomfort;<br>Extrasystoles | Simvastatin<br>Cipraxel | S<br>S | Unk<br>Unk | Watson<br>Not Reported |
|---------------------------------------------|-------------------------|--------|------------|------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2010              | 7467742       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2007028656 |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------|
| Abdominal Pain; Abnormal<br>Dreams; Fatigue;<br>Headache; Middle<br>Insomnia; Nausea;<br>Nightmare; Somnolence;<br>Vomiting; Weight<br>Increased | Varenicline<br>Neurontin<br>Lexapro |              |            | S<br>S<br>S |              |                    |                 | Pfizer<br>Pfizer<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2010              | 7468255       | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-<br>2007030841 |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|-------------------------------------------------------------------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Crying; Depression;<br>Dizziness; Lethargy;<br>Mental Impairment;<br>Nausea; Tremor | Chantix<br>Lexapro |              |            | S<br>S      |              |                    |                 | Pfizer<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2010              | 7475694       | DIRECT           | Y                  | LT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Escitalopram Oxalate |              |            | S           | Oral         | 2.5mg Qd Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2010              | 6799281       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-08P-056-<br>0483616-00 |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 |                      |   |      |              |
|---------------------------------------------------------------------------------|----------------------|---|------|--------------|
| Cholestasis; Gamma-Glutamyltransferase Increased; Hepatitis; Lithiasis; Pyrexia | Depakene             | S | Oral | Not Reported |
|                                                                                 | Escitalopram Oxalate | S | Oral | Not Reported |
|                                                                                 | Pyrimethamine        | C | Oral | Not Reported |
|                                                                                 | Sulfadiazine         | C | Oral | Not Reported |
|                                                                                 | Claritin             | C | Oral | Not Reported |
|                                                                                 | Cyamemazine          | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2010              | 7470318       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2007037583 |                      | 60 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue               | Chantix        |              |            | S           |              |                    |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lotrel         |              |            | C           |              |                    |                 | Not Reported |
|                       | Toprol XL      |              |            | C           |              |                    |                 | Not Reported |
|                       | Gemfibrozil    |              |            | C           |              |                    |                 | Not Reported |
|                       | Zocor          |              |            | C           |              |                    |                 | Not Reported |
|                       | Aspirine       |              |            | C           |              |                    |                 | Not Reported |
|                       | Lunesta        |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2010              | 7471000       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2007041984 |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Dreams; Lethargy | Chantix        |              |            | S           |              |                    |                 | Pfizer       |
|                           | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                           | Prevacid       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Jul-2010              | 7471573       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2007035298 |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dysgeusia; Erectile Dysfunction; Flatulence; | Chantix        |              |            | S           |              |                    |                 | Pfizer       |
|                                              | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypoaesthesia; Nervous  
System Disorder;  
Paraesthesia

| <u>FDA Received Date</u>                                         | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------------------|----------------|
| 13-Jul-2010                                                      | 7471756            | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2007049673 |                      | 44 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Crying; Emotional<br>Disorder; Ill-Defined<br>Disorder; Vomiting | Chantix<br>Lexapro |                  |                    | S<br>S          |                              |                      |                 | Pfizer<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                             | <u>Country</u> |
|-----------------------------------------------------------------------------------------|----------------------------------------------------------------|------------------|--------------------|-----------------------|------------------------------|----------------------|-----------------|------------------------------------------------------------------------|----------------|
| 13-Jul-2010                                                                             | 7472108                                                        | NON-EXPEDITED    | Y                  |                       | US-PFIZER INC-<br>2007042410 |                      | 47 YR           | Male                                                                   | USA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                             |                |
| Dizziness; Drug<br>Interaction; Emotional<br>Disorder; Irritability;<br>Malaise; Nausea | Chantix<br>Acetylsalicylic Acid<br>Aleve<br>Opioids<br>Lexapro |                  |                    | S<br>C<br>C<br>C<br>S |                              |                      |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|----------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------------------------------|----------------|
| 13-Jul-2010                                                    | 7498495                                        | EXPEDITED (15-DAY) | N                  | OT              | 1000014694           |                                  | 31 YR           | Male                                         | BRA            |
| <u>Preferred Term</u>                                          | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Condition<br>Aggravated; Drug<br>Ineffective; Vertigo | Lexapro                                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                 |                |
|                                                                | Lexapro                                        |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                 |                |
|                                                                | Lexapro                                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                 |                |
|                                                                | Valerian Officinalis<br>Clonazepam<br>Zolpidem |                    |                    | C<br>C<br>C     |                      |                                  |                 | Not Reported<br>Not Reported<br>Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| 13-Jul-2010                 | 7502918               | EXPEDITED (15-DAY) | Y                  | OT              | 2010SCPR001150       |                                                       | 46 YR           | Female       | IND            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Anxiety; Blood   | Imipramine            |                    |                    | S               |                      | 75 Mg/Day                                             | 365 DAY         | Not Reported |                |
| Follicle Stimulating        | Escitalopram Oxalate  |                    |                    | S               |                      | 20 Mg, Qd                                             | 365 DAY         | Not Reported |                |
| Hormone Increased;          | Glyburide             |                    |                    | S               | Oral                 | 5 Mg, Qd, Oral                                        |                 | Not Reported |                |
| Cerebral Cyst; Condition    |                       |                    |                    |                 |                      |                                                       |                 |              |                |
| Aggravated; Drug            |                       |                    |                    |                 |                      |                                                       |                 |              |                |
| Interaction; Galactorrhoea; |                       |                    |                    |                 |                      |                                                       |                 |              |                |
| Persistent Depressive       |                       |                    |                    |                 |                      |                                                       |                 |              |                |
| Disorder; Sleep Disorder    |                       |                    |                    |                 |                      |                                                       |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jul-2010                 | 7504281               | EXPEDITED (15-DAY) |                    | OT              | 1000014956           |                                                       | 43 YR           | Female       | ITA            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Vaginal Haemorrhage         | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 13 Gtt (13 Gtt, 1 In 1 D),<br>Oral                    |                 | Not Reported |                |
|                             | Delorazepam           |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jul-2010                 | 7504305               | EXPEDITED (15-DAY) | Y                  | HO              | 1000014979           |                                                       | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Fall; Fractured    | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| Ischium; Haematoma;         | Fluindione            |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |                |
| Haemorrhage; Pubis          | Aspirin Lysine        |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D),<br>Oral                      |                 | Not Reported |                |
| Fracture; Respiratory       | Hemigoxine            |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| Distress                    | Candesartan Cilexetil |                    |                    | C               |                      |                                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                         | Inexium            |                    | C               |                                                 |                                           |                 |              | Not Reported   |
|-------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------|-----------------|--------------|----------------|
|                                           |                         | Vastarel           |                    | C               |                                                 |                                           |                 |              | Not Reported   |
|                                           |                         | Lorazepam          |                    | C               |                                                 |                                           |                 |              | Not Reported   |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2010                               | 7299603                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000011612                                      |                                           | 50 YR           | Male         | DNK            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Borderline Glaucoma;<br>Ocular Hyperaemia | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | 5 Mg (5 Mg, 1 In 1 D), Oral               |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2010                               | 7391179                 | EXPEDITED (15-DAY) | N                  | DE              | US-SHIRE-SPV1-2010-00928                        |                                           |                 | Unknown      | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Ventricular<br>Arrhythmia       | Vyvanse                 |                    |                    | S               | Unknown                                         | 30 Mg, 1x/Day:Qd                          |                 | Not Reported |                |
|                                           | Heroin                  |                    |                    | S               |                                                 |                                           |                 | Not Reported |                |
|                                           | Lamictal                |                    |                    | S               | Unknown                                         | 200 Mg, 1x/Day:Qd                         |                 | Not Reported |                |
|                                           | Abilify                 |                    |                    | S               | Unknown                                         | 30 Mg, 1x/Day:Qd                          |                 | Not Reported |                |
|                                           | Lexapro                 |                    |                    | S               | Unknown                                         | 10 Mg, 1x/Day:Qd                          |                 | Not Reported |                |
|                                           | Clonazepam              |                    |                    | S               |                                                 |                                           |                 | Not Reported |                |
|                                           | Methadone Hydrochloride |                    |                    | S               |                                                 |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2010                               | 7425222                 | EXPEDITED (15-DAY) | Y                  | OT              | DE-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15148372 |                                           | 49 YR           | Female       | DEU            |
| <u>Preferred Term</u>                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Generalised Oedema   | Abilify                 |                    |                    | S               | Oral                                            |                                           | 4 WEEK          | Not Reported |                |
|                                           | Lithium                 |                    |                    | C               |                                                 |                                           |                 | Not Reported |                |
|                                           | Escitalopram Oxalate    |                    |                    | C               |                                                 |                                           |                 | Not Reported |                |
|                                           | Lithium Carbonate       |                    |                    | S               | Oral                                            | Quilonum Retard Taken<br>Before 06apr2010 |                 | Not Reported |                |
|                                           | Cipralext               |                    |                    | S               | Oral                                            | Taken Before 06apr2010                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------|-----------------|--------------|----------------|
| 14-Jul-2010                                  | 7465641                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000014735               |                         | 20 YR           | Female       | CZE            |
| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                                    | Escitalopram Oxalate    |                    |                    | S               | Oral                     | 5 Mg (1, In 1 D), Oral  |                 | Not Reported |                |
|                                              | Escitalopram Oxalate    |                    |                    | S               | Oral                     | 10 Mg, Oral, 5 Mg, Oral |                 | Not Reported |                |
|                                              |                         |                    |                    |                 | Oral                     | 10 Mg, Oral, 5 Mg, Oral |                 |              |                |
|                                              | Trazodone               |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Risperidone             |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Aripiprazole            |                    |                    | C               |                          |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2010                                  | 7474089                 | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2007055083 |                         | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression; Drug Interaction        | Chantix                 |                    |                    | S               |                          |                         |                 | Pfizer       |                |
|                                              | Lexapro                 |                    |                    | S               |                          |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jul-2010                                  | 7474353                 | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2007058026 |                         | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Interaction; Headache | Chantix                 |                    |                    | S               |                          |                         |                 | Pfizer       |                |
|                                              | Percocet                |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Methadone Hydrochloride |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Verapamil Hydrochloride |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Hydrochlorothiazide     |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Zocor                   |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Tranxene T-Tab          |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Glucophage              |                    |                    | C               |                          |                         |                 | Not Reported |                |
|                                              | Lexapro                 |                    |                    | S               |                          |                         |                 | Not Reported |                |
|                                              | Provigil                |                    |                    | S               |                          |                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------|-----------------|------------------------|----------------|
| 14-Jul-2010                                                      | 7474748              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2007061388                        |                                  |                 | Unknown                | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>             |                |
| Cardiac Disorder                                                 | Chantix<br>Lexapro   |                    |                    | S<br>S          |                                                 |                                  |                 | Pfizer<br>Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 15-Jul-2010                                                      | 7511435              | EXPEDITED (15-DAY) | Y                  | OT              | 1000015014                                      |                                  | 59 YR           | Female                 | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Interaction;<br>Hypertonia; Muscle<br>Spasms; Pain          | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported           |                |
|                                                                  | Tylenol With Codeine |                    |                    | S               | Oral                                            | (1 Dosage Forms), Oral           |                 | Not Reported           |                |
|                                                                  | Clonazepam           |                    |                    | C               |                                                 |                                  |                 | Not Reported           |                |
|                                                                  | Paxil                |                    |                    | C               |                                                 |                                  |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 16-Jul-2010                                                      | 7371023              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013209                                      |                                  | 29 YR           | Female                 | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>             |                |
| Blood Antidiuretic<br>Hormone Decreased;<br>Polydipsia; Polyuria | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported           |                |
|                                                                  | Restex (Tablets)     |                    |                    | C               |                                                 |                                  |                 | Not Reported           |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
| 16-Jul-2010                                                      | 7479824              | EXPEDITED (15-DAY) | Y                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15187461 |                                  | 59 YR           | Female                 | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>             |                |
| Drug Interaction;<br>Respiratory Acidosis;<br>Serotonin Syndrome | Morphine Sulfate     |                    |                    | S               |                                                 |                                  |                 | Endo                   |                |
|                                                                  | Etomidate            |                    |                    | S               |                                                 |                                  |                 | Not Reported           |                |
|                                                                  | Vecuronium Bromide   |                    |                    | S               |                                                 |                                  |                 | Not Reported           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |                                       |                |  |              |
|-------------------------|---|---------------------------------------|----------------|--|--------------|
| Cefazolin               | S |                                       |                |  | Sandoz       |
| Trazodone Hydrochloride | S |                                       |                |  | Apothecon    |
| Escitalopram Oxalate    | S |                                       |                |  | Not Reported |
| Fentanyl                | S | Intravenous (not otherwise specified) | Divided 8doses |  | Not Reported |

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------|--------------------|------------------|--------------------------|----------------------|-----------------|--------------------------------------------------------|----------------|
| 16-Jul-2010                                                                                                                            | 7480093                                    | NON-EXPEDITED    | N                  | OT               | US-PFIZER INC-2007080688 |                      | 57 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Feeling Jittery;<br>Nervousness; Palpitations                                                                                          | Chantix<br>Lexapro<br>Antihypertensives    |                  |                    | S<br>S<br>C      |                          |                      |                 | Pfizer<br>Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 16-Jul-2010                                                                                                                            | 7480432                                    | NON-EXPEDITED    | N                  | HO               | US-PFIZER INC-2007080965 |                      |                 | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Crying; Drug Interaction;<br>Headache; Migraine                                                                                        | Chantix<br>Seroquel<br>Klonopin<br>Lexapro |                  |                    | S<br>S<br>S<br>S |                          |                      |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 16-Jul-2010                                                                                                                            | 7480480                                    | NON-EXPEDITED    | N                  |                  | US-PFIZER INC-2007082444 |                      | 35 YR           | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Dizziness; Drug<br>Interaction; Emotional<br>Disorder; Feeling<br>Abnormal; Headache;<br>Insomnia; Poor Quality<br>Sleep; Restlessness | Chantix<br>Lexapro<br>Lexapro              |                  |                    | S<br>S<br>S      |                          | Every Day            |                 | Pfizer<br>Not Reported<br>Not Reported                 |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>     | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|----------------------------|--------------------------|--------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------|----------------|
| 16-Jul-2010                                                                              | 7481721                                                       | NON-EXPEDITED      | N                  |                            | US-PFIZER INC-2007088152 |                                                              |                 | Female                                                                                 | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>             | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Abnormal Dreams; Anger; Drug Interaction; Irritability                                   | Chantix<br>Lexapro                                            |                    |                    | S<br>S                     |                          |                                                              |                 | Pfizer<br>Not Reported                                                                 |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>     | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 16-Jul-2010                                                                              | 7482283                                                       | NON-EXPEDITED      | N                  |                            | US-PFIZER INC-2007091840 |                                                              | 46 YR           | Female                                                                                 | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>             | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Somnolence                                                                               | Chantix<br>Lexapro<br>Lexapro<br>Nexium<br>Flexeril<br>Valium |                    |                    | S<br>S<br>S<br>C<br>C<br>C | Oral                     |                                                              |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>     | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>                                                                             | <u>Country</u> |
| 16-Jul-2010                                                                              | 7509896                                                       | EXPEDITED (15-DAY) | Y                  | HO                         | 1000015028               |                                                              | 66 YR           | Female                                                                                 | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>             | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>                                                                             |                |
| Haematocrit Decreased; Haemoglobin Decreased; Overdose; White Blood Cell Count Increased | Lexapro                                                       |                    |                    | S                          | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported                                                                           |                |
|                                                                                          |                                                               |                    |                    |                            | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral; 30 Mg (20 Mg, 1 In 1 D), Oral |                 |                                                                                        |                |
|                                                                                          | Gabapentin                                                    |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Simvastatin                                                   |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Verapamil Hydrochloride                                       |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Lisinopril                                                    |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Levothyroid                                                   |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Omeprazole                                                    |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |
|                                                                                          | Temazepam                                                     |                    |                    | C                          |                          |                                                              |                 | Not Reported                                                                           |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                      |                    |                    |                 |                              |                                  |                 |              |                |
|-----------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Hydrocodone                                                           |                                      | C                  |                    | Not Reported    |                              |                                  |                 |              |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2010                                                           | 7512793                              | EXPEDITED (15-DAY) | Y                  | DS              | 1000015049                   |                                  | 57 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cold Sweat; Headache;<br>Muscular Weakness;<br>Nausea; Vision Blurred | Escitalopram Oxalate                 |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                       | Nebivolol Hydrochloride<br>(Tablets) |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                       | Candesartan Cilexetil (Tablets)      |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                       | Omeprazole                           |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                       | Simvastatin                          |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                       | Lorazepam                            |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jul-2010                                                           | 7512796                              | EXPEDITED (15-DAY) | Y                  | DS              | 1000015022                   |                                  | 25 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Libido Decreased;<br>Paralysis                                        | Escitalopram Oxalate                 |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jul-2010                                                           | 7483614                              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2007097486 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anger; Drug<br>Interaction; Irritability                   | Chantix<br>Lexapro                   |                    |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                       |                                      |                    |                    | S               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2010                                                           | 6790883                              | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-<br>2008020292 |                                  | 53 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                                                                              |                            |      |                                                                                        |
|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------|------|----------------------------------------------------------------------------------------|
| Abdominal Discomfort;<br>Depression; Dizziness;<br>Drug Interaction; Fatigue;<br>Hyperphagia; Malaise | Chantix<br>Valtrex<br>Lodine<br>Zantac<br>Trazodone Hydrochloride<br>Lexapro | S<br>C<br>C<br>C<br>C<br>S | Oral | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------|------|----------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2010              | 7475702       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014803           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Ovarian Cyst          | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2010              | 7486577       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-TEVA-241187USA    |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                           |
|-----------------------------------------|-------------------------------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------------------------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram Oxalate<br>Trazodone Hydrochloride<br>Fentanyl |              |            | S<br>S<br>S | Intravenous (not<br>otherwise specified) | 250 Ug             |                 | Not Reported<br>Barr<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jul-2010              | 7487523       | EXPEDITED (15-DAY) | N                  | DE              | A0870970A            |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                      |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-------------------------------------------------|
| Completed Suicide;<br>Dependence; Depression;<br>Intentional Product<br>Misuse; Loss Of<br>Consciousness;<br>Withdrawal Syndrome | Lamictal<br>Lexapro<br>Fentanyl |              |            | S<br>S<br>S |              |                    |                 | Glaxosmithkline<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 19-Jul-2010                                                                                                                                 | 7488682                        | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2008010870 |                      | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Depression;<br>Disturbance In Attention;<br>Dizziness; Drug<br>Ineffective; Emotional<br>Disorder; Headache;<br>Nausea; Nervousness | Chantix                        |                  |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                                                                                                             | Wellbutrin XI                  |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Lexapro                        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Chondroitin/Glucosamine        |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Acetylsalicylic Acid           |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | All Other Therapeutic Products |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | All Other Therapeutic Products |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Digestives, Incl Enzymes       |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Calcium                        |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Asacol                         |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Omeprazole                     |                  |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2010                                                                                                                                 | 7489171                        | NON-EXPEDITED    | Y                  | DE, OT          | US-PFIZER INC-2008015811 |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                           | Chantix                        |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                                             | Lexapro                        |                  |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2010                                                                                                                                 | 7489894                        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2008021014 |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Fatigue;<br>Vitamin B12 Deficiency;<br>Vitamin D Deficiency                                                               | Chantix                        |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                                             | Levothyroxine Sodium           |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Lisinopril                     |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Zetia                          |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Insulin Nos                    |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Vitamin D2                     |                  |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                                             | Lumigan                        |                  |                    | C               | Ophthalmic               |                      |                 | Not Reported |                |
|                                                                                                                                             | Ciclosporin                    |                  |                    | C               |                          |                      |                 | Not Reported |                |

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|                                                                                   |                        |                    |                    |                 |                              |                                               |                 |              |                |
|-----------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|------------------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Cymbalta<br>Lexapro                                                               |                        |                    | C<br>S             |                 | Not Reported<br>Not Reported |                                               |                 |              |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2010                                                                       | 7497317                | DIRECT             | N                  |                 |                              |                                               | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Marital Problem; Muscle Twitching; Paranoia; Thinking Abnormal        | Lexapro                |                    |                    | S               | Oral                         | 20mg Daily Po                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2010                                                                       | 7522432                | EXPEDITED (15-DAY) | Y                  | OT              | 1000015087                   |                                               | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Ovarian Cyst                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                         | 20 Mg (20 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2010                                                                       | 7486938                | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000014878                   |                                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Epistaxis; International Normalised Ratio Fluctuation; Overdose | Escitalopram Oxalate   |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
|                                                                                   | Previscan (Fluindione) |                    |                    | S               |                              | 0.75 Dosage Forms (0.75 Dosage Forms 1 In D)  |                 | Not Reported |                |
|                                                                                   | Previscan (Fluindione) |                    |                    | S               |                              | 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D) |                 | Not Reported |                |
|                                                                                   | Prozac                 |                    |                    | C               |                              |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2010                                                                       | 7521921                | EXPEDITED (15-DAY) | N                  | HO              | 1000012654                   |                                               | 20 YR           | Male         | DNK            |

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| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Aggression; Agitation; Anxiety; Burnout Syndrome; Condition Aggravated; Confusional State; Decreased Appetite; Depersonalisation/Derealisation Disorder; Depression; Dyskinesia; Dysuria; Fatigue; Initial Insomnia; Intentional Self-Injury; Muscular Weakness; Nervousness; Panic Attack; Sexual Dysfunction; Somnolence; Suicidal Ideation; Weight Decreased; Yawning | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Stresam (Tablets)       |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Magne B6 (Tablets)      |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          |                         |                    |                    |                 |                      |                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2010                                                                                                                                                                                                                                                                                                                                                              | 7522071                 | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2010-01712   |                               | 55 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Extrasystoles                                                                                                                                                                                                                                                                                                                                                   | Simvastatin             |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Cipralext               |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jul-2010                                                                                                                                                                                                                                                                                                                                                              | 7344603                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000012502           |                               | 15 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania; Off Label Use                                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Clorazepate Dipotassium |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Risperdal               |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                          | Topiramate (Tabelts)    |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------|-------------------------|
| 21-Jul-2010                                                                            | 7467483                 | EXPEDITED (15-DAY)        | Y                           | OT                       | NO-MERCK-1007NOR00008         |                               | 55 YR                    | Male                   | NOR                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Extrasystoles                                                                          | Simvastatin             |                           |                             | S                        | Oral                          |                               |                          | Not Reported           |                         |
|                                                                                        | Escitalopram Oxalate    |                           |                             | S                        | Unknown                       |                               |                          | Not Reported           |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 21-Jul-2010                                                                            | 7492551                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2008023419      |                               | 46 YR                    | Male                   | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Drug Ineffective; Drug Interaction                                                     | Chantix<br>Lexapro      |                           |                             | S<br>S                   |                               |                               |                          | Pfizer<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 21-Jul-2010                                                                            | 7492962                 | NON-EXPEDITED             | Y                           | OT                       | US-PFIZER INC-2008025093      |                               |                          | Unknown                | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Seizure                                                                                | Chantix<br>Lexapro      |                           |                             | S<br>S                   |                               |                               |                          | Pfizer<br>Not Reported |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>    | <a href="#">Country</a> |
| 21-Jul-2010                                                                            | 7522491                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000015129                    |                               | 35 YR                    | Female                 | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>    |                         |
| Abdominal Pain Upper; Dizziness; Feeling Abnormal; Vaginal Haemorrhage; Vision Blurred | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported           |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------|-----------------|----------------------|----------------|
| 22-Jul-2010                                                                                               | 7465965                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000014727                                      |                                  | 43 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Breast Haematoma;<br>Cholelithiasis; Pancreatitis                                                         | Escitalopram Oxalate     |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported         |                |
|                                                                                                           | Escitalopram Oxalate     |                    |                    | S               | Oral                                            | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported         |                |
|                                                                                                           | Alprazolam               |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Stilnox                  |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Athymil                  |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jul-2010                                                                                               | 7494766                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15197809 |                                  | 84 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Acute Kidney Injury;<br>Agitation; Fall;<br>Hypotension; Respiratory<br>Tract Inflammation;<br>Somnolence | Coaprovel                |                    |                    | S               |                                                 |                                  |                 | Bristol Myers Squibb |                |
|                                                                                                           | Dafalgan Codeine         |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Ixprim                   |                    |                    | S               |                                                 | 1 Df: 37.5mg/325 Mg              | 4 DAY           | Not Reported         |                |
|                                                                                                           | Zopiclone                |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Xanax                    |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Cetirizine Hydrochloride |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Loperamide Hydrochloride |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Escitalopram Oxalate     |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Xatral                   |                    |                    | S               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Acarbose                 |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Previscan (Fluindione)   |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 22-Jul-2010                                                                                               | 7495823                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2008042251                    |                                  | 50 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Abnormal Behaviour;<br>Anger; Anxiety; Depressed<br>Mood; Drug Interaction;                               | Chantix                  |                    |                    | S               | Oral                                            |                                  |                 | Pfizer               |                |
|                                                                                                           | Lorazepam                |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |
|                                                                                                           | Zoloft                   |                    |                    | C               |                                                 |                                  |                 | Not Reported         |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                 |         |   |              |
|-------------------------------------------------------------------------------------------------|---------|---|--------------|
| Emotional Disorder;<br>Fatigue; Loss Of Personal<br>Independence In Daily<br>Activities; Stress | Lexapro | S | Not Reported |
|-------------------------------------------------------------------------------------------------|---------|---|--------------|

| <u>FDA Received Date</u>                           | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|----------------------------------------------------|--------------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|----------------------------------------|----------------|
| 22-Jul-2010                                        | 7496833                        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2008056324 |                      | 33 YR           | Female                                 | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Drug Screen False<br>Positive; Nausea;<br>Vomiting | Chantix<br>Lexapro<br>Prevacid |                  |                    | S<br>S<br>C     |                              |                      |                 | Pfizer<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 22-Jul-2010                                                                                                                    | 7527117                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000015158           |                                                           | 93 YR           | Male                                         | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Abnormal Behaviour;<br>Aggression; Agitation;<br>Disorientation;<br>Hallucination, Visual;<br>Overdose; Withdrawal<br>Syndrome | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 1 Dosage Forms (1<br>Dosage Forms, 1 In 1 D),<br>Oral     |                 | Not Reported                                 |                |
|                                                                                                                                | Piribedil                   |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D),<br>Oral                          |                 | Not Reported                                 |                |
|                                                                                                                                | Stilnox                     |                    |                    | S               | Oral                 | 0.5 Dosage Forms (0.5<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported                                 |                |
|                                                                                                                                | Xanax                       |                    |                    | S               | Oral                 | 1.5 Dosage Forms (0.5<br>Dosage Forms, 3 In 1 D),<br>Oral |                 | Not Reported                                 |                |
|                                                                                                                                | Xyzall<br>Kardegic<br>Mecir |                    |                    | C<br>C<br>C     |                      |                                                           |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2010              | 7527320       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000014445           |                      | 47 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------------------|-----------------|--------------|----------------|
| Bronchitis; Empyema;<br>Fibrin D Dimer Increased;<br>General Physical Health<br>Deterioration;<br>Haemophilus Infection;<br>Lymphocyte Percentage<br>Increased; Neutrophil<br>Percentage Increased;<br>Normochromic Normocytic<br>Anaemia; Nutritional<br>Condition Abnormal;<br>Platelet Count Increased;<br>Pleural Adhesion; Pleural<br>Effusion; Pneumonia;<br>Streptococcal Infection;<br>Tachycardia; Therapy<br>Non-Responder; White<br>Blood Cell Count<br>Increased | Escitalopram Oxalate                        |                    |                    | S               |                                    | 10 Mg (10 Mg, 1 In 1 D)          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Mirtazapine                                 |                    |                    | S               |                                    | 15 Mg (15 Mg, 1 In 1 D)          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Zopiclone                                   |                    |                    | S               |                                    | 7.5 Mg (7.5 Mg, 1 In 1 D)        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2010                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 7535147                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000015104                         |                                  | 65 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Initial Insomnia;<br>Restlessness; Sleep<br>Disorder                                                                                                                                                                                                                                                                                                                                                                                                                         | Escitalopram Oxalate                        |                    |                    | S               | Oral                               | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Escitalopram Oxalate                        |                    |                    | S               | Oral                               | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jul-2010                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 8354749                                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-<br>2010SA041272 |                                  | 84 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Somnolence                                                                                                                                                                                                                                                                                                                                                                                                                                           | Xatral                                      |                    |                    | S               | Oral                               |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Tramadol Hydrochloride And<br>Acetaminophen |                    |                    | S               | Oral                               |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |   |      |              |
|--|--------------------------|---|------|--------------|
|  | Cetirizine Hydrochloride | S | Oral | Not Reported |
|  | Zopiclone                | S | Oral | Not Reported |
|  | Xanax                    | S | Oral | Not Reported |
|  | Dafalgan Codeine         | S | Oral | Not Reported |
|  | Loperamide               | S | Oral | Not Reported |
|  | Escitalopram Oxalate     | S | Oral | Not Reported |
|  | Coaprovel                | S | Oral | Not Reported |
|  | Acarbose                 | C | Oral | Not Reported |
|  | Previscan (Fluindione)   | C |      | Not Reported |
|  | Paracetamol              | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2010              | 7369627       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013222           |                      | 34 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Confusional State; Derealisation; Dizziness; Dry Mouth; Headache; Insomnia; Loss Of Consciousness; Malaise; Nausea; Restlessness; Syncope; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg 910 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                            | Dalacin              |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2010              | 7383434       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013471           |                      | 10 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Abnormal Behaviour; Hallucination; Insomnia; Off Label Use | Escitalopram Oxalate |              |            | S           |              |                            |                 | Not Reported |
|                                                            | Escitalopram Oxalate |              |            | S           |              |                            |                 | Not Reported |
|                                                            | Carbamazepine        |              |            | S           |              | 1600 Mg (800 Mg, 2 In 1 D) |                 | Not Reported |
|                                                            | Carbamazepine        |              |            | S           |              |                            |                 | Not Reported |
|                                                            | Lamotrigine          |              |            | S           |              | 400 Mg (200 Mg, 2 In 1 D)  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                    |                      |                    |                    |                 |                      |                               |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Lamotrigine                                                                                                                                                                                                                        |                      | S                  |                    | Not Reported    |                      |                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                                                                                                                                                                        | 7388220              | EXPEDITED (15-DAY) | Y                  | OT              | 1000013499           |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Feeling Abnormal; Hostility; Thinking Abnormal                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               |                      | (5 Mg)                        |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Escitalopram Oxalate |                    |                    | S               |                      | (10 Mg)                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                                                                                                                                                                        | 7422756              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000014266           |                               | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatomegaly; Myalgia; Nausea; Prothrombin Level Decreased | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg 910 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Lamotrigine          |                    |                    | S               |                      | 50 Mg (50 Mg, 1 In 1 D)       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                                                                                                                                                                        | 7498321              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000014947           |                               | 28 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Sopor; Suicide Attempt                                                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                 | (500 Mg, Once), Oral          |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Amitriptyline        |                    |                    | S               | Oral                 | (1225 Mg, Once), Oral         |                 | Not Reported |                |
|                                                                                                                                                                                                                                    | Melperone            |                    |                    | S               | Oral                 | (1250 Mg, Once), Oral         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
| 23-Jul-2010                                                                        | 7500815              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2009178746 |                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams                                                                    | Chantix              |                    |                    | S               |                          | 1 Mg, 2x/Day                |                 | Pfizer       |                |
|                                                                                    | Lexapro              |                    |                    | S               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                        | 7509478              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000014857               |                             | 75 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Pneumonia; Respiratory Failure; Torsade De Pointes | Escitalopram Oxalate |                    |                    | S               |                          | 10 Mg (10 Mg, 1 In 1 D)     |                 | Not Reported |                |
|                                                                                    | Rivastigmine         |                    |                    | S               |                          | 3 Mg                        |                 | Not Reported |                |
|                                                                                    | Lidocaine            |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                                                    | Cortisone            |                    |                    | C               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                        | 7528665              | EXPEDITED (15-DAY) | Y                  | OT              | 1000015147               |                             |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                     | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                    | Amiodarone           |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                                                    | Avapro               |                    |                    | C               |                          |                             |                 | Not Reported |                |
|                                                                                    | Amlodipine           |                    |                    | C               |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jul-2010                                                                        | 7528701              | EXPEDITED (15-DAY) | Y                  | OT              | 1000015194               |                             | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Petit Mal Epilepsy                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D)     |                 | Not Reported |                |
|                                                                                    | Triphasil-21         |                    |                    | C               |                          | ,Oral                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jul-2010              | 7528726       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014788           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Suicide Attempt | Escitalopram Oxalate |              |            | S           | Oral         | Oral; 20 Mg (20 Mg, 1 In 1 D), Oral                       |                 | Not Reported |
|                                          |                      |              |            |             | Oral         | Oral; 20 Mg (20 Mg, 1 In 1 D), Oral                       |                 |              |
|                                          | Alprazolam           |              |            | S           | Oral         | Oral, 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                          |                      |              |            |             | Oral         | Oral, 0.5 Dosage Forms (0.5 Dosage Forms, 1 In 1 D), Oral |                 |              |
|                                          | Zolpidem             |              |            | S           | Oral         | Oral, 5 Mg (5 Mg, 1 In 1 D), Oral                         |                 | Not Reported |
|                                          |                      |              |            |             | Oral         | Oral, 5 Mg (5 Mg, 1 In 1 D), Oral                         |                 |              |
|                                          | Alcohol              |              |            | S           | Oral         | 1/2 Bottle, Oral                                          |                 | Not Reported |
|                                          |                      |              |            |             |              |                                                           |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2010              | 7115698       | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000008598           |                      |            | Male       | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Anencephaly; Maternal<br>Drugs Affecting Foetus | Lexapro                |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |
|                                                 | Prenatal Vitamin (Nos) |              |            | C           |                |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2010              | 7158622       | EXPEDITED (15-DAY) | Y                  | OT              | 1000009329           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Dissociative Identity<br>Disorder; Drug<br>Intolerance; Feeling | Escitalopram Oxalate |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D), |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                       |                    |   |      |              |
|-------------------------------------------------------|--------------------|---|------|--------------|
| Abnormal; Schizophrenia;<br>Suicidal Ideation; Tremor | Hydrocortisone     | C | Oral | Not Reported |
|                                                       | Lercan             | C |      | Not Reported |
|                                                       | Flecainide Acetate | C |      | Not Reported |
|                                                       | Fractal            | C |      | Not Reported |
|                                                       | Kardegic           | C |      | Not Reported |
|                                                       | Orocal D3          | C |      | Not Reported |
|                                                       |                    |   |      |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2010              | 7491741       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014898           |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety; Dizziness;<br>Palpitations; Sleep<br>Disorder; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                                                | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                                                | Zolodrom             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                | Singulair            |              |            | C           |              |                                  |                 | Not Reported |
|                                                                | Aspirin Cardio       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                | Atorvastatin         |              |            | C           |              |                                  |                 | Not Reported |
|                                                                | Remeron              |              |            | C           |              |                                  |                 | Not Reported |
|                                                                | Eltroxin             |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2010              | 7533194       | EXPEDITED (15-DAY) | N                  | HO              | 1000015225           |                      | 34 YR      | Female     | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Gastrointestinal Disorder;<br>Papilloedema | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2010              | 7533197       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015226           |                      | 46 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                       |                      |   |      |                                  |              |
|---------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Galactorrhoea;<br>Hyperprolactinaemia | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|---------------------------------------|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2010              | 7412813       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000013676           |                      | 27 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Dizziness;<br>Obsessive Thoughts;<br>Overdose; Restlessness | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 | Not Reported |
|                                                                      |                      |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 |              |
|                                                                      |                      |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D), Oral; 10 Mg (10 Mg, 1<br>In 1 D), Oral |                 |              |
|                                                                      | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg 910 Mg, 1 In 1 D),<br>Oral; 20 Mg 920 Mg, 1 In 1<br>D), Oral; 30 Mg (30 Mg, 1<br>In 1 D), Oral |                 | Not Reported |
|                                                                      |                      |              |            |             | Oral         | 10 Mg 910 Mg, 1 In 1 D),<br>Oral; 20 Mg 920 Mg, 1 In 1<br>D), Oral; 30 Mg (30 Mg, 1<br>In 1 D), Oral |                 |              |
|                                                                      |                      |              |            |             | Oral         | 10 Mg 910 Mg, 1 In 1 D),<br>Oral; 20 Mg 920 Mg, 1 In 1<br>D), Oral; 30 Mg (30 Mg, 1<br>In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2010              | 7502519       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJCH-2010016835  |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Blood Alcohol Abnormal; | Benadryl       |              |            | S           | Oral         | Text:Several Tablets |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                 |         |   |         |                          |              |
|-------------------------------------------------|---------|---|---------|--------------------------|--------------|
| Loss Of Consciousness;<br>Road Traffic Accident | Lexapro | S | Unknown | Text:Unknown             | Not Reported |
|                                                 | Alcohol | S | Oral    | Text:Two Glasses Of Wine | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Jul-2010              | 7503020       | EXPEDITED (15-DAY) | Y                  | HO              | US-MYLANLABS-2010S1012425 |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|--------------------------|--------------|------------|-------------|---------------------------------------|----------------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Escitalopram Oxalate     |              |            | S           | Unknown                               |                                              |                 | Alphapharm   |
|                                         | Insulin Nos              |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Gabapentin               |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Lansoprazole             |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Lorazepam                |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Oxycodone                |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Cetirizine Hydrochloride |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Etomidate                |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Vecuronium Bromide       |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Morphine                 |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Cefazolin                |              |            | C           | Unknown                               |                                              |                 | Not Reported |
|                                         | Fentanyl                 |              |            | S           | Intravenous (not otherwise specified) | 250mcg In Divided Doses Between 8am And 11am |                 | Not Reported |
|                                         | Trazodone                |              |            | S           | Unknown                               |                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2010              | 7530644       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015233           |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Homicide; Suicide Attempt | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                           | Zyprexa        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|-------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 27-Jul-2010                              | 7533201                                                                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000015213           |                                                                    |                 | Male         | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Mood Altered                             | Escitalopram Oxalate                                                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                              | 7320185                                                                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000011920           |                                                                    | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Homicidal Ideation;<br>Suicidal Ideation | Escitalopram Oxalate                                                                |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                          |                                                                                     |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                          | Propoxyphene Hydrochloride<br>And Acetaminophen<br>Paracetamol<br>Lexomil (Tablets) |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                          |                                                                                     |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                          |                                                                                     |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                              | 7370228                                                                             | EXPEDITED (15-DAY) | Y                  | OT              | 1000013185           |                                                                    | 55 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Palpitations                 | Escitalopram Oxalate                                                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |                |
|                                          | Aprovel                                                                             |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
|                                          | Levothyrox                                                                          |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                              | 7382983                                                                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000013472           |                                                                    | 27 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Autonomic Nervous System Imbalance; Clonus; Dizziness; Drug Interaction; Hyperreflexia; Mydriasis; Restlessness; Serotonin Syndrome; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                             | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                             | Tamiflu              |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                             | Clonazepam           |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2010              | 7385940       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013545           |                      | 18 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|
| Dysuria; Ejaculation Delayed; Nocturia; Overdose; Polyuria; Prostatic Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral |                 | Not Reported |
|                                                                                |                      |              |            |             | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral |                 |              |
|                                                                                |                      |              |            |             | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 30 Mg (15 Mg, 2 In 1 D), Oral |                 |              |
|                                                                                | Methotrexate         |              |            | C           |              |                                                                                               |                 | Not Reported |
|                                                                                | Folic Acid           |              |            | C           |              |                                                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 28-Jul-2010              | 7505174       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20100707467 |                      | 84 YR      | Male       | FRA            |

| <u>Preferred Term</u>           | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury; Somnolence | Tramadol Hydrochloride And Acetaminophen |              |            | S           | Oral         |                    | 4 DAY           | Not Reported |
|                                 | Cetirizine Hydrochloride                 |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                       |   |         |              |
|--|-----------------------|---|---------|--------------|
|  | Xatral                | S | Oral    | Not Reported |
|  | Zopiclone             | S | Oral    | Not Reported |
|  | Xanax                 | S | Oral    | Not Reported |
|  | Dafalgan Codeine      | S | Oral    | Not Reported |
|  | Loperamide            | S | Oral    | Not Reported |
|  | Escitalopram Oxalate  | S | Oral    | Not Reported |
|  | Coaprovel             | S | Oral    | Not Reported |
|  | Acarbose              | C | Unknown | Not Reported |
|  | Prevican (Fluindione) | C | Unknown | Not Reported |
|  | Paracetamol           | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 28-Jul-2010              | 7505674       | EXPEDITED (15-DAY) | Y                  | OT              | US-ASTRAZENECA-2010SE33504 |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accidental Overdose;<br>Mania | Seroquel       |              |            | S           | Oral         |                    | 3 DAY           | Zeneca       |
|                               | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Vicodin        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                               | Xanax          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                               | Alcohol        |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Jul-2010              | 7506682       | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2009S1015568 |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lacrimation Increased;<br>Yawning | Lexapro                |              |            | S           | Oral         |                    |                 | Alphapharm   |
|                                   | Tramadol Hydrochloride |              |            | S           | Oral         |                    |                 | Alphapharm   |
|                                   | Vicodin                |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            | Trazodone                                |                    | C                  | Oral            |                          |                             |                 | Not Reported |                |
|------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
|                                                            | Trazodone                                |                    | C                  | Oral            |                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                                                | 7517517                                  | DIRECT             | N                  | OT              |                          |                             | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dependence; Drug Ineffective; Drug Withdrawal Syndrome     | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | 2 X 20mg Daily Po           |                 | Forest       |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                                                | 7521179                                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000015056               |                             | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Activated Partial Thromboplastin Time Prolonged; Haematoma | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | 1-2 Mg (1 In 1 D), Oral     |                 | Not Reported |                |
|                                                            | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                            | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | 8 Mg (8 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                            | Unspecified Ingredient                   |                    |                    | S               | Topical                  | Topical                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jul-2010                                                | 8354772                                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2010089675 |                             | 84 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Overdose; Somnolence                  | Xanax                                    |                    |                    | S               | Oral                     | 0.25 Mg, 3x/Day             |                 | Pfizer       |                |
|                                                            | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               | Oral                     | 2 Tablets/Day               | 4 DAY           | Not Reported |                |
|                                                            | Zopiclone                                |                    |                    | S               | Oral                     | 1 Tablet/Day                |                 | Not Reported |                |
|                                                            | Cetirizine Hydrochloride                 |                    |                    | S               | Oral                     | 10 Mg, 1x/Day               |                 | Not Reported |                |
|                                                            | Dafalgan Codeine                         |                    |                    | S               | Oral                     | Unk                         | 4 DAY           | Not Reported |                |
|                                                            | Loperamide                               |                    |                    | S               | Oral                     | Unk                         |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                        |   |      |                |              |
|--|------------------------|---|------|----------------|--------------|
|  | Escitalopram Oxalate   | S | Oral | Unk            | Not Reported |
|  | Xatral                 | S | Oral | Unk            | Not Reported |
|  | Coaprovel              | S | Oral | 300 Mg, Unk    | Not Reported |
|  | Acarbose               | C |      | 100 Mg, 3x/Day | Not Reported |
|  | Previscan (Fluindione) | C |      |                | Not Reported |
|  | Paracetamol            | C |      |                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2010              | 7383484       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013474           |                      | 37 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Anxiety; Condition         | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Aggravated; Discomfort;    | Lithium Carbonate    |              |            | C           |              |                             |                 | Not Reported |
| Feeling Hot; Hypertension; | Micronor (Tablets)   |              |            | C           |              |                             |                 | Not Reported |
| Malaise; Middle Insomnia;  |                      |              |            |             |              |                             |                 |              |
| Nausea; Paraesthesia;      |                      |              |            |             |              |                             |                 |              |
| Presyncope; Tachycardia    |                      |              |            |             |              |                             |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2010              | 7388754       | EXPEDITED (15-DAY) | N                  | HO              | 1000013528           |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Alanine Aminotransferase | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),  |                 | Not Reported |
| Increased; Anaemia;      |                         |              |            |             |              | Oral                      |                 |              |
| Aspartate                | Lexapro                 |              |            | S           | Oral         | (10 Mg, Every Other Day), |                 | Not Reported |
| Aminotransferase         |                         |              |            |             |              | Oral                      |                 |              |
| Increased; Blood         | Exforte Hct             |              |            | C           |              |                           |                 | Not Reported |
| Potassium Decreased;     | Metoprolol              |              |            | C           |              |                           |                 | Not Reported |
| Dizziness; Fatigue;      | Nexium                  |              |            | C           |              |                           |                 | Not Reported |
| Oedema Peripheral;       | Palgic                  |              |            | C           |              |                           |                 | Not Reported |
| Uterine Haemorrhage;     | Aspirin (81 Milligram)  |              |            | C           |              |                           |                 | Not Reported |
| Uterine Leiomyoma        | Lutein (20 Milligram)   |              |            | C           |              |                           |                 | Not Reported |
|                          | Calcium (500 Milligram) |              |            | C           |              |                           |                 | Not Reported |
|                          | Fish Oil                |              |            | C           |              |                           |                 | Not Reported |
|                          | L-Lysine                |              |            | C           |              |                           |                 | Not Reported |
|                          | Vitamin C               |              |            | C           |              |                           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2010              | 7412772       | EXPEDITED (15-DAY) | Y                  | HO              | 1000013952           |                      | 62 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Petechiae             | Escitalopram Oxalate            |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |
|                       | Escitalopram Oxalate            |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Alprazolam                      |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Kardegic                        |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Dafalgan                        |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Morphine                        |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Cortancyl                       |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Gabapentine                     |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Inexium                         |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Imovane                         |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Skenan                          |              |            | C           |              |                                                              |                 | Not Reported |
|                       | Rivotril (Drops (For Oral Use)) |              |            | C           |              |                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2010              | 7507451       | EXPEDITED (15-DAY) | Y                  | HO              | US-SANOFI-AVENTIS-2010SA042981 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Drug Interaction; Familial Tremor; Fatigue | Multaq         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                        | Propranolol    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                        | Primidone      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                        | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2010              | 7535771       | EXPEDITED (15-DAY) | Y                  | DE, OT          | 1000015221           |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                                         |        |             |                                    |                              |
|----------------------------------------------------------------------------|-----------------------------------------|--------|-------------|------------------------------------|------------------------------|
| Completed Suicide;<br>Condition Aggravated;                                | Lexapro                                 | S      | Oral        | (1 In 1 D), Oral                   | Not Reported                 |
| Depression; Drug<br>Dependence; Drug<br>Withdrawal Syndrome;               | Fentanyl<br>Fentanyl Transdermal System | S<br>S | Transdermal | 100 Mcg (1 In 1 D),<br>Transdermal | Not Reported<br>Not Reported |
| Gun Shot Wound;<br>Intentional Product<br>Misuse; Loss Of<br>Consciousness | Fentanyl Transdermal System<br>Lamictal | S<br>S | Transdermal | 25 Mcg (1 In 1 D),<br>Transdermal  | Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 29-Jul-2010                       | 7535906                | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | 1000012050                    |                               | 50 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|--------------------------------------|--------------------------|---------------------|
| Cerebral Vasoconstriction;<br>Headache; Serotonin<br>Syndrome | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg (20 Mg, 1 In 1 D),<br>Oral     |                          | Not Reported        |
|                                                               | Xanax                   |                       |                     | S                    | Oral                  | 0.75 Mg (0.75 Mg, 1 In 1<br>D), Oral |                          | Not Reported        |
|                                                               | Propranolol             |                       |                     | S                    | Oral                  | 160 Mg (80 Mg, 2 In 1 D),<br>Oral    |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 30-Jul-2010                       | 7382989                | EXPEDITED (15-DAY)        | N                           | OT                       | 1000013475                    |                               | 57 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                                               | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a>        | <a href="#">Dosage Text</a>                      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|------------------------------|--------------------------------------------------|--------------------------|---------------------|
| Agitation; Decreased<br>Appetite; Feeling<br>Abnormal; Feeling Of<br>Despair; Insomnia;<br>Suicidal Ideation | Escitalopram Oxalate    |                       |                     | S                    | Oral<br>Oral<br>Oral<br>Oral | See Image<br>See Image<br>See Image<br>See Image |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 30-Jul-2010                       | 7388225                | EXPEDITED (15-DAY)        |                             | HO                       | 1000013498                    |                               |                     | Female              | CAN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                        |                                          |                      |                    |                 |                          |                                                 |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|----------------------|--------------------|-----------------|--------------------------|-------------------------------------------------|-----------------|--------------|----------------|
| Bradycardia; Loss Of Consciousness                                                                                                     |                                          | Escitalopram Oxalate |                    | S               |                          | Not Reported                                    |                 |              |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2010                                                                                                                            | 7512161                                  | EXPEDITED (15-DAY)   | N                  | OT              | US-PFIZER INC-2010092700 |                                                 | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort; Back Pain; Dizziness Postural; Ill-Defined Disorder; Nausea; Vomiting                                            | Lipitor                                  |                      |                    | S               | Oral                     | 20 Mg, 1x/Day                                   |                 | Pfizer       |                |
|                                                                                                                                        | Chantix                                  |                      |                    | S               | Oral                     | Unk                                             |                 | Pfizer       |                |
|                                                                                                                                        | Chantix                                  |                      |                    | S               | Oral                     | 1 Mg, 2x/Day                                    |                 | Pfizer       |                |
|                                                                                                                                        | Lisinopril                               |                      |                    | S               |                          | 20 Mg, 1x/Day                                   |                 | Not Reported |                |
|                                                                                                                                        | Lexapro                                  |                      |                    | S               | Oral                     | 20 Mg, 1x/Day                                   |                 | Not Reported |                |
|                                                                                                                                        | Humalog                                  |                      |                    | C               | Subcutaneous             | 20 To 40 Units As Needed                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2010                                                                                                                            | 7513320                                  | NON-EXPEDITED        | N                  |                 | US-PFIZER INC-2008019934 |                                                 | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Urticaria                                                                                                       | Lipitor                                  |                      |                    | S               |                          |                                                 |                 | Pfizer       |                |
|                                                                                                                                        | Lexapro                                  |                      |                    | S               |                          |                                                 |                 | Not Reported |                |
|                                                                                                                                        | Lexapro                                  |                      |                    | S               |                          |                                                 |                 | Not Reported |                |
|                                                                                                                                        | Protonix                                 |                      |                    | S               |                          |                                                 |                 | Not Reported |                |
|                                                                                                                                        | Menest                                   |                      |                    | S               |                          |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Jul-2010                                                                                                                            | 7537828                                  | EXPEDITED (15-DAY)   | Y                  | HO              | 1000015294               |                                                 | 84 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Agitation; Bronchial Obstruction; Confusional State; Fall; Hyperthermia; Hypotension; Inflammation; International | Escitalopram Oxalate                     |                      |                    | S               | Oral                     | Oral                                            |                 | Not Reported |                |
|                                                                                                                                        | Tramadol Hydrochloride And Acetaminophen |                      |                    | S               | Oral                     | 2 Dosage Forms (2 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                        | Zopiclone                                |                      |                    | S               | Oral                     | 1 Dosage Forms (1                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                              |                        |   |      |                                      |              |
|------------------------------------------------------------------------------------------------------------------------------|------------------------|---|------|--------------------------------------|--------------|
| Normalised Ratio<br>Decreased; Mydriasis;<br>Overdose; Paralysis;<br>Productive Cough;<br>Somnolence; Withdrawal<br>Syndrome | Xanax                  | S | Oral | Dosage Forms, 1 In 1 D),<br>Oral     | Not Reported |
|                                                                                                                              | Cetirizine             | S | Oral | 0.75 Mg (0.25 Mg, 3 In 1<br>D), Oral | Not Reported |
|                                                                                                                              | Acetaminophen          | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     | Not Reported |
|                                                                                                                              | Loperamide             | S | Oral | Oral                                 | Not Reported |
|                                                                                                                              | Xatral                 | S | Oral | Oral                                 | Not Reported |
|                                                                                                                              | Coaprovel              | S | Oral | (300 Mg), Oral                       | Not Reported |
|                                                                                                                              | Glucor                 | C |      |                                      | Not Reported |
|                                                                                                                              | Previscan (Fluindione) | C |      |                                      | Not Reported |
|                                                                                                                              | Paracetamol            | C |      |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jul-2010              | 7538064       | EXPEDITED (15-DAY) | N                  | OT              | DSA_43546_2010       |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Mania         | Ativan         |              |            | S           |              | Df                 |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | Df                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 31-Jul-2010              | 7514651       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2009170707 |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Fatigue; Flushing; | Lipitor              |              |            | S           |              | 20 Mg, 1x/Day      |                 | Pfizer       |
| Neuropathy Peripheral;      | Acetylsalicylic Acid |              |            | S           |              |                    |                 | Pfizer       |
| Pain; Paraesthesia;         | Lexapro              |              |            | S           |              | Unk                |                 | Not Reported |
| Pruritus                    | Prilosec             |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2010              | 7420419       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014257           |                      | 46 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------------|-----------------|--------------|----------------|
| Blood Creatinine Increased; Epilepsy; Loss Of Consciousness   | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                               | Nordaz (Tablets)     |                    |                    | C               |                                          |                             |                 | Not Reported |                |
|                                                               | Zolpidem             |                    |                    | C               |                                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2010                                                   | 7507911              | EXPEDITED (15-DAY) | N                  | HO, OT          | US-BRISTOL-MYERS SQUIBB COMPANY-15212111 |                             | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Embolism; Thrombosis                                | Abilify              |                    |                    | S               | Oral                                     |                             |                 | Not Reported |                |
|                                                               | Xanax                |                    |                    | S               |                                          |                             |                 | Not Reported |                |
|                                                               | Lexapro              |                    |                    | S               |                                          |                             |                 | Not Reported |                |
|                                                               | Coumadin             |                    |                    | C               |                                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2010                                                   | 7518089              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2006126634                 |                             |                 | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased; Psoriasis                             | Norvasc              |                    |                    | S               | Oral                                     |                             |                 | Pfizer       |                |
|                                                               | Benazepril           |                    |                    | S               | Oral                                     |                             |                 | Not Reported |                |
|                                                               | Lexapro              |                    |                    | S               |                                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2010                                                   | 7521947              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2009151425                 |                             | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Drug Withdrawal Syndrome; Malaise; Somnolence | Amlodipine Besylate  |                    |                    | S               |                                          | 10 Mg, Unk                  |                 | Pfizer       |                |
|                                                               | Atenolol             |                    |                    | S               |                                          |                             |                 | Not Reported |                |
|                                                               | Lexapro              |                    |                    | S               |                                          |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 02-Aug-2010                                                                                    | 7531319                                                              | DIRECT             | N                  |                 |                      |                                           | 31 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Malaise; Product Quality Issue                                                        | Lexapro                                                              |                    |                    | S               | Oral                 | 10mg Daily Po                             |                 | Not Reported |                |
|                                                                                                | Lexapro                                                              |                    |                    | S               |                      |                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2010                                                                                    | 7545255                                                              | EXPEDITED (15-DAY) | Y                  | CA, OT          | JPI-P-011556         |                                           |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Transposition Of The Great Vessels; Ventricular Septal Defect | Xyrem                                                                |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Modafinil                                                            |                    |                    | S               | Transplacental       | 200 Mg (200 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                | Levothyroxine                                                        |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Metformin Hydrochloride                                              |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Buspirone Hydrochloride                                              |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Escitalopram Oxalate                                                 |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Mometasone Furoate                                                   |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
|                                                                                                | Ascorbic Acid\Biotin\Minerals\Retinol\Tocopherol\Vitamin B\Vitamin D |                    |                    | S               | Transplacental       | Transplacental                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2010                                                                                    | 7513039                                                              | EXPEDITED (15-DAY) | Y                  |                 | 1000015018           |                                           | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Dizziness; Dyspnoea; Feeling Hot; Headache; Tinnitus; Vomiting       | Lexapro                                                              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral                |                 | Not Reported |                |
|                                                                                                | Lexapro                                                              |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D), Oral              |                 | Not Reported |                |
|                                                                                                | Caffeine Anhydrou (Tablets)                                          |                    |                    | C               |                      |                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                |   |  |              |
|--|--------------------------------|---|--|--------------|
|  | Pantoprazole (Tablets)         | C |  | Not Reported |
|  | Alprazolam                     | C |  | Not Reported |
|  | Isometheptene Mucate (Tablets) | C |  | Not Reported |
|  | Dipyrrone Sodium (Tablets)     | C |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2010              | 7522858       | EXPEDITED (15-DAY) | N                  | OT              | US-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-00944RO |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Rash | Digoxin                |              |            | S           | Oral         |                    |                 | Roxane       |
|                        | Feldene                |              |            | S           |              |                    |                 | Not Reported |
|                        | Gabapentin             |              |            | S           |              |                    |                 | Not Reported |
|                        | Folic Acid             |              |            | S           |              |                    |                 | Not Reported |
|                        | Atenolol               |              |            | S           |              |                    |                 | Not Reported |
|                        | Zyrtec                 |              |            | S           |              |                    |                 | Not Reported |
|                        | Tramadol Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                        | Norvir                 |              |            | S           |              |                    |                 | Not Reported |
|                        | Ferrous Sulfate        |              |            | S           |              |                    |                 | Not Reported |
|                        | Diphenhydramine        |              |            | S           |              |                    |                 | Not Reported |
|                        | Loperamide             |              |            | S           |              |                    |                 | Not Reported |
|                        | Atrovent               |              |            | S           |              |                    |                 | Not Reported |
|                        | Cozaar                 |              |            | S           |              |                    |                 | Not Reported |
|                        | Lexapro                |              |            | S           |              |                    |                 | Not Reported |
|                        | Epogen                 |              |            | S           |              |                    |                 | Not Reported |
|                        | Abilify                |              |            | S           |              |                    |                 | Not Reported |
|                        | Carvedilol             |              |            | S           |              |                    |                 | Not Reported |
|                        | Seroquel               |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 03-Aug-2010              | 7523535       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2008022181 |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Feeling Drunk | Lyrica         |              |            | S           |              |                    |                 | Pfizer       |
|                                 | Fentanyl       |              |            | C           |              |                    |                 | Not Reported |
|                                 | Zocor          |              |            | C           |              |                    |                 | Not Reported |
|                                 | Diclofenac     |              |            | C           |              |                    |                 | Not Reported |
|                                 | Amitriptyline  |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |              |
|----------|---|--------------|
| Klonopin | S | Not Reported |
| Lexapro  | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2010              | 7523956       | EXPEDITED (15-DAY) | N                  | OT              | US-MERCK-1007USA03871 |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Rash | Cozaar                        |              |            | S           | Oral         |                    |                 | Merck        |
|                        | Feldene                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Gabapentin                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Folic Acid                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Digoxin                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Atenolol                      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Zyrtec                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Tramadol Hydrochloride        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Norvir                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Ferrous Sulfate               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Diphenhydramine Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Loperamide Hydrochloride      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Atrovent                      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Lexapro                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Epogen                        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Abilify                       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Carvedilol                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Seroquel                      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2010              | 7541045       | EXPEDITED (15-DAY) | N                  | OT              | 1000015334           |                      | 14 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                  |                                           |                    |                    |                 |                      |                                                                  |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| Leukaemia Recurrent                                                                                                                                              |                                           | Lexapro            |                    | S               |                      | Not Reported                                                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2010                                                                                                                                                      | 7541047                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000015381           |                                                                  | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Steatosis;<br>Pancreatitis                                                                                                                               | Lexapro                                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1d),<br>Oral                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Erectile Dysfunction Medication           |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Testosterone                              |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2010                                                                                                                                                      | 7541768                                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000015446           |                                                                  | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Decreased<br>Appetite; Fatigue;<br>Hyperhidrosis;<br>Menorrhagia;<br>Paraesthesia; Peripheral<br>Coldness; Somnolence;<br>Uterine Leiomyoma;<br>Yawning | Escitalopram Oxalate                      |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                  |                                           |                    |                    |                 | Oral                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                                                                                                                  | Synthroid                                 |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Infufer (Injection)                       |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Amoxicillin-Clavulanic Acid<br>(Capsules) |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Mvi (Tablets)                             |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                                                                                                                  | Advil                                     |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2010                                                                                                                                                      | 7393513                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000013758           |                                                                  | 82 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Conversion<br>Disorder; Insomnia                                                                                                                      | Escitalopram Oxalate                      |                    |                    | S               | Oral                 | Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral                           |                 | Not Reported |                |
|                                                                                                                                                                  |                                           |                    |                    |                 | Oral                 | Oral; 10 Mg (10 Mg, 1 In 1                                       |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |                                              |              |
|----------------------|---|------|----------------------------------------------|--------------|
| Escitalopram Oxalate | S | Oral | D), Oral<br>20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|----------------------|---|------|----------------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2010              | 7441672       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000014510           |                      | 72 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Ataxia; Drug Interaction;<br>Dysarthria; Fall;<br>Supraventricular<br>Extrasystoles; Ventricular<br>Extrasystoles | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral; 15 Mg (15 Mg, 1<br>In 1 D), Oral         |                 | Not Reported |
|                                                                                                                   |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral; 15 Mg (15 Mg, 1<br>In 1 D), Oral         |                 |              |
|                                                                                                                   |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral; 15 Mg (15 Mg, 1<br>In 1 D), Oral         |                 |              |
|                                                                                                                   | Amitriptyline        |              |            | S           | Oral         | 175 Mg (175 Mg, 1 In 1 D),<br>Oral; 125 Mg (125 Mg, 1 In<br>1 D), Oral; 100 Mg (100<br>Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                   |                      |              |            |             | Oral         | 175 Mg (175 Mg, 1 In 1 D),<br>Oral; 125 Mg (125 Mg, 1 In<br>1 D), Oral; 100 Mg (100<br>Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                   |                      |              |            |             | Oral         | 175 Mg (175 Mg, 1 In 1 D),<br>Oral; 125 Mg (125 Mg, 1 In<br>1 D), Oral; 100 Mg (100<br>Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                   | Butyrophenone        |              |            | S           | Oral         | 50 Mg (50 Mg, 1 In 1 D),<br>Oral; 75 Mg (75 Mg, 1 In 1<br>D), Oral                                         |                 | Not Reported |
|                                                                                                                   |                      |              |            |             | Oral         | 50 Mg (50 Mg, 1 In 1 D),<br>Oral; 75 Mg (75 Mg, 1 In 1<br>D), Oral                                         |                 |              |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                      |                      | Lanitop            |                    | C               |                              |                                  |                 |              | Not Reported   |
|----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                      |                      | Triamteren         |                    | C               |                              |                                  |                 |              | Not Reported   |
|                                                                      |                      | Tavor (Lorazepam)  |                    | C               |                              |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2010                                                          | 7504257              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014961                   |                                  | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression                                  | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2010                                                          | 7525669              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2009170500 |                                  | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoaesthesia                                                        | Lyrica               |                    |                    | S               |                              | 75 Mg, 2x/Day                    |                 | Pfizer       |                |
|                                                                      | Lexapro              |                    |                    | S               |                              | 10 Mg, Unk                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2010                                                          | 7528187              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2008069076 |                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction                                                     | Lexapro              |                    |                    | S               |                              |                                  |                 | Not Reported |                |
|                                                                      | Selzentry            |                    |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                      | Zyprexa              |                    |                    | S               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Aug-2010                                                          | 7539192              | EXPEDITED (15-DAY) | N                  | OT              | 1000015363                   |                                  | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Aortic<br>Dilatation; Congenital | Lexapro              |                    |                    | S               | Transplacental               | Transplacental                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Aortic Valve  
Incompetence; Maternal  
Drugs Affecting Foetus;  
Multiple Congenital  
Abnormalities; Ventricular  
Septal Defect

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2010              | 7543386       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015411           |                      | 86 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Agitation; Blood Pressure Abnormal; Disorientation; Electroencephalogram Abnormal; Hyponatraemia; Malaise; Speech Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                            | Esberiven            |              |            | C           |              |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2010              | 7543387       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015412           |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Anaemia; Drug Interaction; Fall; Gait Disturbance; Haematoma; International Normalised Ratio Increased; Muscle Haemorrhage | Escitalopram Oxalate   |              |            | S           | Oral         | 10mg (10mg, 2 In 2d), Oral                      |                 | Not Reported |
|                                                                                                                            | Previscan (Fluindione) |              |            | S           | Oral         | 1 Dosage Forms ( 1 Dosage Forms, 1 In 1d), Oral |                 | Not Reported |
|                                                                                                                            | Aotal                  |              |            | C           |              |                                                 |                 | Not Reported |
|                                                                                                                            | Diffu K                |              |            | C           |              |                                                 |                 | Not Reported |
|                                                                                                                            | Stilnox                |              |            | C           |              |                                                 |                 | Not Reported |
|                                                                                                                            | Seresta                |              |            | C           |              |                                                 |                 | Not Reported |
|                                                                                                                            | Vitamine B1 B6         |              |            | C           |              |                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2010              | 7543394       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015382           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                      |   |      |                                                                  |              |
|----------------------------------------------------------------------------|----------------------|---|------|------------------------------------------------------------------|--------------|
| Acute Kidney Injury;<br>Coma; Confusional State;<br>Hallucination, Visual; | Escitalopram Oxalate | S | Oral | (440mg, Once), Oral                                              | Not Reported |
| Heart Rate Increased;                                                      | Effexor              | S | Oral | (3375 Mg, Once) Oral                                             | Not Reported |
| Intentional Overdose;                                                      | Baclofen             | S | Oral | 220 Mg, Once), Oral                                              | Not Reported |
| Nervous System Disorder;                                                   | Zolpidem             | S | Oral | 50 Mg Once, Oral                                                 | Not Reported |
| Rhabdomyolysis; Suicide Attempt                                            | Lormetazepam         | S | Oral | 18 Mg, Once, Oral                                                | Not Reported |
|                                                                            | Periciazine          | S | Oral | 30 Mg, Once, Oral                                                | Not Reported |
|                                                                            | Alcohol              | S | Oral | Several Glasses Of<br>Whiskey And 3 Bottles Of<br>Wine Once Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2010              | 7528614       | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-G06457010     |                      | 47 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Coma; Confusional State;<br>Hallucination, Visual; | Effexor Xr           |              |            | S           | Oral         | Overdose Amount= 3375 Mg                                     | 1 DAY           | Wyeth        |
| Intentional Overdose;                                                      | Baclofen             |              |            | S           | Oral         | Overdose Amount= 220 Mg                                      | 1 DAY           | Unknown      |
| Peripheral Motor<br>Neuropathy;                                            | Alcohol              |              |            | S           | Oral         | Overdose Amount=                                             | 1 DAY           | Unknown      |
| Rhabdomyolysis; Suicide Attempt                                            |                      |              |            |             |              | Several Drings Of Whisky<br>Alcohol And 3 Bottles Of<br>Wine |                 |              |
|                                                                            | Lormetazepam         |              |            | S           | Oral         | Overdose Amount= 18 Mg                                       | 1 DAY           | Schering     |
|                                                                            | Periciazine          |              |            | S           | Oral         | Overdose Amount= 30 Mg                                       | 1 DAY           | Not Reported |
|                                                                            | Escitalopram Oxalate |              |            | S           | Oral         | Overdose Amount= 440 Mg                                      | 1 DAY           | Lundbeck     |
|                                                                            | Zolpidem             |              |            | S           | Oral         | Overdose Amount= 50 Mg                                       | 1 DAY           | Unknown      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2010              | 7529614       | EXPEDITED (15-DAY) | Y                  | HO              | US-WATSON-2010-10191 |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |                      |   |                                          |                 |              |
|-----------------------------------------|----------------------|---|------------------------------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Fentanyl Citrate     | S | Intravenous (not<br>otherwise specified) | 250 U/G, Single | Watson       |
|                                         | Escitalopram Oxalate | S |                                          | Unk             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2010              | 7536104       | DIRECT           | Y                  |                 |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Crying;<br>Insomnia | Lexapro        |              |            | S           | Oral         | Daily Po           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7475909       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014822           |                      | 55 YR      | Male       | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Electrocardiogram<br>Change; Extrasystoles | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                            | Simvastatin          |              |            | C           |              |                         |                 | Not Reported |
|                                            | Metoprolol           |              |            | C           |              |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7512963       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015016           |                      | 57 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abdominal Pain;<br>Constipation;<br>Haemorrhoids;<br>Metrorrhagia; Off Label<br>Use; Proctitis; Rectal<br>Haemorrhage | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                       | Estreva (Gel)        |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                       | Progesterone         |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7530595       | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15224348 |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |                        |   |         |      |        |
|------------------------|------------------------|---|---------|------|--------|
| Drug Interaction; Rash | Atenolol               | S | Capsule | Oral | Sandoz |
|                        | Abilify                | S |         |      |        |
|                        | Ferrous Sulfate        | S |         |      |        |
|                        | Feldene                | S |         |      |        |
|                        | Gabapentin             | S |         |      |        |
|                        | Folic Acid             | S |         |      |        |
|                        | Digoxin                | S |         |      |        |
|                        | Zyrtec                 | S |         |      |        |
|                        | Tramadol Hydrochloride | S |         |      |        |
|                        | Norvir                 | S |         |      |        |
|                        | Diphenhydramine        | S |         |      |        |
|                        | Loperamide             | S |         |      |        |
|                        | Atrovent               | S |         |      |        |
|                        | Cozaar                 | S |         |      |        |
|                        | Lexapro                | S |         |      |        |
|                        | Epogen                 | S |         |      |        |
|                        | Carvedilol             | S |         |      |        |
|                        | Seroquel               | S |         |      |        |
|                        | Lactose                | S |         |      |        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7530745       | EXPEDITED (15-DAY) | N                  | HO              | DK-PURDUE-GBR-2010-0006579 |                      | 31 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Rhabdomyolysis; Urinary Retention | Oxycodone Hydrochloride |              |            | S           | Oral         | 10 Mg, Bid         |                 | Purdue       |
|                                                                     | Ciprallex               |              |            | S           | Oral         | 20 Mg, Daily       | 13 DAY          | Not Reported |
|                                                                     | Tramadol                |              |            | S           | Oral         | 100 Mg, Qid        | 391 DAY         | Not Reported |
|                                                                     | Lyrica                  |              |            | S           | Oral         | 75 Mg, Unk         | 7 DAY           | Not Reported |
|                                                                     | Seroquel                |              |            | S           | Oral         | 100 Mg, Unk        | 360 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7532002       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2008033807 |                      | 42 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                       |                     |        |      |                        |
|---------------------------------------------------------------------------------------|---------------------|--------|------|------------------------|
| Blood Potassium Increased; Blood Sodium Increased; Drug Interaction; Fatigue; Malaise | Dilantin<br>Lexapro | S<br>S | Oral | Pfizer<br>Not Reported |
|---------------------------------------------------------------------------------------|---------------------|--------|------|------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Aug-2010              | 7543607       | EXPEDITED (15-DAY) | Y                  | OT              | DSA_43265_2010       |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Feeling Abnormal; Movement Disorder | Xenazine       |              |            | S           | Oral         | (12.5 Mg Tid Oral)       |                 | Not Reported |
|                                     | Lexapro        |              |            | S           |              | (Df), (Df)<br>(Df), (Df) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Aug-2010              | 7522294       | EXPEDITED (15-DAY) | N                  | OT              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>BP-08 |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Drug Interaction; Rash | Atrovent               |              |            | S           |              |                    |                 | Boehringer Ingelheim |
|                        | Feldene                |              |            | S           |              |                    |                 | Not Reported         |
|                        | Gabapentin             |              |            | S           |              |                    |                 | Not Reported         |
|                        | Folic Acid             |              |            | S           |              |                    |                 | Not Reported         |
|                        | Digoxin                |              |            | S           |              |                    |                 | Not Reported         |
|                        | Tramadol Hydrochloride |              |            | S           |              |                    |                 | Not Reported         |
|                        | Norvir                 |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Atenolol               |              |            | S           |              |                    |                 | Not Reported         |
|                        | Zyrtec                 |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Ferrous Sulfate        |              |            | S           |              |                    |                 | Not Reported         |
|                        | Diphenhydramine        |              |            | S           |              |                    |                 | Not Reported         |
|                        | Loperamide             |              |            | S           |              |                    |                 | Not Reported         |
|                        | Cozaar                 |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Lexapro                |              |            | S           | Oral         |                    |                 | Not Reported         |
|                        | Epogen                 |              |            | S           |              |                    |                 | Not Reported         |
|                        | Abilify                |              |            | S           |              |                    |                 | Not Reported         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 | Carvedilol             |                    |                    | S               |                            |                             |                 |              | Not Reported   |
|---------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------|-----------------|--------------|----------------|
|                                                                                 | Seroquel               |                    |                    | S               |                            |                             |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2010                                                                     | 7533891                | EXPEDITED (15-DAY) | N                  | OT              | US-ASTRAZENECA-2010SE35835 |                             |                 | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Rash                                                          | Atenolol               |                    |                    | S               | Unknown                    |                             |                 | Zeneca       |                |
|                                                                                 | Seroquel               |                    |                    | S               | Oral                       |                             |                 | Not Reported |                |
|                                                                                 | Atrovent               |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Abilify                |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Carvedilol             |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Cozaar                 |                    |                    | S               | Oral                       |                             |                 | Not Reported |                |
|                                                                                 | Digoxin                |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Diphenhydramine        |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Epogen                 |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Folic Acid             |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Ferrous Sulfate        |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Gabapentin             |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Loperamide             |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Lexapro                |                    |                    | S               | Oral                       |                             |                 | Not Reported |                |
|                                                                                 | Norvir                 |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Feldene                |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Tramadol Hydrochloride |                    |                    | S               |                            |                             |                 | Not Reported |                |
|                                                                                 | Zyrtec                 |                    |                    | S               | Oral                       |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Aug-2010                                                                     | 7546167                | EXPEDITED (15-DAY) | Y                  | HO              | 1000015451                 |                             | 80 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; General Physical Health Deterioration; Headache; Hyponatraemia; Nausea | Escitalopram Oxalate   |                    |                    | S               | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                 | Buflomedil             |                    |                    | C               |                            |                             |                 | Not Reported |                |
|                                                                                 | Aldactazine            |                    |                    | C               |                            |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 10-Aug-2010                                                         | 7268639              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011314           |                                 | 31 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Rhabdomyolysis; Urinary Retention | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                     | Oxycontin            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                     | Tramadol             |                    |                    | S               | Oral                 | 200 Mg (50 Mg, 4 In 1 D), Oral  |                 | Not Reported |                |
|                                                                     | Seroquel             |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                     | Lyrica               |                    |                    | S               | Oral                 | 150 Mg (75 Mg, 2 In 1 D), Oral  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2010                                                         | 7417964              | EXPEDITED (15-DAY) | Y                  | OT              | 1000014191           |                                 | 56 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anosmia; Dysgeusia                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2010                                                         | 7537668              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000015260           |                                 | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | (600 Mg, Once), Oral            |                 | Not Reported |                |
|                                                                     | Tramadol             |                    |                    | S               | Oral                 | (1000 Mg, Once), Oral           |                 | Not Reported |                |
|                                                                     | Atacand              |                    |                    | S               | Oral                 | (112 Mg, Once), Oral            |                 | Not Reported |                |
|                                                                     | Alcohol              |                    |                    | S               | Oral                 | (Once), Oral                    |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
| 10-Aug-2010              | 7548427              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014319               |                             | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperhidrosis;           | Escitalopram Oxalate |                    |                    | S               | Oral                     | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| Hypoglycaemic Seizure;   | Escitalopram Oxalate |                    |                    | S               |                          | 10 Mg (10 Mg, 1 In 1 D)     |                 | Not Reported |                |
| Malaise; Maternal        | Ibuprofen            |                    |                    | C               |                          |                             |                 | Not Reported |                |
| Exposure During          | Timoferol            |                    |                    | C               |                          |                             |                 | Not Reported |                |
| Pregnancy; Paraesthesia; | Antidiabetics Nos    |                    |                    | C               |                          |                             |                 | Not Reported |                |
| Pregnancy; Tremor        |                      |                    |                    |                 |                          |                             |                 |              |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2010              | 7455690              | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010080715 |                             |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Rash   | Feldene              |                    |                    | S               |                          | Unk                         |                 | Pfizer       |                |
|                          | Gabapentin           |                    |                    | S               |                          | Unk                         |                 | Pfizer       |                |
|                          | Atenolol             |                    |                    | S               |                          | Unk                         |                 | Pfizer       |                |
|                          | Folic Acid           |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Digoxin              |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Zyrtec               |                    |                    | S               | Oral                     | Unk                         |                 | Not Reported |                |
|                          | Tramadol             |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Norvir               |                    |                    | S               | Oral                     | Unk                         |                 | Not Reported |                |
|                          | Ferrous Sulfate      |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Diphenhydramine      |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Loperamide           |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Atrovent             |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Cozaar               |                    |                    | S               | Oral                     | Unk                         |                 | Not Reported |                |
|                          | Lexapro              |                    |                    | S               | Oral                     | Unk                         |                 | Not Reported |                |
|                          | Epogen               |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
|                          | Abilify              |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |     |              |
|------------|---|-----|--------------|
| Carvedilol | S | Unk | Not Reported |
| Seroquel   | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2010              | 7537121       | EXPEDITED (15-DAY) | N                  | HO              | B0668624A            |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|---------------------------------------|
| Apgar Score Abnormal;<br>Cleft Palate; Cough;<br>Cyanosis; Dehydration;<br>Eye Disorder; Fontanelle<br>Depressed;<br>Haemangioma;<br>Hypertonia; Hypotonia;<br>Malaise; Malnutrition;<br>Maternal Exposure During<br>Pregnancy; Mucosal<br>Dryness; Muscular<br>Weakness; Oesophagitis;<br>Palatal Disorder; Pallor;<br>Poor Sucking Reflex;<br>Regurgitation; Stridor;<br>Vomiting; Weight Gain<br>Poor | Deroxat<br>Escitalopram Oxalate<br>Syntocinon |              |            | S<br>S<br>C |              | 20mg Per Day       | 1 DAY           | Glaxosmithkline<br>Unknown<br>Unknown |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 11-Aug-2010              | 7537493       | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-10P-163-<br>0662073-00 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|---------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------------|
| Initial Insomnia; Libido<br>Increased; Photophobia;<br>Restlessness | Lexapro<br>Naproxen |              |            | S<br>C      |              |                    |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Aug-2010              | 7556466       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015519           |                      | 55 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>              | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Hepatitis | Escitalopram Oxalate                        |              |            | S           | Oral         | Oral                                             |                 | Not Reported |
|                                    | Meteospasmyl (Alverine Citrate\Dimethicone) |              |            | S           | Oral         | 4 Dosage Forms (2 Dosage Forms, 2 In 1 D), Oral  |                 | Not Reported |
|                                    | Unspecified Ingredient                      |              |            | S           | Oral         | 10 Dosage Forms (5 Dosage Forms, 2 In 1 D), Oral |                 | Not Reported |
|                                    | Ibuprofen                                   |              |            | S           | Oral         | Oral                                             |                 | Not Reported |
|                                    | Karaya                                      |              |            | C           |              |                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2010              | 7405614       | EXPEDITED (15-DAY) | Y                  | OT              | FR-ROCHE-705447      |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Foetal Death          | Rivotril                    |              |            | S           | Unknown      |                                                       |                 | Roche        |
|                       | Amitriptyline Hydrochloride |              |            | S           | Oral         | 18 Drops Morning And Evening                          |                 | Roche        |
|                       | Amitriptyline Hydrochloride |              |            | S           | Oral         | Strength: 40 Mg/Ml; Dose: 1 Bottle; Drug Intoxication |                 | Roche        |
|                       | Bromazepam                  |              |            | S           | Unknown      |                                                       |                 | Roche        |
|                       | Bromazepam                  |              |            | S           | Unknown      | Drug Intoxication                                     |                 | Roche        |
|                       | Prazepam                    |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Topiramate                  |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zyprexa                     |              |            | S           | Unknown      | Coated Tablet                                         |                 | Not Reported |
|                       | Zyprexa                     |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zyprexa                     |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zyprexa                     |              |            | S           | Unknown      |                                                       |                 | Not Reported |
|                       | Zopiclone                   |              |            | S           | Unknown      | Form: Divisible Coated Tablet                         |                 | Not Reported |
|                       | Chlorpromazine              |              |            | S           | Oral         |                                                       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |                                         |                       |
|------------------------|---|---------|-----------------------------------------|-----------------------|
| Oxazepam               | S | Unknown |                                         | Not Reported          |
| Spasfon-Lyoc           | S | Oral    | Form: Lyophilisate                      | Not Reported          |
| Effexor                | S | Unknown |                                         | Not Reported          |
| Effexor                | S | Unknown | Dose Increased                          | Not Reported          |
| Stilnox                | S | Unknown | Form: Divisible Coated Tablet           | Not Reported          |
| Theralene              | S | Oral    |                                         | Not Reported          |
| Theralene              | S | Oral    | Dose Reduced                            | Not Reported          |
| Escitalopram Oxalate   | S | Unknown | Form: Divisible Coated Tablet           | Not Reported          |
| Akineton               | S | Unknown | Drug Name: Akineton L.P., Coated Tablet | Not Reported          |
| Periciazine            | S | Oral    | 10-0-40 Drops                           | Not Reported          |
| Clamoxyl (Amoxicillin) | S | Unknown | Form: Dispersible Tablet                | Not Reported          |
| Econazole Nitrate      | C | Vaginal |                                         | 7 DAY<br>Not Reported |
| Flagyl                 | C | Oral    | Coated Tablet                           | 7 DAY<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Aug-2010              | 7538214       | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-10P-163-0660700-00 |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Rash | Norvir                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Lexapro                |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Feldene                |              |            | S           |              |                    |                 | Not Reported |
|                        | Gabapentin             |              |            | S           |              |                    |                 | Not Reported |
|                        | Folic Acid             |              |            | S           |              |                    |                 | Not Reported |
|                        | Digoxin                |              |            | S           |              |                    |                 | Not Reported |
|                        | Atenolol               |              |            | S           |              |                    |                 | Not Reported |
|                        | Zyrtec                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Tramadol Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                        | Ferrous Sulfate        |              |            | S           |              |                    |                 | Not Reported |
|                        | Diphenhydramine        |              |            | S           |              |                    |                 | Not Reported |
|                        | Loperamide             |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |            |   |      |  |  |  |  |              |
|--|------------|---|------|--|--|--|--|--------------|
|  | Atrovent   | S |      |  |  |  |  | Not Reported |
|  | Cozaar     | S | Oral |  |  |  |  | Not Reported |
|  | Epogen     | S |      |  |  |  |  | Not Reported |
|  | Abilify    | S |      |  |  |  |  | Not Reported |
|  | Carvedilol | S |      |  |  |  |  | Not Reported |
|  | Seroquel   | S |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Aug-2010              | 7544814       | DIRECT           | Y                  | DS, HO          |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Hypophagia; Lethargy;<br>Pyrexia; Seizure;<br>Serotonin Syndrome;<br>Tremor | Zyvox                   |              |            | S           | Intravenous (not otherwise specified) | 600mg Q12 Iv       |                 | Pfizer       |
|                                                                             | Lexapro                 |              |            | S           | Oral                                  | 20mg Daily Po      |                 | Forest       |
|                                                                             | Doripenem               |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Soma                    |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Potassium Chloride      |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Methadone Hydrochloride |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Lovenox                 |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Duoneb                  |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Fluconazole             |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Zosyn                   |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Protonix                |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Nystatin                |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Zofran                  |              |            | C           |                                       |                    |                 | Not Reported |
|                                                                             | Norco                   |              |            | C           |                                       |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Aug-2010              | 7344295       | EXPEDITED (15-DAY) | N                  | OT              | 1000012336           |                      | 39 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Alcohol Use; Dizziness;<br>Drug Ineffective;<br>Hallucination;<br>Tachyphrenia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 13-Aug-2010                                                | 7539898                  | EXPEDITED (15-DAY) |                    | HO              | FR-PFIZER INC-2010098512 |                               | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Fulminant                                        | Atarax                   |                    |                    | S               | Oral                     | 50 Mg, Daily                  | 20 DAY          | Pfizer       |                |
|                                                            | Diffu K                  |                    |                    | S               | Oral                     | 600 Mg, Daily                 |                 | Not Reported |                |
|                                                            | Cymbalta                 |                    |                    | S               | Oral                     | 60 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Anafranil                |                    |                    | S               | Oral                     | 25 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Lorazepam                |                    |                    | S               | Oral                     | 1.25 Mg, Daily                |                 | Not Reported |                |
|                                                            | Aspirin                  |                    |                    | S               | Oral                     | 75 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Gliclazide               |                    |                    | S               | Oral                     | 30 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Lansoprazole             |                    |                    | S               | Oral                     | 15 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Furosemide               |                    |                    | S               | Oral                     | 40 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 10 Mg, Daily                  |                 | Not Reported |                |
|                                                            | Tamsulosin Hydrochloride |                    |                    | S               | Oral                     | 0.4 Mg, Daily                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Aug-2010                                                | 7551802                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000015599               |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Blood Alcohol Abnormal; Loss Of Consciousness | Lexapro                  |                    |                    | S               | Oral                     | Several Tablets, Oral         |                 | Not Reported |                |
|                                                            | Benadryl                 |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                                            | Alcohol                  |                    |                    | S               | Oral                     | 2 Glasses Of Wine, Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2010                                                | 7518200                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000015052               |                               | 31 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fall; Hyperhidrosis;                            | Escitalopram Oxalate     |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                              |                      |   |      |                                  |              |
|----------------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Restlessness; Seizure;<br>Serotonin Syndrome | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|----------------------------------------------|----------------------|---|------|----------------------------------|--------------|

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Aug-2010                       | 7527143                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000015159                    |                               | 50 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Hypersensitivity             | Escitalopram Oxalate    |                           |                             | S                        |                               |                               | 59 DAY                   | Not Reported        |                         |
|                                   | Escitalopram Oxalate    |                           |                             | S                        |                               |                               | 3 DAY                    | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>  | <a href="#">Country</a> |
|-----------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|----------------------|-------------------------|
| 16-Aug-2010                       | 7542411                     | EXPEDITED (15-DAY)        | N                           | HO                       | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15236318 |                               | 68 YR                    | Female               | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>  |                         |
| Acute Kidney Injury; Fall;        | Irbesartan                  |                           |                             | S                        | Oral                                            |                               |                          | Bristol Myers Squibb |                         |
| Hepatic Steatosis;                | Escitalopram Oxalate        |                           |                             | S                        | Oral                                            |                               |                          | Not Reported         |                         |
| Hyperkalaemia;                    | Prazepam                    |                           |                             | C                        |                                                 |                               |                          | Not Reported         |                         |
| Hyponatraemia;                    | Daflon (Diosmin/Hesperidin) |                           |                             | C                        | Oral                                            |                               |                          | Not Reported         |                         |
| Hypothyroidism;                   | Acetaminophen               |                           |                             | C                        | Oral                                            |                               |                          | Not Reported         |                         |
| Pancreatitis Chronic              | Efferalgan Codeine          |                           |                             | C                        | Oral                                            | 1 Df=1 Intake.                |                          | Not Reported         |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Aug-2010                       | 7542465                 | EXPEDITED (15-DAY)        | Y                           | OT                       | FR-MYLANLABS-<br>2010S1013886 |                               | 66 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Interaction;                 | Escitalopram Oxalate    |                           |                             | S                        | Unknown                       |                               |                          | Alphapharm          |                         |
| Serotonin Syndrome                | Fentanyl                |                           |                             | S                        | Nasal                         | 200 Microg/Puff               |                          | Not Reported        |                         |
|                                   | Oxycodone               |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2010              | 7553453       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015521           |                      | 87 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Disturbance In Attention;<br>Fall; Hepatitis Fulminant;<br>Incoherent; Pleural<br>Effusion; Somnolence | Escitalopram Oxalate     |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral       |                 | Not Reported |
|                                                                                                        | Cymbalta                 |              |            | S           | Oral         | 60 Mg (60 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                        | Atarax                   |              |            | S           | Oral         | 50 Mg (25 Mg, 2 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                        | Anafranil                |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D) ,<br>Oral  |                 | Not Reported |
|                                                                                                        | Lorazepam                |              |            | S           | Oral         | 1.25mg (1.25mg , 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                                        | Aspirin                  |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                        | Gliclazide               |              |            | S           |              | 30 Mg (30 Mg, 1 In 1 D),Oral       |                 | Not Reported |
|                                                                                                        | Lansoprazole             |              |            | S           |              | 15 Mg (15 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                        | Furosemide               |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                        | Diffu K                  |              |            | S           | Oral         | 600 Mg (600 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                        | Tamsulosin Hydrochloride |              |            | S           | Oral         | 0.4 Mg (0.4 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2010              | 7553535       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015590           |                      | 77 YR      | Male       | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Generalised Tonic-Clonic<br>Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |              |
|--------------|---|--------------|
| Amlodipine   | C | Not Reported |
| Aspirin      | C | Not Reported |
| Lansoprazole | C | Not Reported |
| Nebivolol    | C | Not Reported |
| Simvastatin  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2010              | 7553764       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015700           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------------------|-----------------|--------------|
| Angioedema; Dry Mouth;<br>Dysphagia;<br>Hypersensitivity | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                          |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral |                 |              |
|                                                          |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D)<br>,Oral, 10 Mg (10 Mg, 1 In 1 D),Oral, 15 Mg (15 Mg, 1 In 1 D),Oral |                 |              |
|                                                          | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D),Oral                                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Aug-2010              | 7554035       | EXPEDITED (15-DAY) | Y                  | HO              | LTI2010A00161        |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Fall; Hepatitis Fulminant | Lansoprazole   |              |            | S           | Oral         | 15 Mg (15 Mg,1 In 1 D)<br>Oral |                 | Not Reported |
|                           | Cymbalta       |              |            | S           | Oral         | 60 Mg (60 Mg,1 In 1 D)<br>Oral | 19 DAY          | Not Reported |
|                           | Atarax         |              |            | S           | Oral         | 25 Mg (25 Mg,1 In 2 D)<br>Oral |                 | Not Reported |
|                           | Anafranil      |              |            | S           | Oral         | 25 Mg (25 Mg,1 In 1 D)         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |      |                                          |              |
|--------------------------|---|------|------------------------------------------|--------------|
| Lorazepam                | S | Oral | Oral<br>1.25 Mg (1.25 Mg, 1 In 1 D) Oral | Not Reported |
| Aspirin                  | S | Oral | 75 Mg (75 Mg,1 In 1 D) Oral              | Not Reported |
| Gliclazide               | S | Oral | 30 Mg (30 Mg,1 In 1 D) Oral              | Not Reported |
| Furosemide (Furosemide)  | S | Oral | 40 Mg (40 Mg,1 In 1 D) Oral              | Not Reported |
| Potassium Chloride       | S | Oral | 600 Mg (600 Mg,1 In 1 D) Oral            | Not Reported |
| Escitalopram Oxalate     | S | Oral | 10 Mg (10 Mg,1 In 1 D) Oral              | Not Reported |
| Tamsulosin Hydrochloride | S | Oral | 0.4 Mg (0.4 Mg,1 In 1 D) Oral            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2010              | 7035747       | EXPEDITED (15-DAY) | Y                  | DS, HO, LT, OT  | DE-JNJFOC-20090608724 |                      | 74 YR      | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular Block;<br>Cardiac Arrest; Coronary<br>Artery Disease;<br>Electrocardiogram Qt<br>Prolonged; Syncope;<br>Torsade De Pointes | Reminyl        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Pipamperone    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                             | Cipralext      |              |            | S           | Unknown      | Since Three Days   |                 | Not Reported |
|                                                                                                                                             | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Cipralext      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Esidrix        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Esidrix        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Amlodipine     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Amlodipine     |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                             | Marcumar       |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |         |              |
|-----------|---|---------|--------------|
| Captopril | C | Unknown | Not Reported |
| Captopril | C | Unknown | Not Reported |
| Calcium   | C | Oral    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2010              | 7413014       | EXPEDITED (15-DAY) | Y                  | OT              | FR-WYE-G06194110     |                      | 40 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Blood Pressure Increased;<br>Escherichia Vaginitis; Fall;<br>Fatigue; Foetal Death;<br>Hella Syndrome; Maternal<br>Exposure During<br>Pregnancy; Proteinuria;<br>Sleep Disorder;<br>Somnolence;<br>Thrombocytopenia;<br>Vaginitis Gardnerella | Effexor Xr                                           |              |            | S           | Oral         | 75 Mg Total Daily                                                                                       |                 | Wyeth        |
|                                                                                                                                                                                                                                               | Bromazepam                                           |              |            | S           | Oral         | Unknown From An<br>Unspecified Date To Oct-<br>2008 And Then, Overdose<br>With 48 Mg On 16-Nov-<br>2008 |                 | Roche        |
|                                                                                                                                                                                                                                               | Rivotril                                             |              |            | S           |              | 2 Doses Total Daily                                                                                     |                 | Roche        |
|                                                                                                                                                                                                                                               | Rivotril                                             |              |            | S           |              | 40 Mg Total Daily                                                                                       |                 | Roche        |
|                                                                                                                                                                                                                                               | Prazepam                                             |              |            | S           |              | Unknown                                                                                                 |                 | Not Reported |
|                                                                                                                                                                                                                                               | Topiramate                                           |              |            | S           |              | Unknown                                                                                                 |                 | Janssen      |
|                                                                                                                                                                                                                                               | Zyprexa                                              |              |            | S           | Oral         |                                                                                                         |                 | Not Reported |
|                                                                                                                                                                                                                                               | Zyprexa                                              |              |            | S           | Oral         | 7.5 Mg Total Daily                                                                                      | 79 DAY          | Not Reported |
|                                                                                                                                                                                                                                               | Zyprexa                                              |              |            | S           | Oral         | 20 Mg Total Daily                                                                                       | 17 DAY          | Not Reported |
|                                                                                                                                                                                                                                               | Zyprexa                                              |              |            | S           | Oral         |                                                                                                         |                 | Not Reported |
|                                                                                                                                                                                                                                               | Zopiclone                                            |              |            | S           | Oral         |                                                                                                         | 3 MTH           | Not Reported |
|                                                                                                                                                                                                                                               | Chlorpromazine Hydrochloride                         |              |            | S           | Oral         |                                                                                                         |                 | Not Reported |
|                                                                                                                                                                                                                                               | Oxazepam                                             |              |            | S           | Oral         | 20 Mg Total Daily                                                                                       |                 | Wyeth        |
|                                                                                                                                                                                                                                               | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) |              |            | S           | Oral         | 160 Mg Total Daily                                                                                      |                 | Not Reported |
|                                                                                                                                                                                                                                               | Stilnox                                              |              |            | S           | Oral         |                                                                                                         |                 | Not Reported |
|                                                                                                                                                                                                                                               | Theralene                                            |              |            | S           | Oral         | 100 Drops Total Daily                                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                               | Theralene                                            |              |            | S           | Oral         | Unknown, But Less Than<br>100 Drops Per Day                                                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |   |      |                                                                                                                  |        |              |
|-----------------------------|---|------|------------------------------------------------------------------------------------------------------------------|--------|--------------|
| Escitalopram Oxalate        | S | Oral |                                                                                                                  | 16 DAY | Lundbeck     |
| Akineton                    | S | Oral |                                                                                                                  |        | Knoll        |
| Periciazine                 | S | Oral | 50 Drops Total Daily                                                                                             |        | Not Reported |
| Clamoxyl (Amoxicillin)      | S | Oral | 3 G Total Daily                                                                                                  |        | Unknown      |
| Amitriptyline Hydrochloride | S | Oral | 36 Drops Per Day From<br>An Unspecified Date To<br>Oct-2008; Overdose With<br>One Full Bottle On 16-<br>Nov-2008 |        | Roche        |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Aug-2010              | 7479804       | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>14921555 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Adverse Drug Reaction;<br>Chondromalacia;<br>Hepatitis; Obstructive<br>Airways Disorder;<br>Osteoarthritis; Pneumonia;<br>Umbilical Hernia | Abilify        |              |            | S           |              | 5 Mg 1/2q                   |                 | Not Reported |
|                                                                                                                                            | Lamictal       |              |            | S           |              | 25mg Bid<br>(1x1wk,Bidx2wk) |                 | Not Reported |
|                                                                                                                                            | Lexapro        |              |            | S           | Oral         | (30x2)10mg Oral             |                 | Not Reported |
|                                                                                                                                            | Xanax          |              |            | S           |              |                             |                 | Not Reported |
|                                                                                                                                            | Imdur          |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Nexium         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Potassium      |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Wellbutrin XL  |              |            | C           |              | 1df=300 Units Nos           | 5 YR            | Not Reported |
|                                                                                                                                            | Lisinopril     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Metoprolol     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Requip         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Lyrica         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Effexor XR     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Prozac         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Paxil CR       |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Glucophage     |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Actos          |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Amaryl         |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Lopresor       |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Norvasc        |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                            | Asa            |              |            | C           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                    |                                        |                    |                    |                 |                           |                                |                 |                                              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------|-----------------|----------------------------------------------|----------------|
| Multi-Vitamin                                                                                                                                                                      |                                        |                    | C                  |                 |                           | Not Reported                   |                 |                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 17-Aug-2010                                                                                                                                                                        | 7544726                                | EXPEDITED (15-DAY) | Y                  | OT              | NO-MYLANLABS-2010S1011806 |                                | 55 YR           | Male                                         | NOR            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Extrasystoles                                                                                                                                                                      | Metoprolol<br>Ciprallex<br>Simvastatin |                    |                    | S<br>S<br>C     |                           |                                |                 | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 17-Aug-2010                                                                                                                                                                        | 7547604                                | DIRECT             | Y                  | OT              |                           |                                | 46 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Anxiety; Balance Disorder;<br>Contusion; Dizziness;<br>Drug Withdrawal<br>Syndrome; Feeling<br>Abnormal; Impaired Work<br>Ability; Limb Injury; Pain In<br>Extremity; Paraesthesia | Lexapro                                |                    |                    | S               | Buccal                    | 10mg 1 Tablet Daily<br>Buccal  |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 17-Aug-2010                                                                                                                                                                        | 7548593                                | DIRECT             | N                  | HO              |                           |                                |                 | Female                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Hypoaesthesia; Pain In<br>Jaw                                                                                                                                                      | Lexapro                                |                    |                    | S               |                           | 10 Mg Tablet 1 Pill @<br>Night |                 | Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 18-Aug-2010                                                                                                                                                                        | 7410158                                | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-JNJFOC-20100510843     |                                | 40 YR           | Female                                       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Foetal Death; Maternal                                                                                                                                                             | Topiramate                             |                    |                    | S               | Oral                      |                                |                 | Not Reported                                 |                |

**FDA Adverse Event Reporting System  
Freedom of Information Act (FOIA)  
Detailed Report**

|                                             |                                                      |   |         |                                                      |        |              |
|---------------------------------------------|------------------------------------------------------|---|---------|------------------------------------------------------|--------|--------------|
| Exposure During<br>Pregnancy; Off Label Use | Econazole Nitrate                                    | S | Vaginal |                                                      | 7 DAY  | Not Reported |
|                                             | Amitriptyline Hydrochloride                          | S | Oral    | 1 Bottle                                             |        | Not Reported |
|                                             | Amitriptyline Hydrochloride                          | S | Oral    |                                                      |        | Not Reported |
|                                             | Bromazepam                                           | S | Oral    |                                                      |        | Not Reported |
|                                             | Bromazepam                                           | S | Oral    |                                                      |        | Not Reported |
|                                             | Rivotril                                             | S | Oral    |                                                      |        | Not Reported |
|                                             | Rivotril                                             | S | Oral    |                                                      |        | Not Reported |
|                                             | Prazepam                                             | S | Oral    |                                                      |        | Not Reported |
|                                             | Zyprexa                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Zyprexa                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Zyprexa                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Zyprexa                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Zopiclone                                            | S | Oral    |                                                      |        | Not Reported |
|                                             | Chlorpromazine Hydrochloride                         | S | Oral    |                                                      |        | Not Reported |
|                                             | Oxazepam                                             | S | Oral    |                                                      |        | Not Reported |
|                                             | Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | S | Oral    |                                                      |        | Not Reported |
|                                             | Effexor                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Effexor                                              | S | Oral    |                                                      |        | Not Reported |
|                                             | Stilnox                                              | S | Oral    |                                                      | 1 MTH  | Not Reported |
|                                             | Theralene                                            | S | Oral    |                                                      |        | Not Reported |
|                                             | Theralene                                            | S | Oral    |                                                      |        | Not Reported |
|                                             | Escitalopram Oxalate                                 | S | Oral    |                                                      | 16 DAY | Not Reported |
|                                             | Akineton                                             | S | Oral    |                                                      |        | Not Reported |
|                                             | Periciazine                                          | S | Oral    | 10 Drops In The Morning /<br>40 Drops In The Evening |        | Not Reported |
|                                             | Clamoxyl (Amoxicillin)                               | S | Oral    |                                                      |        | Not Reported |
|                                             | Flagyl                                               | S | Vaginal |                                                      | 7 DAY  | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|--------------------------|-----------------|-----------------|----------------|
| 18-Aug-2010                                                                                              | 7528620                | EXPEDITED (15-DAY) | Y                  | HO, OT          | JP-ASTRAZENECA-2010SE36223 |                          | 36 YR           | Female          | DEU            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Agitation; Alcohol Poisoning; Intentional Overdose; Suicide Attempt                                      | Atacand                |                    |                    | S               | Oral                       | 112 Mg, 14 Tablets Once  | 1 DAY           | Astrazeneca     |                |
|                                                                                                          | Cipraxel               |                    |                    | S               | Oral                       | 600 Mg, 30 Tablets Once  | 1 DAY           | Not Reported    |                |
|                                                                                                          | Tramadol Hydrochloride |                    |                    | S               | Oral                       | 1000 Mg, 10 Tablets Once | 1 DAY           | Not Reported    |                |
|                                                                                                          | Alcohol                |                    |                    | S               | Oral                       | Unknown Amount Of Vodka  | 1 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Aug-2010                                                                                              | 7535708                | EXPEDITED (15-DAY) | N                  | OT              | 1000015297                 |                          | 47 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Impatience; Insomnia; Irritability; Negative Thoughts; Panic Attack; Restlessness; Tachyphrenia | Escitalopram Oxalate   |                    |                    | S               | Oral                       | See Image                | 1 WEEK          | Not Reported    |                |
|                                                                                                          |                        |                    |                    |                 | Oral                       | See Image                |                 |                 |                |
|                                                                                                          |                        |                    |                    |                 | Oral                       | See Image                | 1 WEEK          |                 |                |
|                                                                                                          | Clonazepam             |                    |                    | C               |                            |                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Aug-2010                                                                                              | 7546987                | EXPEDITED (15-DAY) | N                  | OT              | B0670309A                  |                          |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Interaction; Rash                                                                                   | Digoxin                |                    |                    | S               | Unknown                    |                          |                 | Glaxosmithkline |                |
|                                                                                                          | Zyrtec                 |                    |                    | S               | Oral                       |                          |                 | Glaxosmithkline |                |
|                                                                                                          | Folic Acid             |                    |                    | S               | Unknown                    |                          |                 | Glaxosmithkline |                |
|                                                                                                          | Atenolol               |                    |                    | S               | Unknown                    |                          |                 | Not Reported    |                |
|                                                                                                          | Tramadol Hydrochloride |                    |                    | S               | Unknown                    |                          |                 | Glaxosmithkline |                |
|                                                                                                          | Norvir                 |                    |                    | S               | Oral                       |                          |                 | Not Reported    |                |
|                                                                                                          | Ferrous Sulfate        |                    |                    | S               | Unknown                    |                          |                 | Glaxosmithkline |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |         |                 |
|--|-----------------|---|---------|-----------------|
|  | Diphenhydramine | S | Unknown | Glaxosmithkline |
|  | Loperamide      | S | Unknown | Not Reported    |
|  | Atrovent        | S | Unknown | Glaxosmithkline |
|  | Cozaar          | S | Oral    | Not Reported    |
|  | Lexapro         | S | Unknown | Not Reported    |
|  | Epogen          | S | Unknown | Not Reported    |
|  | Abilify         | S | Unknown | Not Reported    |
|  | Carvedilol      | S | Unknown | Glaxosmithkline |
|  | Seroquel        | S | Unknown | Not Reported    |
|  | Feldene         | S | Unknown | Glaxosmithkline |
|  | Gabapentin      | S | Unknown | Glaxosmithkline |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Aug-2010                                                    | 7567320        | EXPEDITED (15-DAY) | N                  | CA              | 1000015720           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Lip; Cleft Palate;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Aug-2010              | 7344516              | EXPEDITED (15-DAY) | Y                  | OT              | 1000012532           |                      |                 | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event         | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 20-Aug-2010                                   | 7528661              | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000015142           |                             | 45 YR           | Female       | DNK            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Intentional Self-Injury; | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |                      |   |      |                              |              |
|-----------------|----------------------|---|------|------------------------------|--------------|
| Suicide Attempt | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),Oral | Not Reported |
|                 | Disulfiram           | C |      |                              | Not Reported |
|                 | Naltrexone           | C |      |                              | Not Reported |
|                 | Clonazepam           | C |      |                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 20-Aug-2010              | 7543667              | EXPEDITED (15-DAY) | N                  | OT              | 1000015430           |                               | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms            | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Lorazepam            |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Aug-2010                                                       | 7554189        | DIRECT           | N                  | OT              |                      |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Emotional Disorder; Weight Increased | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 20-Aug-2010                                                                                                                                                           | 7567342              | EXPEDITED (15-DAY) | Y                  | HO              | 1000015717           |                                        | 1 DAY           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Ammonia Increased; Cough; Cyanosis Neonatal; Dehydration; Extensor Plantar Response; Eye Movement Disorder; Fontanelle Depressed; Haemangioma; Haemoglobin Decreased; | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 20mg, (20mg, 1 In 1 D), Transplecental |                 | Not Reported |                |
|                                                                                                                                                                       | Deroxat              |                    |                    | S               | Transplacental       | Transplacental                         |                 | Not Reported |                |
|                                                                                                                                                                       | Syntocinon           |                    |                    | C               |                      |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypertonia; Hypophagia;  
Hyporeflexia; Hypotonia;  
Leukoplakia Oral; Malaise;  
Malnutrition; Maternal  
Drugs Affecting Foetus;  
Mucosal Dryness;  
Musculoskeletal Stiffness;  
Oesophagitis; Palatal  
Disorder; Pallor; Platelet  
Count Increased; Poor  
Sucking Reflex;  
Regurgitation; Selective  
Eating Disorder; Stridor;  
Vomiting; Weight Gain  
Poor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2010              | 7550074       | EXPEDITED (15-DAY) | Y                  | OT              | US-SANOFI-AVENTIS-<br>2010SA048398 |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>               | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|----------------------------|--------------------|-----------------|----------------------------------------------|
| Hand Fracture; Road<br>Traffic Accident; Sleep-<br>Related Eating Disorder;<br>Somnambulism | Ambien<br>Lexapro<br>Seroquel |              |            | S<br>S<br>S | Oral<br>Unknown<br>Unknown |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2010              | 7550098       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2010103404 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                             |
|-----------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------|
| Drug Ineffective; Drug<br>Interaction; Feeling<br>Abnormal; Joint Lock;<br>Serotonin Syndrome | Zoloft<br>Lexapro<br>Wellbutrin |              |            | S<br>S<br>S |              | Unk<br>Unk<br>Unk  |                 | Pfizer<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 23-Aug-2010              | 7550341       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2010099772 |                      |            | Female     | USA            |

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| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Constipation; Drug Interaction; Somnolence                                        | Chantix              |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                                   | Valproic Acid        |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                                   | Levetiracetam        |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                                   | Phenobarbital        |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                                   | Lexapro              |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2010                                                                       | 7550667              | EXPEDITED (15-DAY) | Y                  | OT              | US-ABBOTT-10P-163-0663761-00 |                                  | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory; Hallucination, Visual                                    | Lexapro              |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                   | Wellbutrin XL        |                    |                    | C               | Oral                         |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2010                                                                       | 7554183              | DIRECT             | N                  | DE              |                              |                                  | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound                                                 | Lexapro              |                    |                    | S               |                              |                                  |                 | Forest       |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Aug-2010                                                                       | 7569609              | EXPEDITED (15-DAY) | Y                  | OT              | 1000015737                   |                                  | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Intentional Overdose; Somnolence; Suicide Attempt; Unevaluable Event | Escitalopram Oxalate |                    |                    | S               | Oral                         | Single Dosage (Once), Oral; Oral |                 | Not Reported |                |
|                                                                                   | Trimipramine         |                    |                    | S               | Oral                         | 2400 Mg (2400 Mg, Once), Oral    |                 | Not Reported |                |
|                                                                                   | Opipramol            |                    |                    | S               | Oral                         | Single Dosage (Once), Oral       |                 | Not Reported |                |

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|                                                          |                         |                    |                    |                 |                              |                                 |                 |              |                |
|----------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------|-----------------|--------------|----------------|
| Alcohol                                                  |                         | S                  |                    | Oral            |                              | Single Amount (Once),<br>Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2010                                              | 7511436                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000015003                   |                                 | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemoglobin Decreased;<br>Platelet Count Decreased       | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 10 Mg (10 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                          | Bendrofluazide          |                    |                    | C               |                              |                                 |                 | Not Reported |                |
|                                                          | Levothyroxine           |                    |                    | C               |                              |                                 |                 | Not Reported |                |
|                                                          | Esomeprazole            |                    |                    | C               |                              |                                 |                 | Not Reported |                |
|                                                          | Pamidronate (Injection) |                    |                    | C               |                              |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2010                                              | 7552124                 | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-<br>2010102775 |                                 |                 | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Serotonin<br>Syndrome                  | Zoloft                  |                    |                    | S               |                              | Unk                             | 2920 DAY        | Pfizer       |                |
|                                                          | Lexapro                 |                    |                    | S               |                              | Unk                             |                 | Not Reported |                |
|                                                          | Wellbutrin              |                    |                    | S               |                              | Unk                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2010                                              | 7557389                 | DIRECT             | N                  | DE              |                              |                                 | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Mood<br>Swings; Personality<br>Change | Chantix                 |                    |                    | S               |                              |                                 |                 | Pfizer       |                |
|                                                          | Lexapro                 |                    |                    | S               |                              |                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Aug-2010                                              | 7570619                 | EXPEDITED (15-DAY) | Y                  | OT              | 1000015773                   |                                 |                 | Male         | DNK            |

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| <u>Preferred Term</u>                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------|---------------------------------|-----------------|--------------|----------------|
| Condition Aggravated;<br>Drug Interaction; Suicidal<br>Ideation | Escitalopram Oxalate        |                    |                    | S               | Oral                               | Oral                            |                 | Not Reported |                |
|                                                                 | Champix                     |                    |                    | S               | Oral                               | Oral                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2010                                                     | 7415415                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-<br>2010SA030705 |                                 | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Alanine<br>Aminotransferase                     | Stilnox                     |                    |                    | S               | Oral                               |                                 | 4 YR            | Not Reported |                |
| Increased; Aspartate<br>Aminotransferase                        | Plavix                      |                    |                    | S               | Oral                               |                                 | 5 YR            | Not Reported |                |
| Increased; C-Reactive<br>Protein Increased;                     | Escitalopram Oxalate        |                    |                    | S               | Oral                               |                                 | 2 DAY           | Not Reported |                |
| Enteritis; Gamma-<br>Glutamyltransferase                        | Lercanidipine Hydrochloride |                    |                    | S               | Oral                               |                                 | 5 MTH           | Not Reported |                |
| Increased; Gastric Ulcer;<br>Gastrooesophageal Reflux           | Tanakan                     |                    |                    | S               | Oral                               |                                 | 17 MTH          | Not Reported |                |
| Disease; Hepatitis Acute;                                       | Ezetrol                     |                    |                    | S               | Oral                               |                                 | 4 YR            | Not Reported |                |
| Hiatus Hernia; Melaena;<br>Throat Irritation; Vomiting          | Sotalol Hydrochloride       |                    |                    | C               | Oral                               |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2010                                                     | 7546154                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000015429                         |                                 | 47 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Unevaluable Event                                               | Escitalopram Oxalate        |                    |                    | S               | Oral                               | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Aug-2010                                                     | 7571462                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000015408                         |                                 | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Intentional<br>Overdose; Road Traffic              | Escitalopram Oxalate        |                    |                    | S               | Oral                               | 20 Mg (20 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |

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|                           |                        |   |               |              |
|---------------------------|------------------------|---|---------------|--------------|
| Accident; Suicide Attempt | Unspecified Ingredient | S | Amount (Once) | Not Reported |
|                           | Alcohol                | S | Amount (Once) | Not Reported |
|                           | Tranxene T-Tab         | C |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2010              | 7572184       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015736           |                      | 68 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Fall; General Physical Health Deterioration; Hepatic Steatosis; Hyperkalaemia; Hyponatraemia; Hypothyroidism; Mixed Liver Injury; Pancreatitis; Renal Failure | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>Oral    |                 | Not Reported |
|                                                                                                                                                               | Irbesartan                  |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                               | Lysanxia (Tablets)          |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                               | Daflon (Diosmin/Hesperidin) |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                               | Efferalgan (Tablets)        |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                               | Efferalgan Codein (Tablets) |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2010              | 6962401       | EXPEDITED (15-DAY) | Y                  | OT              | 1000005412           |                      | 58 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Arthralgia; Lymphatic Disorder; Petechiae; Thrombocytopenia | Lexapro                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                   |                 | Not Reported |
|                                                             | Lexapro                       |              |            | S           | Oral         | 5 Mg (10 Mg, 1 In 2 D),<br>Oral                                    |                 | Not Reported |
|                                                             | Lexapro                       |              |            | S           | Oral         | 10 Mg 910 Mg, 1 In 1 D),<br>Oral; 20 Mg 920 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                             |                               |              |            |             | Oral         | 10 Mg 910 Mg, 1 In 1 D),<br>Oral; 20 Mg 920 Mg, 1 In 1 D),<br>Oral |                 |              |
|                                                             | Antihyperintensive Medication |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                             | Metformin                     |              |            | C           |              |                                                                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                              | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| 26-Aug-2010                                                                                           | 7436055                  | EXPEDITED (15-DAY) | Y                  | RI              | 1-22851292                               |                                        | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hypoxia;<br>Respiratory Acidosis;<br>Serotonin Syndrome;<br>Somnolence; Tachycardia | Fentanyl Patch           |                    |                    | S               | Intravenous (not<br>otherwise specified) | 250 Mcg, Divided Doses,<br>Intravenous |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate     |                    |                    | S               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Insulin Nos              |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Trazodone Hydrochloride  |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Gabapentin               |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Lansoprazole             |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Lorazepam                |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Oxycodone                |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Cetirizine Hydrochloride |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Etomidate                |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Vecuronium Bromide       |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Morphine                 |                    |                    | C               |                                          |                                        |                 | Not Reported |                |
|                                                                                                       | Cefazolin                |                    |                    | C               |                                          |                                        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------|----------------------|-----------------|--------------|----------------|
| 26-Aug-2010              | 7554564                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-NOVOPROD-<br>313515 |                      | 64 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>           | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Haemorrhage       | Victoza                     |                    |                    | S               | Subcutaneous           | Uk/Sc                |                 | Novo Nordisk |                |
|                          | Escitalopram Oxalate        |                    |                    | S               |                        | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Aspirin                     |                    |                    | S               | Oral                   | 300 Mg, Qd           |                 | Not Reported |                |
|                          | Glucophage                  |                    |                    | C               | Oral                   | 2000 Mg, Qd          |                 | Not Reported |                |
|                          | Simvastatin                 |                    |                    | C               | Oral                   | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Lercanidipine Hydrochloride |                    |                    | C               |                        | 20 Mg, Qd            |                 | Not Reported |                |
|                          | Coaprovel                   |                    |                    | C               |                        | 300/25mg             |                 | Not Reported |                |
|                          | Allopurinol                 |                    |                    | C               |                        |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2010              | 7554740       | EXPEDITED (15-DAY) | Y                  | DE              | GB-PERRIGO-10GB012429 |                      | 25 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose  | Ibuprofen                   |              |            | S           | Oral         | Unk                | 1 DAY           | Perrigo      |
|                       | Cipralext                   |              |            | S           | Oral         | 220 Mg, Single     | 1 DAY           | Not Reported |
|                       | Cipralext                   |              |            | S           | Oral         | 10 Mg, Qd          | 7 DAY           | Not Reported |
|                       | Cipralext                   |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                       | Alcohol                     |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |
|                       | Fluoxetine                  |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |
|                       | Nortriptyline Hydrochloride |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |
|                       | Oxazepam                    |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |
|                       | Temazepam                   |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2010              | 7573995       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015775           |                      | 58 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; Herpes Simplex Test Positive; Hyperthermia; Smooth Muscle Antibody Positive; Weight Decreased | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2010              | 7582072       | EXPEDITED (15-DAY) | Y                  | OT              | OXER20100002         |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Drug Interaction; Serotonin Syndrome; Vision Blurred; Weight Decreased | Oxycodone Hydrochloride |              |            | S           | Oral         | 120 Mg, Q Day, Oral              |                 | Not Reported |
|                                                                        | Fentanyl (Fentanyl)     |              |            | S           | Nasal        | Four Puffs Of 200 Ug/Puff, Nasal |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Escitalopram Oxalate

S

5 Mg, Once A Day

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 27-Aug-2010              | 7556390       | EXPEDITED (15-DAY) | Y                  | HO              | FR-EISAI INC.-E3810-04030-SPO-FR |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Reaction With Eosinophilia And Systemic Symptoms | Pariet (Rabeprazole)          |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Motilium                      |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Previscan (Fluindione)        |              |            | S           | Oral         |                    | 81 DAY          | Not Reported |
|                                                       | Hydrochlorothiazide/Valsartan |              |            | S           | Oral         | Unknown            | 4 MTH           | Not Reported |
|                                                       | Escitalopram Oxalate          |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Gaviscon                      |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Tahor                         |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Amlodipine                    |              |            | S           | Oral         | Unknown            |                 | Not Reported |
|                                                       | Di-Gesic                      |              |            | C           |              |                    |                 | Not Reported |
|                                                       | Oxybutynin                    |              |            | C           |              |                    |                 | Not Reported |
|                                                       | Nebivolol                     |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 27-Aug-2010              | 7556740       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20100805331 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis Relapsing | Topiramate           |              |            | S           | Oral         |                    |                 | Not Reported |
|                        | Crestor              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Inexium              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Propranolol          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Creon                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Sulpiride            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                        | Acetaminophen        |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                             |                    |                    |                 |                       |                                                                                        |                 |              |                |
|------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Humalog                                                          |                             |                    | S                  |                 | Unknown               |                                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2010                                                      | 7557133                     | EXPEDITED (15-DAY) | Y                  | DE              | GB-JNJFOC-20100808035 |                                                                                        | 25 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose                       | Ibuprofen                   |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Alcohol                     |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Cipralex                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Fluoxetine                  |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Nortriptyline Hydrochloride |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Oxazepam                    |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
|                                                                  | Temazepam                   |                    |                    | S               | Oral                  |                                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                                                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Aug-2010                                                      | 7574326                     | DIRECT             | Y                  | OT              |                       |                                                                                        | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Breast Swelling; Breast<br>Tenderness; Restless<br>Legs Syndrome | Lexapro                     |                    |                    | S               | Oral                  | 5mgm 1x Daily Oral<br>10mgm 1x Daily Oral<br>5mgm 1x Daily Oral<br>10mgm 1x Daily Oral |                 | Forest       |                |
|                                                                  | Cardura                     |                    |                    | C               |                       |                                                                                        |                 | Not Reported |                |
|                                                                  | Tenormin                    |                    |                    | C               |                       |                                                                                        |                 | Not Reported |                |
|                                                                  | Crestor                     |                    |                    | C               |                       |                                                                                        |                 | Not Reported |                |
|                                                                  | Nexium                      |                    |                    | C               |                       |                                                                                        |                 | Not Reported |                |
|                                                                  | Asa                         |                    |                    | C               |                       |                                                                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |   |              |
|--|----------------|---|--------------|
|  | Valium         | C | Not Reported |
|  | Fish Oil       | C | Not Reported |
|  | Centrum Silver | C | Not Reported |
|  | Vitamin B12    | C | Not Reported |
|  | Vit E          | C | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|---------------------|------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 30-Aug-2010                                  | 7566278             | NON-EXPEDITED    |                    |                 | -MYLANLABS-2009S1015505 |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Gait Disturbance; Osteoporosis; Tremor | Lexapro             |                  |                    | S               | Oral                    |                      |                 | Alphapharm   |                |
|                                              | Metoprolol Tartrate |                  |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                              | Lisinopril          |                  |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                              | Vitamins Nos        |                  |                    | C               |                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 30-Aug-2010                                                                                                                | 7572302        | DIRECT           | N                  | RI              |                      |                      | 63 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Decreased Activity; Dyspepsia; Fear; Feeling Abnormal; Hypophagia; Insomnia; Malaise; Suicidal Ideation; Unevaluable Event | Lexapro        |                  |                    | S               |                      | 10mg 1 Dose          |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 31-Aug-2010                                                                                                       | 7527076              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000015135           |                                                                                | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Decreased; Body Temperature Fluctuation; Caesarean Section; Hyperreflexia; Maternal Drugs Affecting | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 30 Mg (30 Mg, 1 In 1 D), Transplacental; 30 Mg (30 Mg, 1 In 1 D), Transmammary |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                      |          |   |                |                                                                                    |              |
|----------------------------------------------------------------------------------------------------------------------|----------|---|----------------|------------------------------------------------------------------------------------|--------------|
| Fetus; Maternal Exposure During Breast Feeding; Respiratory Disorder; Restlessness; Sleep Disorder; Tremor; Vomiting | Seroquel | S | Transplacental | 600 Mg (600 Mg, 1 In 1 D), Transplacental; 600 Mg (600 Mg, 1 In 1 D), Transmammary | Not Reported |
|----------------------------------------------------------------------------------------------------------------------|----------|---|----------------|------------------------------------------------------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|------------|------------|----------------|
| 31-Aug-2010              | 7567621       | EXPEDITED (15-DAY) | Y                  | OT              | IN-TYCO HEALTHCARE/MALLIN CKRODT-T201001847 |                      | 46 YR      | Female     | IND            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Mood; Drug Interaction; Galactorrhoea; Intracranial Mass; Sleep Disorder | Tofranil-Pm          |              |            | S           |              | 75 Mg, Qd          |                 | Tyco         |
|                                                                                    | Escitalopram Oxalate |              |            | S           |              | 20 Mg, Qd          | 365 DAY         | Not Reported |
|                                                                                    | Glibenclamide        |              |            | S           |              | 5 Mg, Qd           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2010              | 7567867       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SOLVAY-00310005089 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Pancreatitis Acute    | Creon                |              |            | S           | Oral         | Daily Dose: Unknown                  |                 | Not Reported |
|                       | Humalog              |              |            | S           | Subcutaneous | Daily Dose: 64 International Unit(S) |                 | Not Reported |
|                       | Acetaminophen        |              |            | S           | Oral         | Daily Dose: 3 Gram(S)                |                 | Not Reported |
|                       | Sulpiride            |              |            | S           | Oral         | Daily Dose: 100 Milligram(S)         |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Daily Dose: 20 Milligram(S)          |                 | Not Reported |
|                       | Propranolol          |              |            | S           | Oral         | Daily Dose: 80 Milligram(S)          |                 | Not Reported |
|                       | Nexium               |              |            | S           | Oral         | Daily Dose: 40 Milligram(S)          |                 | Not Reported |
|                       | Topiramate           |              |            | S           | Oral         | Daily Dose: 100 Milligram(S)         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |      |                                |              |
|---------|---|------|--------------------------------|--------------|
| Crestor | S | Oral | Daily Dose: 10<br>Milligram(S) | Not Reported |
|---------|---|------|--------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2010              | 7579043       | EXPEDITED (15-DAY) | N                  | HO              | 1000015932           |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Dry Mouth; Normal<br>Pressure Hydrocephalus;<br>Productive Cough | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2010              | 7580429       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000015964           |                      | 83 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Dyskinesia; Hyperhidrosis;<br>Hyperkalaemia;<br>Hypertension; Psychotic<br>Disorder; Pyrexia; Renal<br>Failure; Rhabdomyolysis;<br>Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral          |                 | Not Reported |
|                                                                                                                                                | Azilect              |              |            | S           | Oral         | 1 Mg (1 Mg, 1 In 1 D), Oral               |                 | Not Reported |
|                                                                                                                                                | Ultracet             |              |            | S           | Oral         | 300 Mg (75 Mg, 4 In 1 D),<br>Oral         |                 | Not Reported |
|                                                                                                                                                | Duragesic            |              |            | S           | Other        | 4.1667 Mcg (12.5 Mcg, 1<br>In 3 D), Other |                 | Not Reported |
|                                                                                                                                                | Stalevo              |              |            | S           | Oral         | 500 Mg (100 Mg, 5 In 1 D),<br>Oral        |                 | Not Reported |
|                                                                                                                                                | Celebrex             |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                                                                | Imovane (Tablets)    |              |            | C           |              |                                           |                 | Not Reported |
|                                                                                                                                                | Sinemet              |              |            | C           |              |                                           | Not Reported    |              |
|                                                                                                                                                | Calciferol (Tablets) |              |            | C           |              |                                           | Not Reported    |              |
|                                                                                                                                                | Ocuvite Lutein       |              |            | C           |              |                                           | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2010              | 7580539       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015134           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                    |                      |   |      |                                    |              |
|----------------------------------------------------------------------------------------------------|----------------------|---|------|------------------------------------|--------------|
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Off Label Use;<br>Overdose; Pregnancy | Escitalopram Oxalate | S | Oral | 30 Mg (30 Mg, 1 In 1 D),<br>Oral   | Not Reported |
|                                                                                                    | Seroquel             | S | Oral | 600 Mg (600 Mg, 1 In 1 D),<br>Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2010              | 7570156       | EXPEDITED (15-DAY) | Y                  | DE              | GXKR2010GB09585      |                      | 25 YR      | Female     | GBR            |

  

| <u>Preferred Term</u>                      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Completed Suicide;<br>Intentional Overdose | Temazepam                   |              |            | S           | Oral         | Unk                            | 1 DAY           | Novartis     |
|                                            | Ibuprofen                   |              |            | S           | Oral         | Unk                            | 1 DAY           | Not Reported |
|                                            | Alcohol                     |              |            | S           | Oral         | Unk                            | 1 DAY           | Not Reported |
|                                            | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg/Day                      |                 | Not Reported |
|                                            | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg/Day                      | 7 DAY           | Not Reported |
|                                            | Escitalopram Oxalate        |              |            | S           | Oral         | 22 X 10 Mg Tablets (220<br>Mg) | 1 DAY           | Not Reported |
|                                            | Fluoxetine                  |              |            | S           | Oral         | Unk                            | 1 DAY           | Not Reported |
|                                            | Nortriptyline Hydrochloride |              |            | S           | Oral         | Unk                            | 1 DAY           | Not Reported |
|                                            | Oxazepam                    |              |            | S           | Oral         | Unk                            | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2010              | 7582829       | EXPEDITED (15-DAY) | N                  | OT              | 1000015941           |                      | 48 YR      | Male       | DNK            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Agoraphobia; Anxiety;<br>Depressed Mood;<br>Dizziness; Dry Mouth;<br>Eating Disorder; Insomnia;<br>Loss Of Libido; Malaise;<br>Multiple Injuries; Muscle<br>Spasms; Muscle<br>Twitching; Suicidal<br>Ideation; Suicide Attempt;<br>Tremor; Withdrawal | Escitalopram Oxalate |              |            | S           | Oral         | Oral                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                       |                      |              |            |             | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral ;<br>10 Mg (10 Mg,1 In 1<br>D),Oral |                 |              |
|                                                                                                                                                                                                                                                       | Amoxicillin          |              |            | C           |              |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                                                       | Neoclarityn          |              |            | C           |              |                                                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                           |   |              |
|----------|---------------------------|---|--------------|
| Syndrome | Thiamine                  | C | Not Reported |
|          | Acamprosate Calcium       | C | Not Reported |
|          | Disulfiram                | C | Not Reported |
|          | Clonazepam                | C | Not Reported |
|          | Mirtazapine               | C | Not Reported |
|          | Buspirone                 | C | Not Reported |
|          | Trazodone Hydrochloride   | C | Not Reported |
|          | Valium                    | C | Not Reported |
|          | Sleeping Tablet (Tablets) | C | Not Reported |
|          | Amitriptyline             | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2010              | 7597462       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015894           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------|-----------------|--------------|
| Muscle Haemorrhage    | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                    |                 | Not Reported |
|                       | Aspirin Lysine       |              |            | S           | Oral         | Oral                                                                |                 | Not Reported |
|                       | Victoza              |              |            | S           | Subcutaneous | 2000 Iu International Units<br>(1000 Iu, 2 In 1 D),<br>Subcutaneous |                 | Not Reported |
|                       | Allopurinol          |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Simvastatin          |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Lercanidipine        |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Coaprovel            |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Glucor               |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Januvia              |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Competact            |              |            | C           |              |                                                                     |                 | Not Reported |
|                       | Glucophage           |              |            | C           |              |                                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 02-Sep-2010              | 7491654       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ABBOTT-10P-163-<br>0657612-00 |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Accidental Overdose;<br>Mania | Vicodin        |              |            | S           |              | Unknown              |                 | Not Reported |
|                               | Vicodin        |              |            | S           |              | Accidental Overdose: |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |  |  |                                      |              |
|-------------------------|---|------|--|--|--------------------------------------|--------------|
|                         |   |      |  |  | Unknown Dose                         |              |
| Lexapro                 | S | Oral |  |  |                                      | Not Reported |
| Lexapro                 | S | Oral |  |  |                                      | Not Reported |
| Lexapro                 | S | Oral |  |  |                                      | Not Reported |
| Lexapro                 | S | Oral |  |  | Accidental Overdose:<br>Unknown Dose | Not Reported |
| Seroquel                | S | Oral |  |  |                                      | Not Reported |
| Seroquel                | S | Oral |  |  | Accidental Overdose:<br>Unknown Dose | Not Reported |
| Seroquel                | S |      |  |  |                                      | Not Reported |
| Xanax                   | S |      |  |  | Unknown                              | Not Reported |
| Xanax                   | S |      |  |  | Accidental Overdose:<br>Unknown Dose | Not Reported |
| Alcohol                 | S | Oral |  |  |                                      | Not Reported |
| Trazodone Hydrochloride | C |      |  |  |                                      | Not Reported |
| Ultram                  | C | Oral |  |  |                                      | Not Reported |
| Imitrex                 | C | Oral |  |  |                                      | Not Reported |
| Skelaxin                | C | Oral |  |  |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2010              | 7548976       | EXPEDITED (15-DAY) | Y                  | OT              | FR-WATSON-2010-10844 |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|-------------------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Serotonin Syndrome | Fentanyl Patch          |              |            | S           | Respiratory<br>(inhalation) | 200 U/G, Per Puff  |                 | Watson       |
|                                         | Oxycodone Hydrochloride |              |            | S           | Oral                        | 120 Mg, Daily      | 183 DAY         | Watson       |
|                                         | Escitalopram Oxalate    |              |            | S           | Unknown                     | 5 Mg, Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2010              | 7576023       | DIRECT           | Y                  | OT              |                      |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                       |         |   |      |             |        |
|---------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------|
| Agitation; Anorgasmia;<br>Atrial Fibrillation; Erectile<br>Dysfunction;<br>Restlessness;<br>Tachycardia; Ventricular<br>Extrasystoles | Lexapro | S | Oral | 10 Mg Qd Po | Forest |
|---------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|-------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2010              | 7581902       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015929           |                      |            | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Pancytopenia; Serotonin<br>Syndrome | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2010              | 7410072       | NON-EXPEDITED    | N                  |                 | A0858789A            |                      | 30 YR      | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Increased Appetite;<br>Weight Increased | Lamictal       |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                         | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                         | Lexapro        |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |
|                                         | Ambien         |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                         | Klonopin       |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2010              | 7580227       | DIRECT           | N                  | DE              |                      |                      | 29 YR      | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Weight<br>Increased | Seroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                     | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                     | Clonazepam     |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2010              | 7583863       | EXPEDITED (15-DAY) | Y                  | DE              | 2010MA002217         |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                     | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Intentional Overdose;<br>Toxicity To Various Agents | Fluoxetine                  |              |            | S           | Oral         | Po                 |                 | Alphapharm   |
|                                                                           | Ibuprofen                   |              |            | S           | Oral         | Po                 |                 | Alphapharm   |
|                                                                           | Oxazepam                    |              |            | S           | Oral         | Po                 |                 | Purepac      |
|                                                                           | Temazepam                   |              |            | S           | Oral         | Po                 |                 | Purepac      |
|                                                                           | Cipralelex                  |              |            | S           | Oral         | 220 Mg; Po         |                 | Not Reported |
|                                                                           | Alcohol (Ethanol)           |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                           | Prozac                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                           | Cipralelex                  |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                           | Nortriptyline Hydrochloride |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                                                           | Cipralelex                  |              |            | S           | Oral         | Po                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2010              | 7585844       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015407           |                      | 37 YR      | Male       | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Affective Disorder;<br>Suicidal Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 100 Mg (10 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Sep-2010              | 7585850       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000015449           |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Completed Suicide;<br>Drowning; Intentional<br>Overdose; Road Traffic<br>Accident | Escitalopram Oxalate   |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D)<br>Oral |                 | Not Reported |
|                                                                                   | Unspecified Ingredient |              |            | S           |              |                                 |                 | Not Reported |
|                                                                                   | Agomelatine            |              |            | S           |              | 25 Mg (25 Mg, 1 In 1 D)         |                 | Not Reported |
|                                                                                   | Rivotril (Tablets)     |              |            | C           |              |                                 |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                              |   |              |
|--|------------------------------|---|--------------|
|  | Inexium                      | C | Not Reported |
|  | Sectral                      | C | Not Reported |
|  | Refresch Collyre (Eye Drops) | C | Not Reported |
|  | Levothyrox                   | C | Not Reported |
|  | Pravastatin                  | C | Not Reported |
|  | Lysanxia                     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2010              | 7504275       | EXPEDITED (15-DAY) |                    | HO              | 1000014950           |                      | 62 YR      | Male       | BRA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Memory Impairment;<br>Psychotic Disorder;<br>Salivary Hypersecretion;<br>Somnolence; Tremor | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                             | Omeprazole     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                             | Octreotide     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                             | Atenolol       |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2010              | 7574534       | NON-EXPEDITED    | N                  |                 | A0865079A            |                      | 41 YR      | Male       | USA            |

| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction;<br>Hyperhidrosis; Nausea;<br>Vomiting | Requip         |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                         | Lexapro        |              |            | S           | Oral         | 10mg Per Day       | 6 DAY           | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2010              | 7575061       | EXPEDITED (15-DAY) | Y                  | DE              | FR-SANOFI-AVENTIS-<br>2010SA051069 |                      | 27 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression; Intentional<br>Overdose | Stilnox              |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                           | Cyamemazine          |              |            | S           | Oral                                     |                    |                 | Not Reported |
|                                                           | Remicade             |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Not Reported |
|                                                           | Escitalopram Oxalate |              |            | S           | Oral                                     |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |              |
|-------------------|---|---------|--------------|
| Diclofenac Sodium | C | Unknown | Not Reported |
| Ventolin          | C | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2010              | 7575166       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20100807875 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Pancreatitis Relapsing | Topiramate                               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Tramadol Hydrochloride                   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Ultracet                                 |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Tramadol Hydrochloride And Acetaminophen |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Crestor                                  |              |            | S           |              |                    |                 | Not Reported |
|                                  | Inexium                                  |              |            | S           |              |                    |                 | Not Reported |
|                                  | Perfalgan                                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Humalog                                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Acetaminophen                            |              |            | S           |              |                    |                 | Not Reported |
|                                  | Sulpiride                                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Creon                                    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Escitalopram Oxalate                     |              |            | S           | Unknown      |                    |                 | Not Reported |
| Propranolol                      |                                          |              | S          | Unknown     |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2010              | 7575310       | EXPEDITED (15-DAY) | Y                  | OT              | US-ASTRAZENECA-2010SE40565 |                      | 22 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hand Fracture; Road Traffic Accident; Sleep-Related Eating Disorder; Somnambulism | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                   | Ambien         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 07-Sep-2010                                                 | 7575635                              | EXPEDITED (15-DAY) | N                  | HO, OT          | CH-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15266760 |                                                      | 37 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety;<br>Electrocardiogram Qt<br>Prolonged; Mood Altered | Abilify                              |                    |                    | S               | Oral                                            | Also 15mg/Day,Dosage<br>Interrupted:21apr10          |                 | Not Reported |                |
|                                                             | Prazine (Promazine<br>Hydrochloride) |                    |                    | S               | Oral                                            |                                                      | 14 DAY          | Not Reported |                |
|                                                             | Haldol                               |                    |                    | S               |                                                 |                                                      | 19 DAY          | Not Reported |                |
|                                                             | Haldol                               |                    |                    | S               |                                                 |                                                      | 19 DAY          | Not Reported |                |
|                                                             | Risperdal                            |                    |                    | S               | Oral                                            | Therapy<br>Dates:22apr10:23apr10,25<br>apr10:28apr10 |                 | Not Reported |                |
|                                                             | Risperdal                            |                    |                    | S               | Oral                                            | Therapy<br>Dates:22apr10:23apr10,25<br>apr10:28apr10 |                 | Not Reported |                |
|                                                             | Cipralex                             |                    |                    | S               | Oral                                            |                                                      |                 | Not Reported |                |
|                                                             | Stilnox                              |                    |                    | C               | Oral                                            |                                                      |                 | Not Reported |                |
|                                                             | Rivotril                             |                    |                    | C               | Oral                                            |                                                      |                 | Not Reported |                |
|                                                             | Clothiapine                          |                    |                    | C               |                                                 |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Sep-2010                                                 | 7588744                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000016044                                      |                                                      | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Pulmonary Oedema                                      | Escitalopram Oxalate                 |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Sep-2010                                                 | 8539218                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000015993                                      |                                                      | 92 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                       | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                                 |                      |                    |                    |                                                |                            |                               |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|------------------------------------------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| Anaemia; Haemorrhagic Disorder                                                                                  | Escitalopram Oxalate | S                  | Oral               | 10 Mg (10 Mg, 1 In 1 D), Oral                  | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Arixtra              | S                  | Subcutaneous       | 2.5 Mg / 0.5 Ml (1 Dosage Forms), Subcutaneous | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Lasix                | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Aldactone            | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Rivotril             | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Bisoprolol Fumarate  | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Fosavance            | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
|                                                                                                                 | Perindopril Erbumine | C                  |                    |                                                | Not Reported               |                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Sep-2010                                                                                                     | 6837154              | EXPEDITED (15-DAY) | Y                  | HO                                             | FR-ASTRAZENECA-2008CG01763 |                               | 66 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Malaise                                                                                                         | Atacand              |                    |                    | S                                              | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                 | Vastarel             |                    |                    | S                                              | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                 | Stilnox              |                    |                    | S                                              | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                 | Escitalopram Oxalate |                    |                    | S                                              | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                 | Effexor              |                    |                    | C                                              | Oral                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                                | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Sep-2010                                                                                                     | 7537676              | EXPEDITED (15-DAY) | Y                  | HO                                             | 1000015323                 |                               | 89 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                                    | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Osmolarity Decreased; Fall; General Physical Health Deterioration; Hyponatraemia; Psychomotor Retardation | Escitalopram Oxalate |                    |                    | S                                              | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                 | Lasix                |                    |                    | S                                              | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                 | Inexium              |                    |                    | C                                              |                            |                               |                 | Not Reported |                |
|                                                                                                                 | Cordarone            |                    |                    | C                                              |                            |                               |                 | Not Reported |                |
|                                                                                                                 | Kardegic             |                    |                    | C                                              |                            |                               |                 | Not Reported |                |
|                                                                                                                 | Equanil              |                    |                    | C                                              |                            |                               |                 | Not Reported |                |
|                                                                                                                 | Atacand              |                    |                    | C                                              |                            |                               |                 | Not Reported |                |

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|                                                                                                                                                                          |                          |                    |                    |                 |                      |                                                              |                 |                 |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|-----------------|----------------|
| Pariet                                                                                                                                                                   |                          | C                  |                    | Not Reported    |                      | Not Reported                                                 |                 | Not Reported    |                |
| Amlodipine                                                                                                                                                               |                          | C                  |                    |                 |                      |                                                              |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Sep-2010                                                                                                                                                              | 7566161                  | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000015589           |                                                              | 42 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Completed Suicide; Psychotic Disorder                                                                                                                           | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |
|                                                                                                                                                                          |                          |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                 |                 |                |
|                                                                                                                                                                          | Buspar                   |                    |                    | C               |                      |                                                              |                 | Not Reported    |                |
|                                                                                                                                                                          | Risperdal                |                    |                    | C               |                      |                                                              |                 | Not Reported    |                |
|                                                                                                                                                                          | Spasmag                  |                    |                    | C               |                      |                                                              |                 | Not Reported    |                |
|                                                                                                                                                                          | Uvedose                  |                    |                    | C               |                      |                                                              |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Sep-2010                                                                                                                                                              | 7570210                  | EXPEDITED (15-DAY) | N                  | HO, OT          | B0666777A            |                                                              | 34 YR           | Female          | ITA            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>      |                |
| Abortion Induced; Agitation; Asthenia; Decreased Appetite; Depression; Drug Ineffective; Feeling Guilty; Insomnia; Maternal Exposure During Pregnancy; Suicidal Ideation | Paroxetine Hydrochloride |                    |                    | S               | Unknown              | 20mg Per Day                                                 |                 | Glaxosmithkline |                |
|                                                                                                                                                                          | Escitalopram Oxalate     |                    |                    | S               | Unknown              | 10mg Per Day                                                 |                 | Not Reported    |                |
|                                                                                                                                                                          | Oxcarbazepine            |                    |                    | S               | Oral                 | 1tab Per Day                                                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 08-Sep-2010                                                                                                                                                              | 7596988                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000016041           |                                                              | 40 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>      |                |

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|                 |                      |   |      |                                  |              |
|-----------------|----------------------|---|------|----------------------------------|--------------|
| Mental Disorder | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|-----------------|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2010              | 7571401       | EXPEDITED (15-DAY) | N                  | HO              | B0671076A            |                      | 92 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Anaemia; Contraindication To Medical Treatment; Haemorrhage; Incorrect Product Administration Duration; Overdose | Arixtra              |              |            | S           | Subcutaneous | 2.5mg Per Day      | 62 DAY          | Glaxosmithkline |
|                                                                                                                  | Escitalopram Oxalate |              |            | S           | Oral         | 10mg Per Day       |                 | Unknown         |
|                                                                                                                  | Lasix                |              |            | C           | Oral         | 20mg Per Day       |                 | Glaxosmithkline |
|                                                                                                                  | Aldactone            |              |            | C           | Oral         | 12.5mg Per Day     |                 | Glaxosmithkline |
|                                                                                                                  | Rivotril             |              |            | C           | Oral         | 3drop As Required  |                 | Not Reported    |
|                                                                                                                  | Bisoprolol Fumarate  |              |            | C           | Oral         | 1.25mg Per Day     |                 | Not Reported    |
|                                                                                                                  | Fosavance            |              |            | C           | Oral         | 70mg Weekly        |                 | Not Reported    |
|                                                                                                                  | Perindopril Erbumine |              |            | C           | Oral         | 2mg Single Dose    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2010              | 7572170       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015808           |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Blood Pressure Increased; Cerebral Haemorrhage | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                                | Omeprazole           |              |            | C           |              |                         |                 | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2010              | 7578662       | EXPEDITED (15-DAY) | Y                  | OT              | US-WYE-H04065608     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hepatitis             | Protonix       |              |            | S           |              | Unknown            |                 | Wyeth      |
|                       | Lexapro        |              |            | S           | Oral         |                    |                 | Lundbeck   |
|                       | Lexapro        |              |            | S           |              |                    |                 | Lundbeck   |
|                       | Clonazepam     |              |            | S           |              | 0.5 Mg Prn         |                 | Unknown    |



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|                     |   |         |         |
|---------------------|---|---------|---------|
| Hydrochlorothiazide | C | Unknown | Unknown |
| Labetalol           | C | Unknown | Unknown |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2010              | 7585851       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015972           |                      | 74 YR      | Male       | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Dyskinesia; Erectile Dysfunction; Paraesthesia | Escitalopram Oxalate                                                                                                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                | Pravastatin                                                                                                         |              |            | C           |              |                               |                 | Not Reported |
|                                                | Vastarel                                                                                                            |              |            | C           |              |                               |                 | Not Reported |
|                                                | Atarax                                                                                                              |              |            | C           |              |                               |                 | Not Reported |
|                                                | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              |                               |                 | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2010              | 7602329       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016064           |                      | 36 YR      | Female     | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Asthenia; Dyskinesia; Fatigue; Sleep Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 5 To 15 Mg Per Day (1 In 1 D),Oral |                 | Not Reported |

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|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2010              | 7540965       | EXPEDITED (15-DAY) | Y                  |                 | 1000015295           |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Gastric Disorder; Metastases To Stomach; Nausea; Ovarian Neoplasm | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Sep-2010                                                                                                                | 7579254                  | NON-EXPEDITED    | N                  |                 | US-WYE-H07957709     |                      | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Dyspepsia;<br>Middle Insomnia                                                                                   | Pristiq Extended Release |                  |                    | S               | Oral                 | Unknown              | 15 DAY          | Wyeth        |                |
|                                                                                                                            | Lunesta                  |                  |                    | S               | Oral                 | 3-4.5 Mg             |                 | Sunovion     |                |
|                                                                                                                            | Lexapro                  |                  |                    | S               | Oral                 | Unknown              | 15 DAY          | Lundbeck     |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2010                                                                                                                | 7579395                  | NON-EXPEDITED    | N                  |                 | US-WYE-H08251709     |                      | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition<br>Aggravated; Dizziness;<br>Headache;<br>Nasopharyngitis; Panic<br>Attack; Tremor; Weight<br>Decreased | Pristiq Extended Release |                  |                    | S               | Oral                 |                      |                 | Wyeth        |                |
|                                                                                                                            | Pristiq Extended Release |                  |                    | S               |                      |                      |                 | Wyeth        |                |
|                                                                                                                            | Lexapro                  |                  |                    | S               | Unknown              | Unspecified          |                 | Lundbeck     |                |
|                                                                                                                            | Xanax                    |                  |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                            | Insulin Nos              |                  |                    | C               |                      |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2010                                                                                                                | 7579512                  | NON-EXPEDITED    | N                  |                 | US-WYE-H08528409     |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Fatigue;<br>Insomnia; Irritability                                                                                | Pristiq Extended Release |                  |                    | S               | Oral                 |                      |                 | Wyeth        |                |
|                                                                                                                            | Lexapro                  |                  |                    | S               |                      |                      |                 | Lundbeck     |                |
|                                                                                                                            | Lexapro                  |                  |                    | S               |                      |                      | 3 DAY           | Lundbeck     |                |
|                                                                                                                            | Trazodone Hydrochloride  |                  |                    | C               |                      |                      |                 | Unknown      |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Sep-2010                                                                                                                | 7579557                  | NON-EXPEDITED    | N                  |                 | US-WYE-H08654109     |                      | 34 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                          |   |      |          |
|----------------------------------------------------|--------------------------|---|------|----------|
| Anxiety; Feeling Jittery;<br>Myalgia; Palpitations | Pristiq Extended Release | S | Oral | Wyeth    |
|                                                    | Lexapro                  | S |      | Lundbeck |
|                                                    | Vitamin B3               | C |      | Wyeth    |
|                                                    | Acetylsalicylic Acid     | C |      | Unknown  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2010              | 7579773       | NON-EXPEDITED    | Y                  |                 | US-WYE-H08744109     |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Dizziness;<br>Feeling Of Body | Pristiq Extended Release |              |            | S           | Oral         |                    |                 | Wyeth        |
| Temperature Change; Hot                | Lexapro                  |              |            | S           |              |                    |                 | Lundbeck     |
| Flush; Hyperhidrosis;                  | Lexapro                  |              |            | S           |              |                    | 1 WEEK          | Lundbeck     |
| Middle Insomnia; Nausea;               | Toprol XL                |              |            | C           |              |                    |                 | Astrazeneca  |
| Sleep Disorder                         | Tamoxifen Citrate        |              |            | C           |              |                    |                 | Unknown      |
|                                        | Plaquenil                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2010              | 7580045       | NON-EXPEDITED    | N                  |                 | US-WYE-H08917509     |                      | 23 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Lower; | Lybrel         |              |            | S           | Oral         |                    | 15 DAY          | Wyeth      |
| Nausea; Uterine Pain  | Lexapro        |              |            | S           | Unknown      | Unknown            | 8 DAY           | Lundbeck   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Sep-2010              | 7580653       | EXPEDITED (15-DAY) | N                  | OT              | A0880541A            |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Feeling | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
| Abnormal; Joint Lock;     | Zoloft         |              |            | S           | Unknown      |                    |                 | Not Reported    |
| Serotonin Syndrome        | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Sep-2010                                                                      | 7587843                 | DIRECT                    |                             |                          |                                          |                               | 50 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alcohol Use; Amnesia; Loss Of Consciousness                                      | Lexapro                 |                           |                             | S                        |                                          | 5 Mg Once/Day                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2010                                                                      | 7594334                 | DIRECT                    | N                           | RI                       |                                          |                               | 36 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Cognitive Disorder                                                      | Lexapro                 |                           |                             | S                        | Oral                                     | 10mg Daily Po                 | 5 YR                     | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Sep-2010                                                                      | 7605115                 | EXPEDITED (15-DAY)        | N                           | OT                       | 1000016048                               |                               |                          | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Sodium Decreased; Diarrhoea; General Physical Health Deterioration; Tremor | Escitalopram Oxalate    |                           |                             | S                        | Oral                                     | 20 Mg (20 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Sep-2010                                                                      | 7582624                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000015962                               |                               | 43 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                    | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia; Torticollis                                                            | Escitalopram Oxalate    |                           |                             | S                        |                                          |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>            | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Sep-2010                                                                      | 7582912                 | EXPEDITED (15-DAY)        | N                           | OT                       | IT-BRISTOL-MYERS SQUIBB COMPANY-15277841 |                               | 78 YR                    | Male                | ITA                     |

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| <u>Preferred Term</u>                                | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>           |                |
|------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------|-----------------|----------------------|----------------|
| Depression; International Normalised Ratio Increased | Coumadin                                 |                    |                    | S               |                      | Interrupted On 18aug2010 Stopped Taking Coumadin For 1 Day Then Reduced |                 | Bristol Myers Squibb |                |
|                                                      | Cipralex                                 |                    |                    | S               | Oral                 | Film Coated Oral Tabs                                                   |                 | Not Reported         |                |
|                                                      | Omeprazole                               |                    |                    | C               | Oral                 | Dosage:20 Mg Modified Release Oral Caps                                 |                 | Not Reported         |                |
|                                                      | Nebivolol                                |                    |                    | C               | Oral                 | 5mg Tabs                                                                |                 | Not Reported         |                |
|                                                      | Hydrochlorothiazide\Olmesartan Medoxomil |                    |                    | C               | Oral                 | Dosage:20mg/25mg Film Coated Oral Tabs                                  |                 | Not Reported         |                |
|                                                      | Alprazolam                               |                    |                    | C               | Oral                 | Dosage:0.75mg/ML Oral Drops                                             |                 | Not Reported         |                |
|                                                      | Simvastatin                              |                    |                    | C               | Oral                 | Dosage:20 Mg Film Coated Oral Tabs                                      |                 | Not Reported         |                |
|                                                      | Glyburide                                |                    |                    | C               | Oral                 | Dosage:400mg + 2.5mg Film Coated Oral Tabs.                             |                 | Not Reported         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 13-Sep-2010                                          | 7603795                                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000016106           |                                                                         |                 | Male                 | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>           |                |
| Pulmonary Fibrosis                                   | Escitalopram Oxalate                     |                    |                    | S               |                      | 10 Mg (10 Mg , 1 In 1 D)                                                | 2 YR            | Not Reported         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 13-Sep-2010                                          | 7603806                                  | EXPEDITED (15-DAY) | Y                  | LT              | 1000016091           |                                                                         | 67 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>           |                |
| Disinhibition; Gun Shot Wound; Suicide Attempt       | Escitalopram Oxalate                     |                    |                    | S               |                      |                                                                         |                 | Not Reported         |                |
|                                                      | Simvastatin                              |                    |                    | C               |                      |                                                                         |                 | Not Reported         |                |
|                                                      | Plavix                                   |                    |                    | C               |                      |                                                                         |                 | Not Reported         |                |
|                                                      | Lysanxia                                 |                    |                    | C               |                      |                                                                         |                 | Not Reported         |                |
|                                                      | Lithium                                  |                    |                    | C               |                      |                                                                         |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Sep-2010                                                                       | 7605042                | EXPEDITED (15-DAY) | Y                  | OT              | 1000016072           |                      | 22 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hand Fracture; Road Traffic Accident; Sleep-Related Eating Disorder; Somnambulism | Lexapro                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Zolpidem               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Seroquel               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                   | Thyroid Medication Nos |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                              | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2010                                                                           | 7544243                  | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-2010100615 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams; Anxiety; Loss Of Personal Independence In Daily Activities; Sedation | Sertraline Hydrochloride |                  |                    | S               | Oral                     | 12.5 Mg, Unk         | 3 DAY           | Pfizer       |                |
|                                                                                       | Prozac                   |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                       | Wellbutrin               |                  |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                       | Lexapro                  |                  |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                       | Paxil                    |                  |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                       | Cymbalta                 |                  |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                       | Elavil                   |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                       | Remeron                  |                  |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2010                                                | 7580914                | EXPEDITED (15-DAY) | Y                  | HO              | IDA-00417            |                      | 58 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Decreased Appetite; Headache; Pancreatitis Acute | Inexium (Esomeprazole) |                    |                    | S               | Oral                 | 40 Mg Daily Oral     | 3 DAY           | Not Reported |                |
|                                                            | Crestor                |                    |                    | S               | Oral                 | 10 Mg Daily Oral     |                 | Not Reported |                |
|                                                            | Topiramate             |                    |                    | S               | Oral                 | 50 Mg Bid Oral       |                 | Not Reported |                |
|                                                            | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 20 Mg Daily Oral     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |   |              |                        |       |              |
|------------------------------------------|---|--------------|------------------------|-------|--------------|
| Creon                                    | S | Oral         | 12000 Iu Oral          |       | Not Reported |
| Sulpiride                                | S | Oral         | 50 Mg Bid Oral         | 3 DAY | Not Reported |
| Acetaminophen                            | S | Oral         | 1 G Tid Oral           |       | Not Reported |
| Humalog                                  | S | Subcutaneous | 32 Iu Bid Subcutaneous |       | Not Reported |
| Propranolol                              | C | Oral         | 40 Mg Bid Oral         |       | Not Reported |
| Tramadol Hydrochloride                   | C |              |                        |       | Not Reported |
| Tramadol Hydrochloride And Acetaminophen | C |              |                        |       | Not Reported |
| Perfalgan                                | C |              |                        |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Sep-2010              | 7583732       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJCH-2010020550  |                      |            | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Rash | Zyrtec          |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                        | Diphenhydramine |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Folic Acid      |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Atenolol        |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Tramadol        |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Digoxin         |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Norvir          |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                        | Ferrous Sulfate |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Loperamide      |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Atrovent        |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Cozaar          |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                        | Lexapro         |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                        | Epogen          |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Abilify         |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Carvedilol      |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Seroquel        |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |
|                        | Feldene         |              |            | S           | Unknown      | Text:Unknown       |                 | Not Reported |

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|                                                |                             |                    |                    |                 |                                                               |                                  |                 |                      |                |
|------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------------------|-----------------|----------------------|----------------|
| Gabapentin                                     |                             |                    | S                  | Unknown         | Text:Unknown                                                  |                                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Sep-2010                                    | 7583992                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>FF-00 |                                  | 61 YR           | Female               | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Compulsions; Obsessive-<br>Compulsive Disorder | Pramipexole Dihydrochloride |                    |                    | S               | Oral                                                          | 3.15 Mg                          |                 | Boehringer Ingelheim |                |
|                                                | Modopar                     |                    |                    | S               | Oral                                                          | 2000 Mg                          |                 | Not Reported         |                |
|                                                | Azilect                     |                    |                    | S               | Oral                                                          | 1 Mg                             |                 | Not Reported         |                |
|                                                | Comtan                      |                    |                    | S               | Oral                                                          | 1200 Mg                          |                 | Not Reported         |                |
|                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                                                          | 20 Mg                            |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Sep-2010                                    | 7584389                     | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-<br>2009290029                                  |                                  | 45 YR           | Female               | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Hostility; Suicidal Ideation                   | Lyrica                      |                    |                    | S               |                                                               | Unk                              |                 | Pfizer               |                |
|                                                | Lexapro                     |                    |                    | S               | Oral                                                          | 10 Mg, 1x/Day                    |                 | Not Reported         |                |
|                                                | Wellbutrin                  |                    |                    | S               | Oral                                                          | 150mg Am And 100mg<br>Pm, 2x/Day |                 | Not Reported         |                |
|                                                | Lunesta                     |                    |                    | C               |                                                               | Unk                              |                 | Not Reported         |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 14-Sep-2010                                    | 7584813                     | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2009308963                                  |                                  | 55 YR           | Female               | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Visual Impairment                              | Lyrica                      |                    |                    | S               |                                                               | 75, Twice Daily                  |                 | Pfizer               |                |
|                                                | Lexapro                     |                    |                    | S               |                                                               |                                  |                 | Not Reported         |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|----------------|------------------|--------------------|-----------------|--------------------------|-----------------------|-----------------|--------------|----------------|
| 14-Sep-2010               | 7585725        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010087665 |                       |                 | Female       | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Weight Increased | Lyrica         |                  |                    | S               |                          | 50 Mg, In The Evening |                 | Pfizer       |                |
|                           | Lexapro        |                  |                    | S               |                          | Unk                   |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 14-Sep-2010                                      | 7586089              | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-WYE-H07130808     |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Circulatory Collapse; Knee Operation | Ibuprofen            |                    |                    | S               | Unknown              | Unknown              |                 | Wyeth        |                |
|                                                  | Zyrtec               |                    |                    | S               | Unknown              | Unknown              |                 | Not Reported |                |
|                                                  | Lipitor              |                    |                    | S               | Unknown              | Unknown              |                 | Not Reported |                |
|                                                  | Oxcarbazepine        |                    |                    | S               | Unknown              | Unknown              |                 | Unknown      |                |
|                                                  | Geodon               |                    |                    | S               | Unknown              | Unknown              |                 | Pfizer       |                |
|                                                  | Escitalopram Oxalate |                    |                    | S               | Unknown              | Unknown              |                 | Unknown      |                |
|                                                  | Lansoprazole         |                    |                    | C               |                      |                      |                 | Unknown      |                |
|                                                  | Lorazepam            |                    |                    | C               |                      |                      |                 | Wyeth        |                |
|                                                  | Metoprolol           |                    |                    | C               |                      |                      |                 | Unknown      |                |
|                                                  | Zolpidem             |                    |                    | C               |                      |                      |                 | Unknown      |                |
|                                                  | Methylphenidate      |                    |                    | C               |                      |                      |                 | Unknown      |                |

| <u>FDA Received Date</u>        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 14-Sep-2010                     | 7606333              | EXPEDITED (15-DAY) | Y                  | OT              | 1000016104           |                               | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychiatric Evaluation Abnormal | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 15-Sep-2010                                                                                    | 7586966                  | EXPEDITED (15-DAY) | Y                  | OT              | GB-ASTRAZENECA-2010SE41875 |                                                            | 69 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                                                                           | Omeprazole               |                    |                    | S               | Oral                       | 20 Mg                                                      |                 | Not Reported |                |
|                                                                                                | Cipraxel                 |                    |                    | S               |                            | 1/1 Day                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2010                                                                                    | 7588535                  | NON-EXPEDITED      | Y                  |                 | US-WYE-H10542509           |                                                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Paraesthesia; Paraesthesia Oral                                      | Pristiq Extended Release |                    |                    | S               | Oral                       |                                                            | 5 DAY           | Wyeth        |                |
|                                                                                                | Lexapro                  |                    |                    | S               |                            | Weaned Off                                                 |                 | Lundbeck     |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2010                                                                                    | 7607619                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000016174                 |                                                            | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Gestational Trophoblastic Detachment; Maternal Drugs Affecting Foetus; Metrorrhagia; Pregnancy | Escitalopram Oxalate     |                    |                    | S               | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                                                                    | 7582629                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000015897                 |                                                            | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depressive Symptom                                                       | Escitalopram Oxalate     |                    |                    | S               | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                |                          |                    |                    |                 | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |                |

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| Xanax                                       |                           | C                  |                    | D), Oral        |                              | Not Reported                                   |                 |              |                |
|---------------------------------------------|---------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                 | 7589732                   | EXPEDITED (15-DAY) | Y                  | OT              | GB-MYLANLABS-2010S1016318    |                                                | 69 YR           | Male         | GBR            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                        | Omeprazole                |                    |                    | S               |                              |                                                |                 | Not Reported |                |
|                                             | Cipralext                 |                    |                    | S               |                              |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                 | 7589829                   | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-10P-163-0670468-00 |                                                | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Nodule                           | Humira                    |                    |                    | S               |                              |                                                |                 | Not Reported |                |
|                                             | Lexapro                   |                    |                    | S               |                              |                                                |                 | Not Reported |                |
|                                             | Ambien Cr                 |                    |                    | C               |                              |                                                |                 | Not Reported |                |
|                                             | Multi-Vitamin             |                    |                    | C               |                              |                                                |                 | Not Reported |                |
|                                             | Flaxseed Oil              |                    |                    | C               |                              |                                                |                 | Not Reported |                |
|                                             | Vitamin D2                |                    |                    | C               |                              |                                                |                 | Not Reported |                |
|                                             | Lactobacillus Acidophilus |                    |                    | C               |                              |                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                 | 7589867                   | EXPEDITED (15-DAY) | N                  | HO, OT          | GB-WATSON-2010-12182         |                                                | 69 YR           | Male         | GBR            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Intracranial Aneurysm | Omeprazole                |                    |                    | S               |                              | Unk                                            |                 | Watson       |                |
|                                             | Cipralext                 |                    |                    | S               |                              | 10 Mg, Daily X16 Days, Then5 Mg Daily For 14 D |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                 | 7602858                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000016045                   |                                                | < 1 DAY         | Female       | CHE            |
| <u>Preferred Term</u>                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                               |                      |   |                |                                         |              |
|---------------------------------------------------------------|----------------------|---|----------------|-----------------------------------------|--------------|
| Bradypnoea; Drug Withdrawal Syndrome                          | Escitalopram Oxalate | S | Transplacental | 10 Mg 910 Mg, 1 In 1 D), Transplacental | Not Reported |
| Neonatal; Hypotonia Neonatal; Maternal Drugs Affecting Foetus | Invega               | S | Transplacental | 9 Mg, Transplacental                    | Not Reported |

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Sep-2010                         | 7610085                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000015674                    |                               |                          | Unknown             | DEU                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gait Disturbance; Movement Disorder | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Sep-2010                                                                                  | 7610103                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000016171                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Maternal Drugs Affecting Foetus | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Sep-2010                               | 7610112                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000016209                    |                               |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fall; Gait Disturbance; Movement Disorder | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Sep-2010                               | 7610116                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000016210                    |                               |                          | Unknown             | DEU                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fall; Gait Disturbance; Movement Disorder | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

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| <u>FDA Received Date</u>                                                                                                                                                                                                                               | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|--------------|----------------|
| 16-Sep-2010                                                                                                                                                                                                                                            | 7611138                                                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000016215           |                                              |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Gait Disturbance;<br>Movement Disorder                                                                                                                                                                                                           | Escitalopram Oxalate                                                        |                    |                    | S               |                      |                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                               | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                                                                                                                                                                                                                            | 7611139                                                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000016213           |                                              |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Gait Disturbance;<br>Movement Disorder                                                                                                                                                                                                           | Escitalopram Oxalate                                                        |                    |                    | S               |                      |                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                               | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Sep-2010                                                                                                                                                                                                                                            | 7611147                                                                     | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000016169           |                                              | 90 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Diastolic<br>Decreased; Blood Urea<br>Increased; Bradycardia;<br>Coma; Drug Interaction;<br>Extrapyramidal Disorder;<br>Fall; Inflammation;<br>Monocyte Count<br>Increased; Neutrophil<br>Count Increased; Subdural<br>Haematoma; Wound | Escitalopram Oxalate                                                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Aspirin                                                                     |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D),<br>Oral             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Lovenox                                                                     |                    |                    | S               | Subcutaneous         | 4000 Iu (4000 Iu, 1 In 1 D),<br>Subcutaneous |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Avlocardyl (Propranolol)<br>(Tablets) (Propranolol)                         |                    |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Aricept (Donepezil) (Tablets)<br>(Donepezil)                                |                    |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Seresta (Oxazepam) (Tablets)<br>(Oxazepam)                                  |                    |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Cetornan (Ornithine<br>Ketoglutarate) (Powder)<br>(Ornithine Ketoglutarate) |                    |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                        | Forlax (Macrogol) (Powder)<br>(Macrogol)                                    |                    |                    | C               |                      |                                              |                 | Not Reported |                |

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|  |                                |   |  |              |
|--|--------------------------------|---|--|--------------|
|  | Diffu K (Potassium Chloride)   | C |  | Not Reported |
|  | (Potassium Chloride)           | C |  | Not Reported |
|  | Diafusor (Glyceryl Trinitrate) | C |  | Not Reported |
|  | (Glyceryl Trinitrate)          | C |  | Not Reported |
|  | Doliprane (Paracetamol)        | C |  | Not Reported |
|  | (Paracetamol)                  |   |  |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2010              | 7655868       | NON-EXPEDITED    | N                  | HO              | DKLU1063423          |                      | 31 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose              | Sabril         |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Keppra         |              |            | S           |              |                    |                 | Not Reported |
|                       | Lamictal       |              |            | S           |              |                    |                 | Not Reported |
|                       | Clonazepam     |              |            | S           |              |                    |                 | Not Reported |
|                       | Mebendazole    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2010              | 7418971       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014190           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Erythema Induratum; Eye Disorder; Eye Swelling; Skin Plaque | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg 920 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Sep-2010              | 7491510       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000014890           |                      | 76 YR      | Female     | DNK            |

| <u>Preferred Term</u>                               | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Intentional Overdose; Mood Altered; Suicide Attempt | Escitalopram Oxalate              |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                     | Unspecified Ingredient            |              |            | S           |              | Unknown Amount              |                 | Not Reported |
|                                                     | Loxen (Nicardipine Hydrochloride) |              |            | C           |              |                             |                 | Not Reported |
|                                                     | Glucophage                        |              |            | C           |              |                             |                 | Not Reported |
|                                                     | Triatec (Ramipril)                |              |            | C           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Lyrica                                                                                           |                             | C                  |                    | Not Reported    |                            |                               |                 |              |                |
|--------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2010                                                                                      | 7546188                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000015448                 |                               | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Fibrinogen Decreased; Epistaxis; Gastrointestinal Haemorrhage; Haematoma; Thrombocytopenia | Escitalopram Oxalate        |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2010                                                                                      | 7587747                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016024                 |                               | 50 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Amnesia; Ataxia; Somnolence                                                          | Lexapro                     |                    |                    | S               | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2010                                                                                      | 7590472                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2010FR60652            |                               | 61 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Compulsions; Depression; Obsessive Thoughts; Obsessive-Compulsive Disorder                       | Comtan                      |                    |                    | S               |                            | 1200 Mg, Qd                   |                 | Orion        |                |
|                                                                                                  | Modopar                     |                    |                    | S               |                            | 2000 Mg, Qd                   |                 | Not Reported |                |
|                                                                                                  | Pramipexole Dihydrochloride |                    |                    | S               |                            | 3.5 Mg, Qd                    |                 | Not Reported |                |
|                                                                                                  | Azilect                     |                    |                    | S               |                            | 1 Mg Per Os At 1 Tablet Daily |                 | Not Reported |                |
|                                                                                                  | Escitalopram Oxalate        |                    |                    | S               |                            | Once Per Day                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Sep-2010                                                                                      | 7590815                     | EXPEDITED (15-DAY) | Y                  | HO              | IT-ASTRAZENECA-2010SE42180 |                               | 73 YR           | Male         | ITA            |

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| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
|----------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------------------|-----------------|----------------------|----------------|
| Confusional State;<br>Disorientation;<br>Electrocardiogram Qt<br>Prolonged; Somnolence | Seroquel                 |                    |                    | S               | Oral                                                          |                                  | 11 DAY          | Zeneca               |                |
|                                                                                        | Escitalopram Oxalate     |                    |                    | S               | Oral                                                          |                                  | 11 DAY          | Not Reported         |                |
|                                                                                        | Amisulpride              |                    |                    | S               | Oral                                                          |                                  | 2038 DAY        | Not Reported         |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Sep-2010                                                                            | 7592048                  | NON-EXPEDITED      | N                  |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>BP-10 |                                  | 61 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Abdominal Pain Upper;<br>Hyperhidrosis;<br>Musculoskeletal Stiffness                   | Mobic                    |                    |                    | S               | Oral                                                          |                                  |                 | Boehringer Ingelheim |                |
|                                                                                        | Lexapro                  |                    |                    | S               | Oral                                                          | 10 Mg                            |                 | Not Reported         |                |
|                                                                                        | Lexapro                  |                    |                    | S               | Oral                                                          | 5 Mg                             |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 17-Sep-2010                                                                            | 7612531                  | EXPEDITED (15-DAY) | N                  | DE              | 1000016234                                                    |                                  | 67 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Loss Of Consciousness;<br>Overdose; Toxicity To<br>Various Agents                      | Lexapro                  |                    |                    | S               | Oral                                                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                               | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Sep-2010                                                                            | 7593546                  | NON-EXPEDITED      | N                  |                 | US-WYE-H10763509                                              |                                  | 49 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>           |                |
| Dizziness; Drug<br>Ineffective; Headache;<br>Hyperhidrosis                             | Pristiq Extended Release |                    |                    | S               | Oral                                                          |                                  | 6 DAY           | Wyeth                |                |
|                                                                                        | Pristiq Extended Release |                    |                    | S               |                                                               |                                  |                 | Wyeth                |                |
|                                                                                        | Lexapro                  |                    |                    | S               |                                                               |                                  |                 | Lundbeck             |                |
|                                                                                        | Ramipril                 |                    |                    | C               |                                                               |                                  |                 | Unknown              |                |
|                                                                                        | Cholestyramine           |                    |                    | C               |                                                               |                                  |                 | Unknown              |                |



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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Sep-2010              | 7594139       | NON-EXPEDITED    | N                  |                 | US-WYE-H12141709     |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Drug Withdrawal Syndrome; Feeling Hot; Insomnia; Pain In Extremity; Palpitations | Pristiq Extended Release |              |            | S           | Oral         |                    | 15 DAY          | Wyeth        |
|                                                                                              | Pristiq Extended Release |              |            | S           | Oral         |                    | 2 DAY           | Wyeth        |
|                                                                                              | Lexapro                  |              |            | S           |              | Unknown            | 6 WEEK          | Lundbeck     |
|                                                                                              | Lexapro                  |              |            | S           |              | "1/2" Amt Unknown  | 2 DAY           | Lundbeck     |
|                                                                                              | Diovan                   |              |            | S           |              | Unknown            |                 | Novartis     |
|                                                                                              | Diazepam                 |              |            | S           |              | Unknown            |                 | Unknown      |
|                                                                                              | Lipitor                  |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                                              | Tramadol                 |              |            | C           |              | Unknown            |                 | Unknown      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 20-Sep-2010              | 7595249       | NON-EXPEDITED    | N                  | OT              | US-ASTRAZENECA-2009SE29840 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ageusia; Constipation; Decreased Appetite; Diarrhoea; Drug Ineffective; Dry Mouth; Dyskinesia; Muscle Twitching; Nightmare; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor | Seroquel                 |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                                                                                                           | Zoloft                   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                           | Trazodone Hydrochloride  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                           | Doxepin Hydrochloride    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                           | Mirtazapine              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                           | Pristiq Extended Release |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                           | Effexor Xr               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                           | Wellbutrin               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                           | Zyprexa                  |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                                                                                                           | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                           | Paroxetine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                           | Cymbalta                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                           | Paxil                    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                           | Prozac                   |              |            | S           |              |                    |                 | Not Reported |

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|                                         | Depakote                |                    | S                  | Unknown         |                                       |                                     |                 | Not Reported |                |
|-----------------------------------------|-------------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------------------|-----------------|--------------|----------------|
|                                         | Vitamins                |                    | C                  |                 |                                       |                                     |                 | Not Reported |                |
|                                         | Fish Oil                |                    | C                  |                 |                                       |                                     |                 | Not Reported |                |
|                                         | Imodium                 |                    | C                  |                 |                                       |                                     |                 | Not Reported |                |
|                                         | Kaolin\Pectin           |                    | C                  |                 |                                       |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2010                             | 7595259                 | NON-EXPEDITED      | Y                  | HO              | US-ASTRAZENECA-2010SE33313            |                                     |                 | Unknown      | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation                     | Seroquel                |                    |                    | S               | Oral                                  |                                     |                 | Zeneca       |                |
|                                         | Lexapro                 |                    |                    | S               |                                       |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2010                             | 7596456                 | EXPEDITED (15-DAY) | Y                  | LT              | DE-JNJFOC-20100903271                 |                                     | 78 YR           | Female       | DEU            |
| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Hypotension; Syncope; Tachycardia | Risperdal               |                    |                    | S               | Oral                                  |                                     |                 | Not Reported |                |
|                                         | Risperdal               |                    |                    | S               | Oral                                  |                                     |                 | Not Reported |                |
|                                         | Aricept                 |                    |                    | S               | Oral                                  |                                     |                 | Not Reported |                |
|                                         | Aricept                 |                    |                    | S               | Oral                                  |                                     |                 | Not Reported |                |
|                                         | Ciprallex               |                    |                    | S               | Oral                                  |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Sep-2010                             | 7597105                 | EXPEDITED (15-DAY) | Y                  | HO              | US-ROCHE-727275                       |                                     | 83 YR           | Male         | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Speech Disorder                         | Bevacizumab             |                    |                    | S               | Intravenous (not otherwise specified) | Last Dose Prior Sae: 26 August 2010 |                 | Roche        |                |
|                                         | Erlotinib Hydrochloride |                    |                    | S               | Unknown                               |                                     |                 | Roche        |                |
|                                         | Cardura                 |                    |                    | S               | Unknown                               |                                     |                 | Not Reported |                |
|                                         | Lexapro                 |                    |                    | S               | Unknown                               |                                     |                 | Not Reported |                |

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|  |                      |   |         |                     |              |
|--|----------------------|---|---------|---------------------|--------------|
|  | Dulcolax (Bisacodyl) | S | Unknown |                     | Not Reported |
|  | Ibuprofen            | S | Unknown |                     | Not Reported |
|  | Novolog              | S | Unknown | Reported As Novalog | Not Reported |
|  | Salmeterol           | S | Unknown |                     | Not Reported |
|  | Simvastatin          | S | Unknown |                     | Not Reported |
|  | Tylenol              | S | Unknown |                     | Not Reported |
|  | Zofran               | S | Unknown |                     | Not Reported |

| <u>FDA Received Date</u>                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 20-Sep-2010                                                                                | 7597425                   | EXPEDITED (15-DAY) | N                  | DE, HO          | B0675157A            |                      | 83 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Melaena; Multiple Organ Dysfunction Syndrome; Septic Shock; Toxic Skin Eruption; Urticaria | Isradipine                |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                                                                            | Diffu K                   |                    |                    | S               | Oral                 |                      |                 | Glaxosmithkline |                |
|                                                                                            | Previscan (Fluindione)    |                    |                    | S               | Oral                 | 5mg At Night         | 2 DAY           | Not Reported    |                |
|                                                                                            | Urbanyl                   |                    |                    | S               | Oral                 |                      |                 | Not Reported    |                |
|                                                                                            | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5mg Twice Per Day    |                 | Not Reported    |                |
|                                                                                            | Unspecified Ingredient    |                    |                    | S               | Oral                 | 50mg Twice Per Day   |                 | Not Reported    |                |
|                                                                                            | Kardegic                  |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                            | Fucidin (Fusidate Sodium) |                    |                    | C               |                      |                      |                 | Not Reported    |                |
|                                                                                            | Xyzal                     |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |
|                                                                                            | Atarax                    |                    |                    | C               |                      |                      |                 | Glaxosmithkline |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Sep-2010              | 7597996              | NON-EXPEDITED    | Y                  | OT              | US-TEVA-248234USA    |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome       | Azilect              |                  |                    | S               | Oral                 |                      |                 | Teva         |                |
|                          | Escitalopram Oxalate |                  |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|-------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|----------------|----------------|
| 20-Sep-2010                                                             | 7598134                  | NON-EXPEDITED      |                    |                 | US-ASTRAZENECA-2010SE14712 |                      | 60 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Abdominal Discomfort; Gastroesophageal Reflux Disease; Weight Increased | Seroquel Xr              |                    |                    | S               | Oral                       |                      |                 | Astrazeneca    |                |
|                                                                         | Seroquel Xr              |                    |                    | S               | Oral                       |                      |                 | Astrazeneca    |                |
|                                                                         | Seroquel Xr              |                    |                    | S               | Oral                       |                      |                 | Astrazeneca    |                |
|                                                                         | Lexapro                  |                    |                    | S               | Unknown                    |                      |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 20-Sep-2010                                                             | 7598774                  | NON-EXPEDITED      | N                  |                 | US-WYE-H12886310           |                      | 33 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Agitation; Anxiety; Insomnia; Palpitations                              | Pristiq Extended Release |                    |                    | S               | Oral                       |                      |                 | Wyeth          |                |
|                                                                         | Lexapro                  |                    |                    | S               | Oral                       |                      |                 | Lundbeck       |                |
|                                                                         | Lexapro                  |                    |                    | S               | Oral                       |                      |                 | Lundbeck       |                |
|                                                                         | Clonazepam               |                    |                    | C               |                            |                      |                 | Unknown        |                |
|                                                                         | Ambien Cr                |                    |                    | C               |                            |                      |                 | Sanofi Aventis |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 20-Sep-2010                                                             | 7598976                  | NON-EXPEDITED      | N                  |                 | US-WYE-H13405510           |                      | 69 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Muscle Twitching                                                        | Pristiq Extended Release |                    |                    | S               | Oral                       |                      |                 | Wyeth          |                |
|                                                                         | Lexapro                  |                    |                    | S               |                            | "Tapering Off"       |                 | Lundbeck       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 20-Sep-2010                                                             | 7615655                  | EXPEDITED (15-DAY) | Y                  | OT              | GB-DEXPHARM-20101450       |                      | 69 YR           | Male           | GBR            |
| <u>Preferred Term</u>                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |                        |        |                                                                                 |                              |
|-----------------------------------------------------------------------------|------------------------|--------|---------------------------------------------------------------------------------|------------------------------|
| Blood Pressure Increased;<br>Cerebral Haemorrhage;<br>Intracranial Aneurysm | Omeprazole<br>Cipraxel | S<br>S | 20 Mg Milligram(S)<br>10 Mg Milligram(S) Sep<br>Dosages/Interval: 1 In 1<br>Day | Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------|------------------------|--------|---------------------------------------------------------------------------------|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2010              | 7616215       | EXPEDITED (15-DAY) | N                  | OT              | 1000016217           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Asthenia; Contusion;<br>Fatigue; Headache;<br>Hyperhidrosis;<br>Hypersomnia; Libido<br>Decreased; Social Anxiety<br>Disorder; Yawning | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2010              | 7617216       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016230           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Compulsions; Obsessive-<br>Compulsive Disorder | Escitalopram Oxalate        |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D)              |                 | Not Reported |
|                                                | Rasagiline Mesylate         |              |            | S           | Oral         | 1 Mg (1 Mg, 1 In 1 D), Oral          |                 | Not Reported |
|                                                | Benserazide\Levodopa        |              |            | S           | Oral         | 2000 Mg (250 Mg, 8 In 1<br>D), Oral  |                 | Not Reported |
|                                                | Pramipexole Dihydrochloride |              |            | S           | Oral         | 3.15 Mg (3.15 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                | Comtan                      |              |            | S           |              | 1200 Mg (200 Mg, 6 In 1<br>D)        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2010              | 7369621       | EXPEDITED (15-DAY) | Y                  | OT              | 1000013205           |                      | 16 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                      |   |      |                                                                    |              |
|-----------------------------------------------|----------------------|---|------|--------------------------------------------------------------------|--------------|
| Off Label Use; Overdose;<br>Suicidal Ideation | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 30 Mg (30 Mg, 1 In 1<br>D), Oral | Not Reported |
|                                               |                      |   | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 30 Mg (30 Mg, 1 In 1<br>D), Oral |              |
|                                               | Alprazolam           | C |      |                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2010              | 7536475       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015258           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Agitation; Hallucination,<br>Auditory; Hallucination,<br>Visual; Paranoia;<br>Psychotic Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                                                                                  | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2010              | 7606584       | DIRECT           | Y                  | HO              |                      |                      | 89 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dysarthria; Fall;<br>Hyponatraemia | Lexapro        |              |            | S           |              |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2010              | 7609986       | DIRECT           | N                  |                 |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Apparent Death; Condition<br>Aggravated; Depression;<br>Disturbance In Attention;<br>Fatigue; Fear; Nausea;<br>Nervousness; Uterine<br>Cancer | Lexapro        |              |            | S           | Oral         | 10 Mg Once A Day Po |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 21-Sep-2010                                                       | 7618383                  | EXPEDITED (15-DAY) | Y                  | OT              | 1000016291           |                                | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphemia; Off Label Use                                          | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                   | Depakote                 |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                   | Lorazepam                |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                   | Atarax                   |                    |                    | C               |                      |                                |                 | Not Reported |                |
|                                                                   | Sertraline Hydrochloride |                    |                    | C               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2010                                                       | 7618635                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000016239           |                                | 83 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxic Skin Eruption; Urticaria                                    | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral  |                 | Not Reported |                |
|                                                                   | Fluindione               |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                   | Isradipine               |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                   | Urbanyl                  |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                   | Docosanol                |                    |                    | S               | Oral                 | 100 Mg (50 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                   | Potassium Chloride       |                    |                    | S               |                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2010                                                       | 7618637                  | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000016086           |                                | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Coma; Intentional Overdose; Suicide Attempt; Vomiting | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Oral                           |                 | Not Reported |                |
|                                                                   | Trimipramine Maleate     |                    |                    | S               | Oral                 | (5000 Mg, Once), Oral          |                 | Not Reported |                |
|                                                                   | Zolpidem                 |                    |                    | S               | Oral                 | (200 Mg, Once), Oral           |                 | Not Reported |                |

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|                                                 |                       | Cocaine (Cocaine)  |                    | S               | Nasal                | Nasal                         |                 | Not Reported |                |
|-------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                 |                       | Alcohol (Ethanol)  |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2010                                     | 7610915               | DIRECT             | N                  | RI              |                      |                               | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Libido; Sexual Dysfunction              | Lexapro               |                    |                    | S               |                      |                               |                 | Forest       |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2010                                     | 7619191               | EXPEDITED (15-DAY) | Y                  | OT              | 1000016290           |                               | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder                                | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                 | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                 | Magnesium (Magnesium) |                    |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2010                                     | 7622817               | EXPEDITED (15-DAY) | Y                  | OT              | 1000016331           |                               | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Investigation Abnormal                          | Escitalopram Oxalate  |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2010                                     | 7469308               | EXPEDITED (15-DAY) | Y                  | OT              | 1000014759           |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                           | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Bulimia Nervosa; Condition Aggravated; | Escitalopram Oxalate  |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                 | Fluoxetine            |                    |                    | S               |                      |                               |                 | Not Reported |                |



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|                                                                                                                                                                                                          |                        |                    |                    |                 |                          |                                            |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------------------|-----------------|--------------|----------------|
| Epilepsy; Focal Dyscognitive Seizures                                                                                                                                                                    |                        | Alprazolam         |                    | C               |                          | Not Reported                               |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2010                                                                                                                                                                                              | 7522470                | EXPEDITED (15-DAY) | Y                  | OT              | 1000015144               |                                            | 32 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Vaginal Haemorrhage                                                                                                                                                                                      | Escitalopram Oxalate   |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral              |                 | Not Reported |                |
|                                                                                                                                                                                                          | Cymbalta               |                    |                    | C               |                          |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2010                                                                                                                                                                                              | 7605667                | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010116226 |                                            | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Arthralgia; Dry Eye; Dry Mouth; Fatigue; Feeling Abnormal; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasal Dryness; Pain; Poor Quality Sleep; Pruritus; Rash; Scab; Vitamin D Decreased | Lyrica                 |                    |                    | S               | Oral                     | 75 Mg, 2x/Day                              |                 | Pfizer       |                |
|                                                                                                                                                                                                          | Lexapro                |                    |                    | S               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Pepcid                 |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Unspecified Ingredient |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Aciphex                |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Norvasc                |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Potassium              |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
|                                                                                                                                                                                                          | Allegra                |                    |                    | C               |                          | Unk                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Sep-2010                                                                                                                                                                                              | 7622716                | EXPEDITED (15-DAY) | Y                  | HO              | 1000016246               |                                            | 67 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Hepatitis                                                                                                                                                                                   | Escitalopram Oxalate   |                    |                    | S               |                          | (1 Dosage Forms)                           |                 | Not Reported |                |
|                                                                                                                                                                                                          | Calciparine            |                    |                    | S               | Subcutaneous             | 22500 Iu (7500 Iu, 3 In 1 D), Subcutaneous |                 | Not Reported |                |

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|                      |   |      |                                                       |              |
|----------------------|---|------|-------------------------------------------------------|--------------|
| Colchicine           | S | Oral | 1 Dosage Forms 91<br>Dosage Forms, 1 In 1 D),<br>Oral | Not Reported |
| Polyethylene Glycols | S |      | (3 Dosage Forms)                                      | Not Reported |
| Normacol             | S |      |                                                       | Not Reported |
| Ketoprofen           | S | Oral | (2 Dosage Forms), Oral                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2010              | 7625327       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016334           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Alcohol Poisoning;<br>Intentional Overdose;<br>Somnolence; Suicide<br>Attempt | Escitalopram Oxalate |              |            | S           | Oral         | (200 Mg, Once), Oral |                 | Not Reported |
|                                                                               | Doxepin              |              |            | S           | Oral         | (425 Mg, Once), Oral |                 | Not Reported |
|                                                                               | Alcohol (Ethanol)    |              |            | S           | Oral         | (Once), Oral         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Sep-2010              | 7632840       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016351           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Coma; Drug Interaction;<br>Hypotension; Muscle<br>Rigidity; Somnolence;<br>Sopor; Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                                       |                 | Not Reported |
|                                                                                                                           | Aricept              |              |            | S           | Oral         | 5 Mg 95 Mg, 1 In 1 D),<br>Oral                                    |                 | Not Reported |
|                                                                                                                           | Aricept              |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                  |                 | Not Reported |
|                                                                                                                           | Risperdal            |              |            | S           | Oral         | 1 M (1 Mg, 1 In 1 D), Oral;<br>0.5 Mg (0.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                           |                      |              |            |             | Oral         | 1 M (1 Mg, 1 In 1 D), Oral;<br>0.5 Mg (0.5 Mg, 1 In 1 D),<br>Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2010              | 7359787       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012903           |                      | 56 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|------------------------------------------------------|-----------------|--------------|----------------|
| Arthralgia; Gait Disturbance; Gamma-Glutamyltransferase Increased; Inflammation; Myalgia; Spondylitis; Transaminases Increased                | Escitalopram Oxalate |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral                        |                 | Not Reported |                |
|                                                                                                                                               | Xanax                |                    |                    | C               |                            |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2010                                                                                                                                   | 7548420              | EXPEDITED (15-DAY) | Y                  | DE              | AU-ASTRAZENECA-2010SE38860 |                                                      | 55 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose                                                                                                                   | Seroquel Xr          |                    |                    | S               | Oral                       | 300-400 Mg Daily                                     |                 | Not Reported |                |
|                                                                                                                                               | Lexapro              |                    |                    | S               | Oral                       |                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2010                                                                                                                                   | 7613718              | DIRECT             | Y                  | HO              |                            |                                                      | 79 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Hyponatraemia                                                                                                              | Escitalopram         |                    |                    | S               | Oral                       | 20 Mg Daily Po                                       |                 | Not Reported |                |
|                                                                                                                                               | Olanzapine           |                    |                    | S               | Oral                       | 2.5 Mg Twice Daily Po                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2010                                                                                                                                   | 7628423              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000016374                 |                                                      | 68 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound; Herpes Zoster; Intentional Self-Injury; Nervousness; Overdose; Tongue Disorder; Trismus; Unevaluable Event | Lexapro              |                    |                    | S               |                            | 30 Mg (30 Mg,1 In 1 D)                               |                 | Not Reported |                |
|                                                                                                                                               | Geodon               |                    |                    | S               | Oral                       | 20 Mg (20 Mg,1 In 1 D),Oral ; 160 Mg (2 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                               |                      |                    |                    |                 | Oral                       | 20 Mg (20 Mg,1 In 1 D),Oral ; 160 Mg (2 In 1 D),Oral |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                    |                                  |                    |                    |                 |                      |                               |                 |              |                |
|--------------------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Nortriptyline Hydrochloride                                        |                                  |                    | C                  |                 |                      |                               |                 |              | Not Reported   |
| Xanax                                                              |                                  |                    | C                  |                 |                      |                               |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2010                                                        | 7580296                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000015915           |                               | 57 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Drug Dependence                                | Lexapro                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                    | Zimovane (Zopiclone) (Zopiclone) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2010                                                        | 7617208                          | DIRECT             | Y                  | LT              |                      |                               | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Flushing; Heart Rate Increased; Hyperhidrosis; Tremor | Lexapro                          |                    |                    | S               |                      |                               |                 | Forest       |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2010                                                        | 7630462                          | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2010AP002029         |                               | 32 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                              | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Rhabdomyolysis                                           | Citalopram Hydrobromide          |                    |                    | S               | Oral                 | 20 Mg; Qd Po                  |                 | Not Reported |                |
|                                                                    | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 20 Mg; Qd Po                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2010                                                        | 7465199                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000014719           |                               | 34 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Muscle Contracture                                     | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

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|                                          |   |              |
|------------------------------------------|---|--------------|
| Minidril (Eugynon) (Eugynon)             | C | Not Reported |
| Levothyroxine Sodium                     | C | Not Reported |
| Solupred (Prednisolone Sodium Metazoate) | C | Not Reported |
| Panos (Tetrazepam) (Tetrazepam)          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2010              | 7679703       | NON-EXPEDITED    | N                  |                 | US-WYE-H15951510     |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; Dizziness; Fatigue; Hypersomnia | Pristiq Extended Release |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Effexor Xr               |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Lexapro                  |              |            | S           |              |                    |                 | Not Reported |
|                                                       | Neurontin                |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2010              | 7619541       | DIRECT           | Y                  | OT              |                      |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged | Haldol         |              |            | S           | Oral         | 5 Mg And 0.5 Mg Q 4 Hours Prn Oral/Im, 8/27-9/1 |                 | Not Reported |
|                                | Lexapro        |              |            | S           |              | 20 Mg Daily Oral, 8/26 - 8/31                   |                 | Not Reported |
|                                | Wellbutrin     |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Zyprexa        |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Macrochantin   |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Geodon         |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Thorazine      |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Abilify        |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Synthroid      |              |            | C           |              |                                                 |                 | Not Reported |
|                                | Premarin       |              |            | C           |              |                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2010              | 7632902       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016478           |                      | 53 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                  | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------|------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Psychiatric Evaluation Abnormal        | Escitalopram Oxalate                                                         |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2010                            | 7632910                                                                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000016468           |                             | 60 YR           | Female       | DNK            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Urinary Incontinence                   | Escitalopram Oxalate                                                         |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                        | Noiafren                                                                     |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                        | Eutirox (Levothyroxine) (Tablets) (Levothyroxine)                            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                        | Atorvastatin Calcium (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                        | Omeprazole (Omeprazole) (Tablets) (Omeprazole)                               |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2010                            | 7632927                                                                      | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2010MA002785         |                             | 32 YR           | Male         | GBR            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Overdose; Rhabdomyolysis               | Citalopram Hydrobromide                                                      |                    |                    | S               | Ophthalmic           | 1400 Mg;X1;Po               |                 | Not Reported |                |
|                                        | Escitalopram Oxalate                                                         |                    |                    | S               | Oral                 | 980 Mg;X1;Po                |                 | Not Reported |                |
|                                        | Con Meds                                                                     |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                        | Prev Meds                                                                    |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>               | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Sep-2010                            | 7633927                                                                      | DIRECT             | Y                  | OT              |                      |                             |                 | Unknown      | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Contraindication To Medical Treatment; | Hyoscyamine Sulfate\Methenamine\Methylene                                    |                    |                    | S               |                      |                             |                 | Mission      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                            |                                                          |   |              |
|----------------------------------------------------------------------------|----------------------------------------------------------|---|--------------|
| Labelled Drug-Drug Interaction Medication Error; Product Prescribing Error | Blue\Phenyl Salicylate\Sodium Phosphate, Dibasic Lexapro | S | Not Reported |
|----------------------------------------------------------------------------|----------------------------------------------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2010              | 7635990       | EXPEDITED (15-DAY) | Y                  | HO              | 2010003910           |                      | 83 YR      | Male       | USA            |

| <u>Preferred Term</u>                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-------------------------|--------------|------------|-------------|---------------------------------------|----------------------------|-----------------|--------------|
| Aphasia; Speech Disorder; Toxicity To Various Agents | Erlotinib Hydrochloride |              |            | S           | Oral                                  | Oral                       |                 | Not Reported |
|                                                      | Bevacizumab             |              |            | S           | Intravenous (not otherwise specified) | (975 Mg, Q3w), Intravenous |                 | Not Reported |
|                                                      | Cardura                 |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Lexapro                 |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Dulcolax (Bisacodyl)    |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Ibuprofen (Ibuprofen)   |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Novolog                 |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Salmeterol              |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Simvastatin             |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Tylenol (Paracetamol)   |              |            | S           |                                       |                            |                 | Not Reported |
|                                                      | Zofran                  |              |            | S           |                                       |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7385671       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | US-ABBOTT-06P-163-0352074-00 |                      | 10 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                        | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Abdominal Pain; Atrioventricular Block First Degree; Chest Pain; Conduction Disorder; Diarrhoea; Disorientation; Dizziness; Drug Interaction; Drug Level Above Therapeutic; Electrocardiogram Qrs Complex Prolonged; Hyperhidrosis; Hypophagia; Hypotension; | Lexapro         |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Depakote        |              |            | C           | Oral         | 500mg In Am, 1000mg At Bedtime |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Synthroid       |              |            | C           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Lexapro         |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Lithium         |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Clonidine       |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              | Methylphenidate |              |            | S           | Oral         |                                |                 | Not Reported |
|                                                                                                                                                                                                                                                              |                 |              |            |             |              |                                |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                          |               |   |      |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---|------|--------------|
| Hypothyroidism; Mania;<br>Pallor; Palpitations;<br>Rhythm Idioventricular;<br>Tachyarrhythmia; Toxicity<br>To Various Agents;<br>Ventricular Extrasystoles;<br>Ventricular Tachycardia;<br>Vomiting; White Blood Cell<br>Count Increased | Oxcarbazepine | S | Oral | Not Reported |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7541786       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PFIZER INC-<br>2010099416 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Completed Suicide;<br>Dyskinesia; Herpes<br>Zoster; Nervousness | Geodon         |              |            | S           |              | 20 Mg, Daily                  |                 | Pfizer       |
|                                                                 | Geodon         |              |            | S           |              | 80 Mg, 2x/Day                 |                 | Pfizer       |
|                                                                 | Geodon         |              |            | S           |              |                               |                 | Pfizer       |
|                                                                 | Lexapro        |              |            | S           |              | 30 Mg, 1x/Day                 | 510 DAY         | Not Reported |
|                                                                 | Lexapro        |              |            | S           |              |                               |                 | Not Reported |
|                                                                 | Nortriptyline  |              |            | C           |              | 50 Mg, Daily                  |                 | Not Reported |
|                                                                 | Xanax          |              |            | C           |              | 1 Mg Twice Daily As<br>Needed | 510 DAY         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7634846       | EXPEDITED (15-DAY) | Y                  | HO              | LTI2010A00215        |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------------|--------------|------------|-------------|--------------|---------------------------------------|-----------------|--------------|
| Optic Neuropathy; Visual<br>Impairment | Lansoprazole               |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D)<br>Oral Years |                 | Not Reported |
|                                        | Lexomil (Bromazepam)       |              |            | S           | Oral         | 18 Mg (6 Mg, 3 In 1 D)<br>Oral Days   |                 | Not Reported |
|                                        | Escitalopram Oxalate       |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D)<br>Oral Days  |                 | Not Reported |
|                                        | Aceprometazine\Meprobamate |              |            | S           | Oral         | 1 Df (1 Df, 1 In 1 D) Oral            |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |      |            |                           |              |
|--------------------------|---|------|------------|---------------------------|--------------|
| Tareg                    | S | Oral | Days       | 160 Mg (160 Mg, 1 In 1 D) | Not Reported |
| Fenofibrate              | S | Oral | Oral Years | 200 Mg (200 Mg, 1 In 1 D) | Not Reported |
| Aspirin                  | S | Oral | Oral Years | 160 Mg (160 Mg, 1 In 1 D) | Not Reported |
| Nicorandil               | S | Oral | Oral Years | 40 Mg (20 Mg, 2 In 1 D)   | Not Reported |
| Acebutolol Hydrochloride | S | Oral | Oral Years | 400 Mg (200 Mg, 2 In 1 D) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7635514       | EXPEDITED (15-DAY) | Y                  | DS, OT          | 1000016466           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety Disorder;<br>Hallucination, Auditory;<br>Overdose; Personality<br>Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7635583       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016484           |                      | 53 YR      | Male       | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Arthralgia; Erectile<br>Dysfunction; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
| Haematospermia; Myalgia              | Xanax                |              |            | S           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Oct-2010              | 7637066       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000016378           |                      | 32 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                      |   |      |                                                            |              |
|----------------------------------------------------------|----------------------|---|------|------------------------------------------------------------|--------------|
| Blood Creatine Increased;<br>Overdose;<br>Rhabdomyolysis | Citalopram           | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                           | Not Reported |
|                                                          | Escitalopram Oxalate | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, (1400 Mg, Once),<br>Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2010              | 7652394       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016662           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pericardial Effusion  | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2010              | 7636219       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016503           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Agitation; Logorrhoea | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                              | Temesta (Lorazepam)  |              |            | C           |              |                    |                 | Not Reported |
|                                              | (Lorazepam)          |              |            |             |              |                    |                 |              |
|                                              | Cordarone            |              |            | C           |              |                    |                 | Not Reported |
|                                              | Xanax                |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2010              | 7617052       | EXPEDITED (15-DAY) | Y                  | HO              | FR-WYE-G06750210     |                      | 50 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------|----------------------|--------------|------------|-------------|-----------------------------|----------------------------------------|-----------------|------------|
| Abnormal Behaviour;<br>Disorientation;<br>Thrombocytopenia | Rhinadvil            |              |            | S           | Oral                        | A Total Of 3 To 4 Tablets<br>In 2 Days | 2 DAY           | Wyeth      |
|                                                            | Budesonide           |              |            | S           | Respiratory<br>(inhalation) | Unknown                                | 2 DAY           | Unknown    |
|                                                            | Ibuprofen            |              |            | S           | Oral                        | Unknown                                | 2 DAY           | Unknown    |
|                                                            | Cefuroxime           |              |            | S           | Oral                        | Unknown                                | 2 DAY           | Unknown    |
|                                                            | Escitalopram Oxalate |              |            | S           | Oral                        | Unknown                                |                 | Lundbeck   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           | Duphaston                                       | C                  | Oral               | Unknown         | Not Reported             |                               |                 |              |                |
|-------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
|                                           | Paracetamol                                     | C                  | Oral               | Unknown         | Unknown                  |                               |                 |              |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Oct-2010                               | 7617395                                         | EXPEDITED (15-DAY) | N                  | HO              | US-SHIRE-SPV1-2010-01703 |                               | 37 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscular Weakness; Off Label Use; Tremor  | Adderall Xr                                     |                    |                    | S               | Oral                     | 20 Mg, 1x/Day:Qd              | 191 DAY         | Not Reported |                |
|                                           | Neratinib                                       |                    |                    | S               | Oral                     | 240 Mg, 1x/Day:Qd             |                 | Not Reported |                |
|                                           | Alprazolam                                      |                    |                    | S               | Oral                     | .5 Mg, As Req'D               | 298 DAY         | Not Reported |                |
|                                           | Diflunisal                                      |                    |                    | S               | Oral                     | 500 Mg, 1x/Day:Qd             | 113 DAY         | Not Reported |                |
|                                           | Lexapro                                         |                    |                    | S               | Oral                     | 10 Mg, 1x/Day:Qd              | 205 DAY         | Not Reported |                |
|                                           | Tamoxifen Citrate                               |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Colecalciferol                                  |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Vitamin B12                                     |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Valtrex                                         |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Loratadine                                      |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Tylenol                                         |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                           | Ibuprofen                                       |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2010                               | 7528666                                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000015180               |                               | 66 YR           | Female       | DNK            |
| <u>Preferred Term</u>                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Vitreous Detachment | Escitalopram Oxalate                            |                    |                    | S               | Oral                     | 10 Mg 910 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                           | Enaplus (Enalapril Maleate) (Enalapril Maleate) |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2010                               | 7537829                                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000015300               |                               | 30 YR           | Female       | SWE            |
| <u>Preferred Term</u>                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                    |   |      |                                  |              |
|-----------------------------------------------------------------------|------------------------------------|---|------|----------------------------------|--------------|
| Abdominal Pain Upper;<br>Nausea; Pain; Pharyngeal<br>Oedema; Vomiting | Escitalopram Oxalate               | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral      | Not Reported |
|                                                                       | Escitalopram Oxalate               | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                       | Propavan (Propiomazine<br>Maleate) | C |      |                                  | Not Reported |
|                                                                       | Atarax (Atarax) (Atarax)           | C |      |                                  | Not Reported |
|                                                                       | Oxascand (Oxazepam)<br>(Oxazepam)  | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2010              | 7603773       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016094           |                      | 28 YR      | Male       | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Somnolence | Escitalopram Oxalate             |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                     |                                  |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |
|                                     | Escitalopram Oxalate<br>Prazepam |              |            | S           |              |                                                                  |                 | Not Reported |
|                                     |                                  |              |            | S           | Oral         | 30 Mg (10 Mg, 3 In 1 D),<br>Oral                                 |                 | Not Reported |
|                                     | Zolpidem                         |              |            |             | Oral         | 30 Mg (10 Mg, 3 In 1 D),<br>Oral                                 |                 |              |
|                                     |                                  |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                 |                 | Not Reported |
|                                     |                                  |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                 |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2010              | 7652416       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016602           |                      | 47 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Ammonia Increased;<br>Blood Alkaline<br>Phosphatase Increased; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |                                               |   |      |                                       |              |
|--------------------------------------------------------------|-----------------------------------------------|---|------|---------------------------------------|--------------|
| Gamma-Glutamyltransferase Increased; Transaminases Increased | Bromazepam                                    | S | Oral | 6 Df (6 Dosage Forms, 1 In 1 D), Oral | Not Reported |
|                                                              | Acetaminophen\Propoxyphene Hydrochloride      | S | Oral | 6 To 10 Df Per Day, Oral              | Not Reported |
|                                                              | Tercian (Cyamemazine) (Tablets) (Cyamemazine) | C |      |                                       | Not Reported |
|                                                              | Valium (Diazepam) (Tablets) (Diazepam)        | C |      |                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2010              | 7382986       | EXPEDITED (15-DAY) | Y                  | LT              | 1000013335           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Condition Aggravated; Depressed Mood; Diarrhoea; Fatigue; Suicidal Ideation; Vomiting; Withdrawal Syndrome | Escitalopram Oxalate               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                            | Fluoxetine                         |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                            | Ventolin (Salbutamol) (Salbutamol) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Oct-2010              | 7437149       | EXPEDITED (15-DAY) | Y                  | OT              | 1000014551           |                      | 53 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Hyperhidrosis; Insomnia; Malaise; Nausea; Sense Of Oppression; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Oct-2010              | 7622345       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-10P-056-0674737-00 |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Optic Neuropathy; Visual Impairment | Fenofibrate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                     | Lansoprazole   |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |   |      |              |
|--|--------------------------|---|------|--------------|
|  | Ciprallex                | S | Oral | Not Reported |
|  | Bromazepam               | S | Oral | Not Reported |
|  | Aceprometazine           | S | Oral | Not Reported |
|  | Maleate/Meproamate       |   |      |              |
|  | Tareg                    | S | Oral | Not Reported |
|  | Aspirin                  | S | Oral | Not Reported |
|  | Nicorandil               | S | Oral | Not Reported |
|  | Acebutolol Hydrochloride | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                                                                                                              | 7169759         | NON-EXPEDITED    | Y                  | OT              | 1000006883           |                                  | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Formication; Mania;<br>Pruritus; Sleep Disorder;<br>Suicidal Ideation; Visual<br>Impairment | Lexapro         |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                          | Vitamins        |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                          | Caprylic Acid   |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                          | Hyaluronic Acid |                  |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                                    | 7170038        | NON-EXPEDITED    | Y                  | HO, OT          | 1000007855           |                                  | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional<br>Overdose; Suicide Attempt | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                | Ativan         |                  |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                               | 7170047        | NON-EXPEDITED    | N                  | OT              | 1000008091           |                        | 70 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Antisocial<br>Behaviour; Asthenia; | Lexapro        |                  |                    | S               | Oral<br>Oral         | See Image<br>See Image |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                |  |  |  |                              |                                                  |  |  |  |                              |
|------------------------------------------------------------------------------------------------|--|--|--|------------------------------|--------------------------------------------------|--|--|--|------------------------------|
| Blood Pressure Increased;<br>Depression; Dizziness;<br>Mental Impairment;<br>Suicidal Ideation |  |  |  | Oral<br>Oral<br>Oral<br>Oral | See Image<br>See Image<br>See Image<br>See Image |  |  |  |                              |
| Avapro<br>Xanax                                                                                |  |  |  | C<br>C                       |                                                  |  |  |  | Not Reported<br>Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7624966                | EXPEDITED (15-DAY)        | Y                           | DS, LT, OT               | US-JNJFOC-20101001719         |                               | 69 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                                                                                                         | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coordination Abnormal;<br>Incoherent; Loss Of<br>Personal Independence In<br>Daily Activities; Product<br>Administration Error;<br>Product Prescribing Error;<br>Serum Serotonin<br>Increased; Therapeutic<br>Product Effect Increased | Risperidone             |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                        | Imitrex                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                        | Lexapro                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                        | Remeron                 |                       |                     | S                    | Unknown               |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                        | Trazodone Hydrochloride |                       |                     | S                    | Unknown               |                             |                          | Not Reported        |
|                                                                                                                                                                                                                                        | Keppra                  |                       |                     | S                    | Unknown               |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7644636                | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000016506                    |                               | 37 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Tremor; Visual Acuity<br>Reduced | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg (20 Mg,1 In 1 D),Oral |                          | Not Reported        |
|                                  | Citalopram              |                       |                     | S                    | Oral                  | Oral                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7698686                | NON-EXPEDITED             | N                           | OT                       | 1000009842                    |                               | 19 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Alopecia; Suicidal Ideation    | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral |                          | Not Reported        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |      |                                                               |              |
|----------|---|------|---------------------------------------------------------------|--------------|
| Lexapro  | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D), Oral | Not Reported |
|          |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |              |
| Cymbalta | C |      |                                                               | Not Reported |
| Vistaril | C |      |                                                               | Not Reported |
| Yaz      | C |      |                                                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010              | 7698693        | NON-EXPEDITED    | Y                  | DE              | 1000008823           |                                  | 90 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Oct-2010              | 7698694        | NON-EXPEDITED    | N                  | DE              | 1000009312           |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                    | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 12-Oct-2010              | 7698700        | NON-EXPEDITED    | N                  | OT              | 1000010560           |                      | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia       | Lexapro        |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2010              | 7698712        | NON-EXPEDITED    | Y                  | OT              | 1000010594           |                      | 56 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |         |   |      |                                |              |
|------------|---------|---|------|--------------------------------|--------------|
| Aggression | Lexapro | S | Oral | 20 Mg (20 Mg, 1 In 1),<br>Oral | Not Reported |
|            | Lortab  | C |      |                                | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7698713                | NON-EXPEDITED             | Y                           | OT                       | 1000010700                    |                               | 52 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Electrocardiogram Qt Prolonged | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7698731                | NON-EXPEDITED             | N                           | OT                       | 1000010901                    |                               | 78 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>                                    | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-----------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------------------------------------|--------------------------|---------------------|
| Blood Pressure Decreased; Dizziness; Hypertension; Restlessness | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                               |                          | Not Reported        |
|                                                                 | Lexapro                 |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |
|                                                                 |                         |                       |                     |                      | Oral                  | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1 D),<br>Oral |                          |                     |
|                                                                 | Hyzaar                  |                       |                     | C                    |                       |                                                                |                          | Not Reported        |
|                                                                 | Toprol XL               |                       |                     | C                    |                       |                                                                |                          | Not Reported        |
|                                                                 | Aspirin                 |                       |                     | C                    |                       |                                                                |                          | Not Reported        |
|                                                                 | Cozaar                  |                       |                     | C                    |                       |                                                                |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7698734                | NON-EXPEDITED             | Y                           | HO                       | 1000011009                    |                               | 49 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|----------------------------------|--------------------------|---------------------|
| Hypersensitivity               | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |
|                                | Albuterol               |                       |                     | C                    |                       |                                  |                          | Not Reported        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                |                  |                    |                              |                      |                                                                      |                 |              |                |
|------------------------------------------------------------------------|----------------|------------------|--------------------|------------------------------|----------------------|----------------------------------------------------------------------|-----------------|--------------|----------------|
| Vistaril<br>Trazodone                                                  |                | C<br>C           |                    | Not Reported<br>Not Reported |                      |                                                                      |                 |              |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                            | 7698736        | NON-EXPEDITED    | N                  | OT                           | 1000011079           |                                                                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Suicide Attempt                               | Lexapro        |                  |                    | S                            | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                            | 7698739        | NON-EXPEDITED    | Y                  | HO                           | 1000011108           |                                                                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling<br>Abnormal; Intentional<br>Overdose; Suicide Attempt | Lexapro        |                  |                    | S                            | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                     |                 | Not Reported |                |
|                                                                        | Klonopin       |                  |                    | S                            | Oral                 | (15 Mg, Once), Oral                                                  |                 | Not Reported |                |
|                                                                        | Ambien         |                  |                    | C                            |                      |                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                            | 7698782        | NON-EXPEDITED    | Y                  | OT                           | 1000011282           |                                                                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Intentional<br>Overdose; Suicide Attempt                   | Lexapro        |                  |                    | S                            | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 210 Mg (210 Mg, 1 In<br>1 D), Oral |                 | Not Reported |                |
|                                                                        |                |                  |                    |                              | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 210 Mg (210 Mg, 1 In<br>1 D), Oral |                 |              |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u> | <u>503B Facility</u>                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                            | 7698791        | NON-EXPEDITED    | Y                  | OT                           | 1000011630           |                                                                      | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>         | <u>Dosage Text</u>                                                   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |                |   |      |                               |              |
|---------------------------------|----------------|---|------|-------------------------------|--------------|
| Pain In Jaw; Tardive Dyskinesia | Lexapro        | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                                 | Metoclopramide | S | Oral | (3 In 1 D), Oral              | Not Reported |
|                                 | Spironolactone | C |      |                               | Not Reported |
|                                 | Diovan         | C |      |                               | Not Reported |
|                                 | Vytorin        | C |      |                               | Not Reported |
|                                 | Metoprolol     | C |      |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7698797       | NON-EXPEDITED    | N                  | OT              | 1000011656           |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------------------------------|-----------------|--------------|
| Fatigue; Serotonin Syndrome | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |
|                             |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 |              |
|                             | Adderall       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                             |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |
|                             |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 |              |
|                             |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7701149       | NON-EXPEDITED    | Y                  | OT              | 1000014382           |                      | 74 YR      | Male       | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anger; Confusional State; Hallucination; Suicidal | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |          |   |      |                                    |              |
|----------|----------|---|------|------------------------------------|--------------|
| Ideation | Lamictal | S | Oral | 350 Mg (350 Mg, 1 In 1 D),<br>Oral | Not Reported |
|          | Digoxin  | C |      |                                    | Not Reported |
|          | Coumadin | C |      |                                    | Not Reported |
|          | Vimpat   | C |      |                                    | Not Reported |
|          | Seroquel | C |      |                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7701153       | NON-EXPEDITED    | N                  | HO              | 1000014713           |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|------------------------------|
| Anxiety; Blood Pressure Increased; Blood Sodium Decreased; Insomnia; Paraesthesia | Lexapro          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |
|                                                                                   | Lexapro          |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                 |
|                                                                                   | Ativan<br>Detrol |              |            | C<br>C      |              |                                  |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7701154       | NON-EXPEDITED    | N                  | OT              | 1000014859           |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Sedation; Sexual Dysfunction; Suicidal Ideation; Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7701183       | NON-EXPEDITED    | Y                  | HO              | 1000014936           |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                       | Seroquel       |              |            | S           |              |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                       | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                                    | 7701218                              | NON-EXPEDITED    | Y                  | OT              | 1000011725           |                                                           | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Hot Flush;<br>Paraesthesia; Syncope | Lexapro                              |                  |                    | S               | Oral                 | 2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                |                                      |                  |                    |                 | Oral                 | 2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral |                 |              |                |
|                                                | Lexapro                              |                  |                    | S               | Oral<br>Oral<br>Oral | See Image<br>See Image<br>See Image                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                    | 7701219                              | NON-EXPEDITED    | Y                  | OT              | 1000015444           |                                                           | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Urticaria                          | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                          |                 | Not Reported |                |
|                                                | Vesicare                             |                  |                    | C               |                      |                                                           |                 | Not Reported |                |
|                                                | Simvastatin                          |                  |                    | C               |                      |                                                           |                 | Not Reported |                |
|                                                | Coumadin                             |                  |                    | C               |                      |                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                    | 7701221                              | NON-EXPEDITED    | Y                  | OT              | 1000011751           |                                                           | 59 YR           | Female       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Glaucoma                                       | Lexapro                              |                  |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral                               |                 | Not Reported |                |
|                                                | Clonazepam (0.25 Milligram, Tablets) |                  |                    | C               |                      |                                                           |                 | Not Reported |                |
|                                                | Ambien Cr                            |                  |                    | C               |                      |                                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                                                                                                         | 7701222                                                       | NON-EXPEDITED    | N                  | OT              | 1000015549           |                                                                     | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue;<br>Headache; Nausea;<br>Suicidal Ideation                                                       | Lexapro                                                       |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                    |                 | Not Reported |                |
|                                                                                                                     | Fioricet                                                      |                  |                    | C               |                      |                                                                     |                 | Not Reported |                |
|                                                                                                                     | Treximet                                                      |                  |                    | C               |                      |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                                                                         | 7701224                                                       | NON-EXPEDITED    | N                  | OT              | 1000011914           |                                                                     | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Headache;<br>Lethargy; Malaise; Mental<br>Impairment; Restlessness;<br>Somnolence; Suicidal<br>Ideation | Lexapro                                                       |                  |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1<br>D),Oral ; 1.25 Mg (1.25<br>Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                     |                                                               |                  |                    |                 | Oral                 | 20 Mg (20 Mg,1 In 1<br>D),Oral ; 1.25 Mg (1.25<br>Mg,1 In 1 D),Oral |                 |              |                |
|                                                                                                                     | Armour Thyroid (Thyroid) (30<br>Milligram, Tablets) (Thyroid) |                  |                    | C               |                      |                                                                     |                 | Not Reported |                |
|                                                                                                                     | Lipitor                                                       |                  |                    | C               |                      |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                                                                         | 7701225                                                       | NON-EXPEDITED    | Y                  | OT              | 1000011924           |                                                                     |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia                                                                                                  | Lexapro                                                       |                  |                    | S               |                      |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                                                                         | 7701229                                                       | NON-EXPEDITED    | N                  | OT              | 1000011971           |                                                                     | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                                                          |                           |   |      |                             |              |
|----------------------------------------------------------------------------------------------------------|---------------------------|---|------|-----------------------------|--------------|
| Anxiety; Increased Appetite; Insomnia; Panic Attack; Swollen Tongue; Visual Impairment; Weight Increased | Lexapro                   | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral | Not Reported |
|                                                                                                          | Synthroid (0.1 Milligram) | C |      |                             | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7701233                 | NON-EXPEDITED             | N                           | OT                       | 1000012025                    |                               | 37 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dystonia; Parkinsonism            | Lexapro                 |                           |                             | S                        | Oral                          | 20 Mg (20 Mg,1 In 1 D),Oral   |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7701236                 | NON-EXPEDITED             | N                           | OT                       | 1000012153                    |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Amnesia; Psychotic Disorder       | Lexapro                 |                           |                             | S                        | Oral                          | Oral                          |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7701238                 | NON-EXPEDITED             | Y                           | OT                       | 1000012423                    |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Serotonin Syndrome                | Lexapro                 |                           |                             | S                        | Oral                          | Oral                          |                          |                     | Not Reported            |
|                                   | Deplin                  |                           |                             | S                        |                               |                               |                          |                     | Not Reported            |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Oct-2010                       | 7701251                 | NON-EXPEDITED             | N                           | DE                       | 1000012425                    |                               | 65 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Completed Suicide                 | Lexapro                 |                           |                             | S                        | Oral                          | Oral                          |                          |                     | Not Reported            |

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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010              | 7701509              | NON-EXPEDITED    | Y                  | OT              | 1000008238           |                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                    | Lexapro              |                  |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010              | 7701510              | NON-EXPEDITED    | Y                  | HO              | 1000008348           |                                  | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis             | Lexapro              |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010              | 7701519              | NON-EXPEDITED    | N                  | OT              | 1000009071           |                                  | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation        | Lexapro              |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                          | Proventil (Inhalant) |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010              | 7701527              | NON-EXPEDITED    | N                  | HO              | 1000009263           |                                  | 26 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis; Pancreatitis  | Lexapro              |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                          | Advair (Inhalant)    |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                          | Albuterol (Inhalant) |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                          | Multi-Vitamin        |                  |                    | C               |                      |                                  |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 12-Oct-2010                                                                                                           | 7701530        | NON-EXPEDITED    | N                  | OT              | 1000009315           |                                                                                             | 15 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Judgement Impaired;<br>Suicidal Ideation                                                                              | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                                                                           | 7701552        | NON-EXPEDITED    | N                  | HO              | 1000009507           |                                                                                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Akathisia;<br>Confusional State;<br>Dizziness; Hypomania;<br>Overdose; Suicidal<br>Ideation; Swelling Face | Lexapro        |                  |                    | S               | Oral                 | See Image                                                                                   |                 | Not Reported |                |
|                                                                                                                       | Lamictal       |                  |                    | S               | Oral                 | See Image                                                                                   |                 |              |                |
|                                                                                                                       |                |                  |                    | S               | Oral                 | See Image                                                                                   |                 |              |                |
|                                                                                                                       |                |                  |                    | S               | Oral                 | See Image                                                                                   |                 |              |                |
|                                                                                                                       |                |                  |                    | S               | Oral                 | 100 Mg Every Morning<br>(100 Mg, 1 In 1 D), Oral;<br>200 Mg Qhs (200 Mg, 1 In<br>1 D), Oral |                 | Not Reported |                |
|                                                                                                                       | Seroquel       |                  |                    | S               | Oral                 | (1 In 1 D), Oral                                                                            |                 | Not Reported |                |
|                                                                                                                       | Wellbutrin     |                  |                    | S               | Oral                 | 150 Mg (150 Mg, 1 In 1 D),<br>Oral                                                          |                 | Not Reported |                |
|                                                                                                                       | Risperdal      |                  |                    | S               | Oral                 | 1 Mg (0.5 Mg, 2 In 1 D),<br>Oral                                                            |                 | Not Reported |                |
|                                                                                                                       | Zyrtec-D       |                  |                    | C               |                      |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                                                                                           | 7701554        | NON-EXPEDITED    | Y                  | OT              | 1000009519           |                                                                                             | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Hostility; Suicidal Ideation                                                                                          | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                            | Wellbutrin                       | S                | Oral               | 250 Mg (2 In 1 D), Oral | Not Reported         |                               |                 |              |                |
|--------------------------------------------|----------------------------------|------------------|--------------------|-------------------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                            | Lyrica                           | S                |                    |                         | Not Reported         |                               |                 |              |                |
|                                            | Lunesta                          | C                |                    |                         | Not Reported         |                               |                 |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                | 7701559                          | NON-EXPEDITED    | Y                  | OT                      | 1000009575           |                               | 19 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                          | Lexapro                          |                  |                    | S                       | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                            | Lantus                           |                  |                    | C                       |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                | 7702136                          | NON-EXPEDITED    | N                  | HO                      | 1000012673           |                               | 66 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Nausea; Urinary Tract Infection | Lexapro                          |                  |                    | S                       | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                            | Xanax (0.25 Mmilligram, Tablets) |                  |                    | C                       |                      |                               |                 | Not Reported |                |
|                                            | Toprol (50 Milligram,Tablets)    |                  |                    | C                       |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                | 7702166                          | NON-EXPEDITED    | Y                  | HO                      | 1000012757           |                               | 15 YR           | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia                                   | Lexapro                          |                  |                    | S                       | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                                | 7702173                          | NON-EXPEDITED    | N                  | OT                      | 1000012939           |                               | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |                |                  |                    |                 |                                  |                                  |                 |              |                |
|-------------------------------------|----------------|------------------|--------------------|-----------------|----------------------------------|----------------------------------|-----------------|--------------|----------------|
| Extrapyramidal Disorder             | Lexapro        |                  | S                  | Oral            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                                  | Not Reported    |              |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                         | 7702187        | NON-EXPEDITED    | Y                  | OT              | 1000012964                       |                                  | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion; Hypertension;<br>Syncope | Lexapro        |                  |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                     | Lorazepam      |                  |                    | S               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                         | 7702195        | NON-EXPEDITED    | N                  | HO              | 1000013165                       |                                  | 76 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased              | Lexapro        |                  |                    | S               | Oral                             | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                     | Lexapro        |                  |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                     | Levodopa       |                  |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                     | Carbidopa      |                  |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                     | Ritalin        |                  |                    | C               |                                  |                                  |                 | Not Reported |                |
|                                     | Ramipril       |                  |                    | C               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                         | 7702221        | NON-EXPEDITED    | N                  | OT              | 1000013822                       |                                  | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Type 2 Diabetes Mellitus            | Lexapro        |                  |                    | S               |                                  |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2010                         | 7702703        | NON-EXPEDITED    | Y                  | OT              | 1000014963                       |                                  | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                          |                |                  |                    |                 |                      |                                  |                                  |            |                |
|----------------------------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|----------------------------------|------------|----------------|
| Intentional Overdose;<br>Suicide Attempt                                                                 |                | Lexapro          |                    | S               | Oral                 |                                  | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>                       | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2010                                                                                              | 7702731        | NON-EXPEDITED    | Y                  | OT              | 1000014083           |                                  | 30 YR                            | Female     | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u>                  | <u>Mfr</u> |                |
| Suicidal Ideation                                                                                        | Lexapro        |                  |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)          |                                  |            | Not Reported   |
|                                                                                                          | Xanax          |                  |                    | C               |                      |                                  |                                  |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>                       | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2010                                                                                              | 7702737        | NON-EXPEDITED    | N                  | OT              | 1000014108           |                                  | 56 YR                            | Female     | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u>                  | <u>Mfr</u> |                |
| Depression; Drug<br>Ineffective; Suicidal<br>Ideation                                                    | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral  |                                  |            | Not Reported   |
|                                                                                                          | Prevacid       |                  |                    | C               |                      |                                  |                                  |            | Not Reported   |
|                                                                                                          | Simvastatin    |                  |                    | C               |                      |                                  |                                  |            | Not Reported   |
|                                                                                                          | Levothyroxine  |                  |                    | C               |                      |                                  |                                  |            | Not Reported   |
|                                                                                                          | Lunesta        |                  |                    | C               |                      |                                  |                                  |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>                       | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2010                                                                                              | 7702759        | NON-EXPEDITED    | N                  | HO              | 1000014202           |                                  | 27 YR                            | Male       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u>                  | <u>Mfr</u> |                |
| Depression; Erectile<br>Dysfunction; Fatigue;<br>Libido Decreased;<br>Paraesthesia; Suicidal<br>Ideation | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                                  |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>                       | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2010                                                                                              | 7702788        | NON-EXPEDITED    | Y                  | OT              | 1000014329           |                                  | 18 YR                            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrioventricular<br>Dissociation; Intentional<br>Self-Injury; Sleep<br>Disorder; Suicide Attempt | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7703623       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016588           |                      | 51 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Optic Neuropathy      | Escitalopram Oxalate     |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral                   |                 | Not Reported |
|                       | Bromazepam               |              |            | S           |              | 18 Mg (6 Mg,3 In 1 D)                         |                 | Not Reported |
|                       | Aceprometazine           |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |
|                       | Tareg                    |              |            | S           | Oral         | 160 Mg (160 Mg,1 In 1 D),Oral                 |                 | Not Reported |
|                       | Fenofibrate              |              |            | S           |              | 200 Mg (200 Mg,1 In 1 D),Other                |                 | Not Reported |
|                       | Aspirin                  |              |            | S           | Oral         | 160 Mg (160 Mg,1 In 1 D),Oral                 |                 | Not Reported |
|                       | Nicorandil               |              |            | S           | Oral         | 40 Mg (20 Mg,2 In 1 D),Oral                   |                 | Not Reported |
|                       | Acebutolol Hydrochloride |              |            | S           | Oral         | 400 Mg (200 Mg,2 In 1 D),Oral                 |                 | Not Reported |
|                       | Lansoprazole             |              |            | S           | Oral         | 30 Mg (30 Mg,1 In 1 D),Oral                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7746948       | NON-EXPEDITED    | N                  | OT              | 1000012534           |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |         |   |      |      |              |
|-----------------|---------|---|------|------|--------------|
| Suicide Attempt | Lexapro | S | Oral | Oral | Not Reported |
|-----------------|---------|---|------|------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Oct-2010              | 7747399       | NON-EXPEDITED    | Y                  | HO              | 1000009395           |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypoaesthesia;<br>Hypoaesthesia Oral; Rash | Lexapro        |              |            | S           | Oral         | See Image          |                 | Not Reported |
|                                            |                |              |            |             | Oral         | See Image          |                 |              |
|                                            |                |              |            |             | Oral         | See Image          |                 |              |
|                                            | Xanax          |              |            | C           |              |                    |                 | Not Reported |
|                                            | Toprol XL      |              |            | C           |              |                    |                 | Not Reported |
|                                            | Aspirin        |              |            | C           |              |                    |                 | Not Reported |
|                                            | Cardizem       |              |            | C           |              |                    |                 | Not Reported |
|                                            | Colace         |              |            | C           |              |                    |                 | Not Reported |
|                                            | Miralax        |              |            | C           |              |                    |                 | Not Reported |
|                                            | Slow-Mag       |              |            | C           |              |                    |                 | Not Reported |
| Centrum                                    |                |              | C          |             |              |                    | Not Reported    |              |
| Asacol                                     |                |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2010              | 7585849       | EXPEDITED (15-DAY) | Y                  | HO              | 1000015887           |                      | 73 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Acute Kidney Injury; Blood<br>Bilirubin Increased; Drug<br>Reaction With Eosinophilia<br>And Systemic Symptoms | Escitalopram Oxalate                               |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                | Fluindione                                         |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                | Diovan Hct                                         |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                | Zopiclone                                          |              |            | S           | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                | Tahor (Atorvastatin)                               |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                | (Atorvastatin)                                     |              |            |             |              |                                    |                 |              |
|                                                                                                                | Amlor (Amlodipine) (Amlodipine)                    |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                | Temerit (Nebivolol<br>Hydrochloride) (5 Milligram) |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                | (Nebivolol Hydrochloride)                          |              |            |             |              |                                    |                 |              |
|                                                                                                                | Diantalvic (Di-Gesic) (Di-Gesic)                   |              |            | C           |              |                                    |                 | Not Reported |
| Ditropan (Oxybutynin)                                                                                          |                                                    |              | C          |             |              |                                    | Not Reported    |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hydrochloride) (Oxybutynin  
Hydrochloride)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2010              | 7626206       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2010FR65244      |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Optic Neuropathy; Pallor; Visual Acuity Reduced; Visual Evoked Potentials Abnormal | Tareg                    |              |            | S           | Oral         | 60 Mg, Qd          |                 | Novartis     |
|                                                                                                | Fenofibrate              |              |            | S           |              | 200 Mg, Qd         |                 | Not Reported |
|                                                                                                | Aspirin                  |              |            | S           |              | 160 Mg, Qd         |                 | Not Reported |
|                                                                                                | Nicorandil               |              |            | S           |              | 40 Mg, Daily       |                 | Not Reported |
|                                                                                                | Acebutolol Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                | Lansoprazole             |              |            | S           |              | 30 Mg, Qd          |                 | Not Reported |
|                                                                                                | Bromazepam               |              |            | S           |              | 18 Mg, Daily       |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate     |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                                                                                                | Aceprometazine           |              |            | S           |              | 01 Df, Qd          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Oct-2010              | 7657447       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016644           |                      | 68 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Drug Interaction; Hypotension; Syncope | Lexapro                            |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                        | Viagra                             |              |            | S           | Oral         | (50 Mg,As Required),Oral    |                 | Not Reported |
|                                        | Simvastatin                        |              |            | C           |              |                             |                 | Not Reported |
|                                        | Plavix (Clopidogrel) (Clopidogrel) |              |            | C           |              |                             |                 | Not Reported |
|                                        | Lisinopril                         |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2010              | 6527296       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20080102280 |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                                       |   |   |      |  |              |
|----------------------------|---------------------------------------|---|---|------|--|--------------|
| Toxicity To Various Agents | Ibuprofen                             |   | S | Oral |  | Not Reported |
|                            | Acetaminophen                         | Y | S | Oral |  | Not Reported |
|                            | Acetaminophen                         |   | S | Oral |  | Not Reported |
|                            | Aspirin                               | Y | S | Oral |  | Not Reported |
|                            | Quetiapine                            |   | S | Oral |  | Not Reported |
|                            | Unspecified Ingredient                |   | S | Oral |  | Not Reported |
|                            | Butalbital Acetaminophen And Caffeine |   | S | Oral |  | Not Reported |
|                            | Escitalopram Oxalate                  |   | S | Oral |  | Not Reported |
|                            | Caffeine                              |   | S | Oral |  | Not Reported |
|                            | Naproxen                              |   | S | Oral |  | Not Reported |
|                            | Fexofenadine Hcl                      |   | S | Oral |  | Not Reported |

| <u>FDA Received Date</u>               | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|-----------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 14-Oct-2010                            | 7662548                                                         | EXPEDITED (15-DAY) | Y                  | OT              | 1000016757           |                             | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                  | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema Peripheral;<br>Weight Increased | Escitalopram Oxalate                                            |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                        | Lamictal                                                        |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                        | Antihypertensives<br>(Antihypertensives)<br>(Antihypertensives) |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 14-Oct-2010                                                | 7662551                                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000016614           |                              | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                      | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Disorientation;<br>Thrombocytopenia | Escitalopram Oxalate                    |                    |                    | S               | Oral                 | Oral                         |                 | Not Reported |                |
|                                                            | Ibuprofen\Pseudoephedrine Hydrochloride |                    |                    | S               | Oral                 | 3 Or 4 Dosage Forms,<br>Oral |                 | Not Reported |                |
|                                                            | Cefuroxime                              |                    |                    | S               | Oral                 | Oral                         |                 | Not Reported |                |
|                                                            | Budesonide                              |                    |                    | S               | Respiratory          | Respiratory (Inhalation)     |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |   |              |      |  |              |
|----------------------------------------------------------|---|--------------|------|--|--------------|
|                                                          |   | (inhalation) |      |  |              |
| Ibuprofen                                                | S | Oral         | Oral |  | Not Reported |
| Paracetamol (Paracetamol)<br>(Paracetamol)               | C |              |      |  | Not Reported |
| Duphaston (Dydrogesterone)<br>(Tablets) (Dydrogesterone) | C |              |      |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Oct-2010              | 7457896       | EXPEDITED (15-DAY) | Y                  | DE              | 1000014686           |                      | 65 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Cyanosis; Drug Interaction; Fall; Haemorrhage; Haemorrhagic Stroke; Pulmonary Embolism; Sudden Death | Escitalopram Oxalate                    |              |            | S           |              | 5 Mg (5 Mg,1 In 1 D) |                 | Not Reported |
|                                                                                                      | Plavix                                  |              |            | S           |              |                      |                 | Not Reported |
|                                                                                                      | Atorvastatin Calcium                    |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                      | Acebutolol (Acebutolol)<br>(Acebutolol) |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                      | Cordarone (Amiodarone)<br>(Amiodarone)  |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                      | Coaprovel (Karvea Hct) (Karvea Hct)     |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                      | Amlodipine Besylate                     |              |            | C           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 15-Oct-2010              | 7626183       | EXPEDITED (15-DAY) | Y                  | HO              | FR-RANBAXY-2010RR-38713 |                      | 51 YR      | Male       | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Optic Neuropathy; Visual Impairment | Fenofibrate          |              |            | S           | Oral         | 200 Mg, Unk        |                 | Ranbaxy      |
|                                     | Lansoprazole         |              |            | S           | Oral         | 30 Mg, Unk         |                 | Not Reported |
|                                     | Bromazepam           |              |            | S           | Oral         | 18 Mg, Unk         |                 | Not Reported |
|                                     | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                     | Acepromazine         |              |            | S           | Oral         | 1 Df, Unk          |                 | Not Reported |
|                                     | Tareg                |              |            | S           | Oral         | 160 Mg, Unk        |                 | Not Reported |
|                                     | Aspirin              |              |            | S           | Oral         | 160 Mg, Unk        |                 | Not Reported |
|                                     | Nicorandil           |              |            | S           | Oral         | 40 Mg, Unk         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                                      |                    |                    |                 |                       |                                               |                 |              |                |
|------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Acebutolol Hydrochloride                                                           |                                      |                    | S                  | Oral            | 400 Mg, Unk           |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2010                                                                        | 7644809                              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016540            |                                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Rebound Effect; Suicidal Ideation                                                  | Escitalopram Oxalate                 |                    |                    | S               |                       | 20 Mg (20 Mg,1 In 1 D)                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2010                                                                        | 7662101                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000016612            |                                               | 23 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Hepatitis                                                             | Escitalopram Oxalate                 |                    |                    | S               | Oral                  | 1 Dosage Form (1 Dosage Forms,1 In 1 D),Oral  |                 | Not Reported |                |
|                                                                                    | Levonorgestrel And Ethinyl Estradiol |                    |                    | S               | Oral                  | 1 Dosage Forms (1 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                    | Tea Leaf                             |                    |                    | S               | Oral                  | 4 Dosage Form (4 Dosage Forms,1 In 1 D),Oral  |                 | Not Reported |                |
|                                                                                    | Zopiclone (Zopiclone)                |                    |                    | C               |                       |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2010                                                                        | 7662943                              | EXPEDITED (15-DAY) | Y                  | OT              | 1000016671            |                                               | 42 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention; Hypomania; Impulsive Behaviour; Irritability; Logorrhoea | Escitalopram Oxalate                 |                    |                    | S               | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral                   |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate                 |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Oct-2010                                                                        | 7684492                              | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20101002875 |                                               | 87 YR           | Female       | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|-----------------------------|---------------------------------------------------------------|-----------------|--------------|
| Agitation; Akinesia;<br>Amnesia; Blood Pressure<br>Systolic Increased;<br>Communication Disorder;<br>Dysstasia; Fall; Gait<br>Disturbance; Haematoma;<br>International Normalised<br>Ratio Increased; Mental<br>Disorder | Haldol                 |              |            | S           | Oral                        | 15 Gtt Morning, 20 Gtt<br>Midday And 12 Gtt<br>Evening        |                 | Not Reported |
|                                                                                                                                                                                                                          | Haldol                 |              |            | S           | Oral                        | 6 Gtt On Morning, 6 Gtt<br>On Midday And 10 Gtt On<br>Evening |                 | Not Reported |
|                                                                                                                                                                                                                          | Oxazepam               |              |            | S           | Oral                        | 1/2 Tablet Per Day<br>(Evening)                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Oxazepam               |              |            | S           | Oral                        |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Exelon                 |              |            | S           | Cutaneous                   |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Escitalopram Oxalate   |              |            | S           | Oral                        |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Escitalopram Oxalate   |              |            | S           | Oral                        | 1/2 Tablet On Morning                                         |                 | Not Reported |
|                                                                                                                                                                                                                          | Singulair              |              |            | C           | Oral                        |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Previscan (Fluindione) |              |            | C           | Oral                        |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Ramipril               |              |            | C           | Oral                        |                                                               |                 | Not Reported |
|                                                                                                                                                                                                                          | Symbicort              |              |            | C           | Respiratory<br>(inhalation) | 400/12 Mcg/Dose Twice<br>Per Day                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2010              | 7546370       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015445           |                      | 29 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Balance Disorder;<br>Dizziness; Fall;<br>Hyponatraemia; Loss Of<br>Consciousness | Lexapro              |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                  | Tylenol With Codeine |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Klonopin             |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Hctz                 |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Potassium            |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Tenormin             |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Phenergan            |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Omeprazole           |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Benadryl             |              |            | C           |              |                                |                 | Not Reported |
|                                                                                  | Tylenol              |              |            | C           |              |                                |                 | Not Reported |

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|                                                                               |                      |                    |                    |                 |                           |                                |                 |              |                |
|-------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------|-----------------|--------------|----------------|
| Aspirin                                                                       |                      |                    | C                  |                 |                           | Not Reported                   |                 |              |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2010                                                                   | 7653177              | DIRECT             | N                  | OT              |                           |                                | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction;<br>Diarrhoea; Feeling<br>Abnormal; Weight<br>Decreased | Lexapro              |                    |                    | S               | Oral                      | 1 One Daily Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2010                                                                   | 7663147              | EXPEDITED (15-DAY) | N                  | OT              | 1000016679                |                                |                 | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Physical Assault; Sexual<br>Abuse                                             | Lexapro              |                    |                    | S               | Oral                      | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2010                                                                   | 6527272              | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-<br>20080101973 |                                | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                    | Ibuprofen            |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Lamotrigine          |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Alprazolam           |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Ramelteon            |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Zaleplon             |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
|                                                                               | Zolpidem             |                    |                    | S               | Oral                      |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2010                                                                   | 7601980              | EXPEDITED (15-DAY) | N                  | HO              | A0882338A                 |                                | 64 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
|-------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|-------------------------------|-----------------|-----------------|----------------|
| Fall; Impaired Driving Ability; Seizure; Subdural Haematoma | Flolan               |                    |                    | S               | Intravenous (not otherwise specified) |                               |                 | Glaxosmithkline |                |
|                                                             | Flolan               |                    |                    | S               | Intravenous (not otherwise specified) |                               |                 | Glaxosmithkline |                |
|                                                             | Aspirin              |                    |                    | S               | Oral                                  | 81mg Per Day                  |                 | Glaxosmithkline |                |
|                                                             | Lexapro              |                    |                    | S               | Unknown                               |                               |                 | Not Reported    |                |
|                                                             | Zoloft               |                    |                    | C               | Unknown                               |                               |                 | Not Reported    |                |
|                                                             | Astelin              |                    |                    | C               | Nasal                                 | 137mcg Unknown                |                 | Glaxosmithkline |                |
|                                                             | Crestor              |                    |                    | C               | Oral                                  | 5mg Unknown                   |                 | Not Reported    |                |
|                                                             | Multi-Vitamin        |                    |                    | C               | Oral                                  | 1tab Per Day                  |                 | Not Reported    |                |
|                                                             | Flonase              |                    |                    | C               | Nasal                                 |                               |                 | Glaxosmithkline |                |
|                                                             | Furosemide           |                    |                    | C               | Oral                                  | 40mg Unknown                  |                 | Glaxosmithkline |                |
|                                                             | Imodium              |                    |                    | C               | Oral                                  | 2mg Unknown                   |                 | Not Reported    |                |
|                                                             | Potassium Chloride   |                    |                    | C               | Oral                                  | 20meq Unknown                 |                 | Glaxosmithkline |                |
|                                                             | Letairis             |                    |                    | C               | Oral                                  | 10mg Unknown                  |                 | Glaxosmithkline |                |
|                                                             | Nexium               |                    |                    | C               | Oral                                  | 4mg Unknown                   |                 | Not Reported    |                |
|                                                             | Oxygen               |                    |                    | C               |                                       | 3l As Directed                |                 | Not Reported    |                |
|                                                             | Restasis             |                    |                    | C               | Ophthalmic                            |                               |                 | Glaxosmithkline |                |
|                                                             | Sodium Chloride      |                    |                    | C               |                                       |                               |                 | Glaxosmithkline |                |
|                                                             | Spironolactone       |                    |                    | C               | Oral                                  | 25mg Unknown                  |                 | Glaxosmithkline |                |
|                                                             | Synthroid            |                    |                    | C               | Oral                                  | 125mcg Unknown                |                 | Glaxosmithkline |                |
|                                                             | Tylenol              |                    |                    | C               | Oral                                  | 325mg Unknown                 |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Oct-2010                                                 | 7602828              | EXPEDITED (15-DAY) | Y                  | OT              | 1000016049                            |                               | 26 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain; Anxiety                                     | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                |   |  |              |
|--|--------------------------------|---|--|--------------|
|  | Buprenorphine (Buprenorphine)  | C |  | Not Reported |
|  | (Buprenorphine)                |   |  |              |
|  | Zolpidem (Zolpidem) (Zolpidem) | C |  | Not Reported |
|  | Alprazolam                     | C |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2010              | 7610083       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016199           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Alcohol Use; Anger; Impaired Driving Ability; Mood Swings; Road Traffic Accident | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2010              | 7633646       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2010FR67435      |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Agitation; Akinesia; Blood Pressure Systolic Increased; Communication Disorder; Dysstasia; Fall; Feeling Abnormal; Gait Disturbance; Haematoma; Heart Rate Increased; International Normalised Ratio Increased | Exelon Patch           |              |            | S           | Transdermal  | 4.6 Mg/24 Hr                      |                 | Novartis     |
|                                                                                                                                                                                                                | Haldol                 |              |            | S           |              | 47 Drops/Day                      |                 | Not Reported |
|                                                                                                                                                                                                                | Haldol                 |              |            | S           |              | 22 Oral Drops/Day                 |                 | Not Reported |
|                                                                                                                                                                                                                | Oxazepam               |              |            | S           | Oral         | 10 Mg/Day                         |                 | Not Reported |
|                                                                                                                                                                                                                | Oxazepam               |              |            | S           | Oral         | 5 Mg/Day                          |                 | Not Reported |
|                                                                                                                                                                                                                | Escitalopram Oxalate   |              |            | S           | Oral         |                                   |                 | Not Reported |
|                                                                                                                                                                                                                | Escitalopram Oxalate   |              |            | S           | Oral         | 5 Mg/Day                          |                 | Not Reported |
|                                                                                                                                                                                                                | Singular               |              |            | C           | Oral         | 10 Mg/Day                         |                 | Not Reported |
|                                                                                                                                                                                                                | Previscan (Fluindione) |              |            | C           |              | 20 Mg                             |                 | Not Reported |
|                                                                                                                                                                                                                | Ramipril               |              |            | C           |              | 5 Mg/Day                          |                 | Not Reported |
|                                                                                                                                                                                                                | Symbicort              |              |            | C           |              | 400/12 Mcg/Dose, 1 Inhalation Bid |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 19-Oct-2010                 | 7664632              | EXPEDITED (15-DAY) | Y                  | DS              | 1000016808           |                               | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Feeling Abnormal | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                             | Xanax                |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                | <u>Case #</u>                                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 19-Oct-2010                                                                             | 7664654                                                                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000016787           |                             | 90 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Fall; Hyponatraemia; Loss Of Consciousness; Quadriplegia; Somnolence | Escitalopram Oxalate                                                                   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                         | Voltarene (Diclofenac Sodium)                                                          |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Omeprazole                                                                             |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Forlax (Macrogol) (Macrogol)                                                           |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Actiskenan (Morphine Sulfate) (Morphine Sulfate)                                       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Tareg (Valsartan) (Valsartan)                                                          |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Vastarel                                                                               |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)                           |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Calciparene (Heparin Calcium) (Heparin Calcium)                                        |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Solumedrol (Methylprednisolone Sodium Succinate) (Methylprednisolone Sodium Succinate) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                         | Ofloxacin                                                                              |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 19-Oct-2010              | 7664665              | EXPEDITED (15-DAY) | Y                  | HO              | 1000016685           |                         | 20 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Oculogyric Crisis        | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                               |   |                         |              |
|--|-----------------------------------------------|---|-------------------------|--------------|
|  | Zuclopenthixol                                | S | 30 Mg (30 Mg, 1 In 1 D) | Not Reported |
|  | Valium (Diazepam) (Tablets)<br>(Diazepam)     | C |                         | Not Reported |
|  | Akineton (Biperiden) (Tablets)<br>(Biperiden) | C |                         | Not Reported |

| <u>FDA Received Date</u>                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 19-Oct-2010                                              | 7664683              | EXPEDITED (15-DAY) | Y                  | OT              | 1000016779           |                                  | 23 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Drug<br>Ineffective | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2010                                                                                                    | 7664813              | EXPEDITED (15-DAY) | Y                  | HO              | IPC201010-000271     |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia; Dizziness;<br>Drug Interaction;<br>Dyspnoea; Orthostatic<br>Hypotension; Sinus Arrest;<br>Syncope | Atenolol             |                    |                    | S               |                      | 25 Mg Daily          |                 | Not Reported |                |
|                                                                                                                | Furosemide           |                    |                    | S               |                      | 20 Mg Daily          |                 | Not Reported |                |
|                                                                                                                | Rivastigmine         |                    |                    | S               |                      | 3 Mg Twice Daily     |                 | Not Reported |                |
|                                                                                                                | Levetiracetam        |                    |                    | S               |                      | 500 Mg Twice Daily   |                 | Not Reported |                |
|                                                                                                                | Fosinopril Sodium    |                    |                    | S               |                      | 20 Mg Twice Daily    |                 | Not Reported |                |
|                                                                                                                | Amlodipine           |                    |                    | S               |                      | 5 Mg Daily           |                 | Not Reported |                |
|                                                                                                                | Minoxidil            |                    |                    | S               |                      | 5 Mg Twice Daily     |                 | Not Reported |                |
|                                                                                                                | Aspirin              |                    |                    | S               |                      | 325 Mg Daily         |                 | Not Reported |                |
|                                                                                                                | Clopidogrel          |                    |                    | S               |                      | 75 Mg Daily          |                 | Not Reported |                |
|                                                                                                                | Escitalopram Oxalate |                    |                    | S               |                      | 5 Mg Daily           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2010              | 7665409       | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000016858           |                      | 72 YR      | Female     | DNK            |



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| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Seizure               | Escitalopram Oxalate          |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                       | Amitriptyline (Amitriptyline) |              |            | C           |              |                             |                 | Not Reported |
|                       | Mirtazapine                   |              |            | C           |              |                             |                 | Not Reported |
|                       | Quetiapine (Quetiapine)       |              |            | C           |              |                             |                 | Not Reported |
|                       | Venlafaxine Hydrochloride     |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2010              | 7667562       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016784           |                      | 76 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Anxiety; Confusional State; Feeling Drunk; Hypomania; Nausea | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral                        |                 | Not Reported |
|                                                              | Agomelatine          |              |            | S           | Oral         | Oral                                               |                 | Not Reported |
|                                                              | Lexomil (Bromazepam) |              |            | S           | Oral         | 1.25 Dosage Form (1.25 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Oct-2010              | 7582610       | EXPEDITED (15-DAY) | N                  | OT              | 1000015944           |                      | 62 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Anger; Anxiety; Compulsions; Condition Aggravated; Confusional State; Dependence; Dizziness; Gambling Disorder; Insomnia; Mania; Marital Problem; Suicidal Ideation; Withdrawal Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral; Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 21-Oct-2010                                                          | 7667890                                                                | EXPEDITED (15-DAY) | N                  | HO              | 1000016738           |                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain; Hyperhidrosis;<br>Pain In Extremity                      | Lexapro                                                                |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2010                                                          | 7668786                                                                | EXPEDITED (15-DAY) | Y                  | OT              | 1000016683           |                                  | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Dyskinesia; Sopor;<br>Tachycardia            | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                      | Olanzapine (Olanzapine)                                                |                    |                    | S               |                      | (900 Mg, Once)                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2010                                                          | 7668876                                                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000016719           |                                  | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastritis Erosive;<br>Haematemesis                                   | Lexapro                                                                |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                      | Nitrazepam (Nitrazepam)                                                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                      | Dexamphetamine<br>(Dexamphetamine Sulfate)<br>(Dexamphetamine Sulfate) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2010                                                          | 7727692                                                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000016832           |                                  | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Akinesia;<br>Dysstasia; Fall;<br>Haematoma; International | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 N 1 D), Oral       |                 | Not Reported |                |
|                                                                      | Haldol                                                                 |                    |                    | S               | Oral                 | 47 Drops (47 Gtt, 1 In 1         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                                                                    |   |           |                                                     |              |
|-----------------------------------------------|--------------------------------------------------------------------|---|-----------|-----------------------------------------------------|--------------|
| Normalised Ratio Increased; Parkinsonian Gait | Oxazepam                                                           | S | Oral      | D), Oral                                            | Not Reported |
|                                               | Exelon                                                             | S | Cutaneous | Oral                                                | Not Reported |
|                                               |                                                                    |   |           | 1 Dosage Form (1 Dosage Forms, 1 In 1 D), Cutaneous | Not Reported |
|                                               | Singulair                                                          | C |           |                                                     | Not Reported |
|                                               | Previscan (Fluindione)                                             | C |           |                                                     | Not Reported |
|                                               | Ramipril                                                           | C |           |                                                     | Not Reported |
|                                               | Symbicort Turbuhaler (Symbicort Turbuhaler) (Symbicort Turbuhaler) | C |           |                                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 22-Oct-2010              | 7637761       | EXPEDITED (15-DAY) | Y                  | OT              | BR-PFIZER INC-2010130473 |                      | 25 YR      | Male       | BRA            |

| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Dysphoria; Sedation; Sexual Dysfunction | Sertraline Hydrochloride |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                           | Citalopram               |              |            | S           |              | Unk                |                 | Not Reported |
|                                                           | Clonazepam               |              |            | S           |              | Unk                |                 | Not Reported |
|                                                           | Escitalopram Oxalate     |              |            | S           |              | 20mg/Day           |                 | Not Reported |
|                                                           | Venlafaxine              |              |            | S           |              | 225mg/Day          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Oct-2010              | 7727148       | EXPEDITED (15-DAY) | Y                  | OT              | 2010MA003629         |                      | 37 YR      | Male       | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tremor; Visual Field Defect | Citalopram Hydrobromide |              |            | S           |              |                    |                 | Purepac      |
|                             | Escitalopram Oxalate    |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                             | Citalopram Hydrobromide |              |            | S           | Oral         | Po                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2010              | 6527205       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20080102116 |                      | 23 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|-----------------|----------------|
| Toxicity To Various Agents                                                                                                                                                                                     | Dextromethorphan Hydrobromide |                    | Y                  | S               | Oral                 |                               |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Escitalopram Oxalate          |                    |                    | S               | Oral                 |                               |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Oct-2010                                                                                                                                                                                                    | 7569986                       | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | A0877887A            |                               | 67 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Coordination Abnormal; Incoherent; Loss Of Personal Independence In Daily Activities; Product Administration Error; Product Prescribing Error; Serum Serotonin Increased; Therapeutic Product Effect Increased | Imitrex                       |                    |                    | S               | Oral                 | 25mg Per Day                  | 6 WEEK          | Glaxosmithkline |                |
|                                                                                                                                                                                                                | Lexapro                       |                    |                    | S               | Oral                 | 20mg Per Day                  |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Remeron                       |                    |                    | S               | Oral                 | 7.5mg At Night                |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Trazodone                     |                    |                    | S               | Oral                 | 50mg At Night                 | 42 DAY          | Not Reported    |                |
|                                                                                                                                                                                                                | Risperdal                     |                    |                    | S               | Oral                 | .25mg At Night                |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Keppra                        |                    |                    | C               | Oral                 | 250mg Twice Per Day           |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Oct-2010                                                                                                                                                                                                    | 7572203                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015768           |                               | 58 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Proteinuria; Renal Cancer Stage I                                                                                                                                                                              | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 25-Oct-2010                                                                                                                                                                                                    | 7582173                       | EXPEDITED (15-DAY) | Y                  | OT              | 1000015919           |                               | 56 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |                |
| Constipation; Depression; Dizziness; Dry Mouth; Erection Increased; Fatigue; Increased Appetite; Muscular                                                                                                      | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Clonazepam                    |                    |                    | S               | Oral                 | 1 Mg (1 Mg,1 In 1 D),Oral     |                 | Not Reported    |                |
|                                                                                                                                                                                                                | Seroquel                      |                    |                    | S               | Oral                 | 200 Mg (200 Mg, 1 In 1 D),    |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                                                                                                   |   |      |      |                                    |              |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---|------|------|------------------------------------|--------------|
| Weakness; Nausea;<br>Somnolence; Suicidal<br>Ideation; Tinnitus; Tremor;<br>Weight Increased | Wellbutrin XI                                                                                     | S | Oral | Oral | 300 Mg (300 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                              | Echinacea Purpurea                                                                                | C |      |      |                                    | Not Reported |
|                                                                                              | Horse Chestnut Extract<br>(Aesculus Hippocastanum<br>Extract) (Aesculus<br>Hippocastanum Extrate) | C |      |      |                                    | Not Reported |
|                                                                                              | Milk Thistle                                                                                      | C |      |      |                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2010              | 7631869       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016422           |                      | 47 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|-------------------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Depression | Escitalopram Oxalate                                                    |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                     | Seresta (Oxazepam)<br>(Oxazepam)                                        |              |            | C           |              |                                  |                 | Not Reported |
|                                     | Zolpidem (Zolpidem (Zolpidem<br>Naltrexone (Naltrexone)<br>(Naltrexone) |              |            | C           |              |                                  |                 | Not Reported |
|                                     |                                                                         |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2010              | 7644503       | EXPEDITED (15-DAY) | Y                  | OT              | 1000016467           |                      | 33 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Colitis Ulcerative    | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Oct-2010              | 7652445       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016548           |                      | 17 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                           |   |      |                      |              |
|-------------------------|---------------------------|---|------|----------------------|--------------|
| Drug Abuse; Tachycardia | Escitalopram Oxalate      | S | Oral | 20 Mg, Once), Oral   | Not Reported |
|                         | Seroquel                  | S | Oral | (100 Mg, Once), Oral | Not Reported |
|                         | Pipamperone Hydrochloride | S | Oral | (40 Mg, Once), Oral  | Not Reported |

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 25-Oct-2010                                                                                                                 | 7660515                 | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | 1000016611           |                                    | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Incoherent; Loss Of<br>Personal Independence In<br>Daily Activities; Serum<br>Serotonin Increased | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                                                             | Imitrex                 |                    |                    | S               | Oral                 | 25 Mg (25 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                                                             | Remeron                 |                    |                    | S               | Oral                 | 7.5 Mg (7.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                             | Trazodone Hydrochloride |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                                                             | Risperdal               |                    |                    | S               | Oral                 | .25 Mg (.25 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                             | Keppra                  |                    |                    | C               |                      |                                    |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 25-Oct-2010                                                                   | 7672562              | EXPEDITED (15-DAY) | Y                  | HO              | 1000014434           |                                  | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product<br>Misuse; Suicide Attempt;<br>Toxicity To Various Agents | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                               | Atarax               |                    |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Oct-2010              | 7672593        | EXPEDITED (15-DAY) | Y                  | OT              | 1000016816           |                      | 35 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                       |                                                                    |                    |                    |                                  |                           |                                  |                 |            |                |
|-----------------------------------------------------------------------|--------------------------------------------------------------------|--------------------|--------------------|----------------------------------|---------------------------|----------------------------------|-----------------|------------|----------------|
| Blood Alcohol Increased;<br>Impaired Driving Ability                  | Lexapro                                                            | S                  | Oral               | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported              |                                  |                 |            |                |
|                                                                       | Alcohol (Ethanol)                                                  | S                  |                    |                                  | Not Reported              |                                  |                 |            |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2010                                                           | 7672883                                                            | EXPEDITED (15-DAY) | Y                  | OT                               | 1000016932                |                                  | 47 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Multiple Sclerosis Relapse                                            | Escitalopram Oxalate                                               |                    |                    | S                                | Oral                      | 15 Mg (15 Mg,1 In 1<br>D),Oral   |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Oct-2010                                                           | 7611133                                                            | EXPEDITED (15-DAY) | Y                  | OT                               | 1000016223                |                                  |                 | Male       | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Interaction; Myositis;<br>Tendonitis                             | Escitalopram Oxalate                                               |                    |                    | S                                | Oral                      | 5-10 Mg Daily, Oral              |                 |            | Not Reported   |
|                                                                       | Azilect                                                            |                    |                    | S                                | Oral                      | 1 Mg (1 Mg, 1 In 1 D), Oral      |                 |            | Not Reported   |
|                                                                       | Lipitor                                                            |                    |                    | S                                | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 |            | Not Reported   |
|                                                                       | Sinemet                                                            |                    |                    | C                                |                           |                                  |                 |            | Not Reported   |
|                                                                       | Requip (Ropinirole<br>Hydrochloride) (Ropinirold<br>Hydrochloride) |                    |                    | C                                |                           |                                  |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                  | <u>Mfr Control #</u>      | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Oct-2010                                                           | 7639727                                                            | EXPEDITED (15-DAY) | Y                  | OT                               | IT-JNJFOC-<br>20101005478 |                                  | 63 YR           | Female     | ITA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                      | <u>Route</u>              | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u> |                |
| Hypotension; Intentional<br>Self-Injury; Sluggishness;<br>Tachycardia | Risperdal                                                          |                    |                    | S                                | Oral                      |                                  |                 |            | Not Reported   |
|                                                                       | Ciprallex                                                          |                    |                    | S                                | Oral                      |                                  |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|--------------|----------------|
| 26-Oct-2010                                                       | 7651830                         | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJCH-2008001005  |                                              | 23 YR           | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                        | Dextromethorphan Hydrobromide   |                    | Y                  | S               | Oral                 | Text:Unspecified                             |                 | Not Reported |                |
|                                                                   | Escitalopram Oxalate            |                    |                    | S               | Oral                 | Text:Unspecified                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2010                                                       | 7673502                         | EXPEDITED (15-DAY) | N                  | OT              | 1000016879           |                                              | 64 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Abnormal Behaviour; Delirium; Hallucination       | Memantine Hydrochloride         |                    |                    | S               | Oral                 | 2 Dosage Form (2 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                   | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 1 Dosage Form (1 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2010                                                       | 7673512                         | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016909           |                                              |                 | Male         | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Memory Impairment; Overdose                                       | Escitalopram Oxalate            |                    |                    | S               | Oral                 | Oral ; 30 Mg (30 Mg,1 In 1 D),Oral           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2010                                                       | 7674103                         | EXPEDITED (15-DAY) | Y                  | HO              | 1000016336           |                                              | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Fall; Gait Disturbance; Orthostatic Hypotension | Escitalopram Oxalate            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                |                 | Not Reported |                |
|                                                                   | Tareg (Valsartan) (Valsartan)   |                    |                    | C               |                      |                                              |                 | Not Reported |                |
|                                                                   | Eupressyl (Urapidil) (Urapidil) |                    |                    | C               |                      |                                              |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                   |   |  |              |
|--|-----------------------------------|---|--|--------------|
|  | Seresta (Oxazepam)                | C |  | Not Reported |
|  | (Oxazepam)                        |   |  |              |
|  | Modopar (Madopar) (Madopar)       | C |  | Not Reported |
|  | Kardegic (Acetylsalicylate        | C |  | Not Reported |
|  | Lysine) (Acetylsalicylate Lysine) |   |  |              |
|  | Trivastal (Piribedil) (Piribedil) | C |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2010              | 7674261       | EXPEDITED (15-DAY) | Y                  | DS              | 1000016867           |                      | 47 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Cognitive Disorder;<br>Disturbance In Attention;<br>Hypersomnia; Memory<br>Impairment | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2010              | 7674422       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000015082           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Cholangitis; Hepatitis;<br>Pancreatic Carcinoma | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral  |                 | Not Reported |
|                                                 | Lyrica               |              |            | S           | Oral         | 75 Mg (75 Mg,1 In 1<br>D),Oral  |                 | Not Reported |
|                                                 | Lyrica               |              |            | S           | Oral         | 150 Mg (50 Mg,3 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2010              | 7674554       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016884           |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Caesarean Section;<br>Cerebral Haemorrhage<br>Neonatal; Cerebral | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg,1 In 1),<br>Transplacental |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Ventricle Dilatation;  
Hydrocephalus; Maternal  
Drugs Affecting Foetus;  
Premature Baby

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 27-Oct-2010                                                                                                                                     | 7677519                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000016882           |                                | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Artificial Rupture Of<br>Membranes; Caesarean<br>Section; HELL Syndrome;<br>Maternal Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Pregnancy | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                                                                     | 7461735                  | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | GB-TEVA-239925ISR    |                                |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Maternal<br>Exposure During<br>Pregnancy                                                                                          | Sertraline Hydrochloride |                    |                    | S               | Transplacental       |                                |                 | Ivax         |                |
|                                                                                                                                                 | Escitalopram Oxalate     |                    |                    | S               | Transplacental       |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                                                                     | 7499650                  | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | GER/UKI/10/0013960   |                                |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Anomaly;<br>Foetal Death; Hypoxic-<br>Ischaemic                                                                                      | Sertraline Hydrochloride |                    |                    | S               | Transplacental       | 100 Mg, Transplacental         |                 | Not Reported |                |
| Encephalopathy; Maternal<br>Drugs Affecting Foetus;<br>Thymus Disorder;<br>Umbilical Cord<br>Abnormality                                        | Cipralax                 |                    |                    | S               | Transplacental       | 20 Mg, Transplacental          |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 28-Oct-2010                                                                                                                                                          | 7644436                   | EXPEDITED (15-DAY) | N                  | OT              | ZA-JNJFOC-20101005149 |                      | 7 YR            | Female       | ZAF            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Asthenia; Derealisation;<br>Diarrhoea; Faeces<br>Discoloured; Irritability;<br>Mood Swings; Nausea;<br>Syncope; Vomiting                    | Concerta                  |                    |                    | S               | Oral                  | 1 In Mane            |                 | Not Reported |                |
|                                                                                                                                                                      | Ciprallex                 |                    |                    | S               | Unknown               | Mane                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                                                                                          | 7645580                   | EXPEDITED (15-DAY) | Y                  | DE              | US-WYE-H13730310      |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                                    | Venlafaxine Hydrochloride |                    |                    | S               | Oral                  | Unknown              |                 | Wyeth        |                |
|                                                                                                                                                                      | Citalopram                |                    |                    | S               | Oral                  | Unknown              |                 | Unknown      |                |
|                                                                                                                                                                      | Alcohol                   |                    |                    | S               | Oral                  | Unknown              |                 | Unknown      |                |
|                                                                                                                                                                      | Escitalopram Oxalate      |                    |                    | S               | Oral                  | Unknown              |                 | Unknown      |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                                                                                          | 7645793                   | NON-EXPEDITED      | N                  |                 | US-WYE-H14973210      |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Apathy; Blood<br>Pressure Increased; Drug<br>Withdrawal Syndrome;<br>Hyperhidrosis; Panic<br>Attack; Somnolence;<br>Therapeutic Product Effect<br>Decreased | Venlafaxine Hydrochloride |                    |                    | S               | Oral                  |                      |                 | Wyeth        |                |
|                                                                                                                                                                      | Venlafaxine Hydrochloride |                    |                    | S               | Oral                  |                      |                 | Wyeth        |                |
|                                                                                                                                                                      | Pristiq Extended Release  |                    |                    | S               | Oral                  |                      |                 | Wyeth        |                |
|                                                                                                                                                                      | Pristiq Extended Release  |                    |                    | S               |                       |                      |                 | Wyeth        |                |
|                                                                                                                                                                      | Lexapro                   |                    |                    | S               | Oral                  |                      |                 | Lundbeck     |                |
|                                                                                                                                                                      | Lexapro                   |                    |                    | S               | Oral                  |                      |                 | Lundbeck     |                |
|                                                                                                                                                                      | Lexapro                   |                    |                    | S               |                       | Dose Was Reduced In  |                 | Lundbeck     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                     |                |                    |                    |                 |                    |                      |                              |                          |              |                |
|-------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------|----------------------|------------------------------|--------------------------|--------------|----------------|
| Premarin<br>Bupropion Hydrochloride |                |                    | C<br>C             |                 | Order To Taper Off |                      |                              | Wyeth<br>Glaxosmithkline |              |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                    | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>               | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                         | 7646390        | NON-EXPEDITED      | Y                  |                 |                    | US-WYE-H18305410     |                              | 56 YR                    | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u>          | <u>Mfr</u>   |                |
| Rash                                | Protonix       |                    |                    |                 | S                  | Oral                 |                              |                          | Wyeth        |                |
|                                     | Coumadin       |                    |                    |                 | S                  |                      | Unspecified Dose, Once Daily |                          | Not Reported |                |
|                                     | Coumadin       |                    |                    |                 | S                  |                      |                              |                          | Not Reported |                |
|                                     | Lexapro        |                    |                    |                 | S                  | Oral                 |                              |                          | Lundbeck     |                |
|                                     | Vitamins Nos   |                    |                    |                 | C                  |                      |                              |                          | Unknown      |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                    | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>               | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                         | 7665305        | DIRECT             | Y                  | DS, OT          |                    |                      |                              | 57 YR                    | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u>          | <u>Mfr</u>   |                |
| Memory Impairment                   | Lexapro        |                    |                    |                 | S                  | Oral                 | 60 Mg Daily Oral             |                          | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                    | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>               | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                         | 7670105        | DIRECT             | Y                  | DE              |                    |                      |                              | 47 YR                    | Male         | USA            |
| <u>Preferred Term</u>               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u>          | <u>Mfr</u>   |                |
| Completed Suicide; Gun Shot Wound   | Lexapro        |                    |                    |                 | S                  | Oral                 | 20mg 1 Daily P.O.            |                          | Forest       |                |
| <u>FDA Received Date</u>            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> |                    | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>               | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                         | 7676779        | EXPEDITED (15-DAY) | Y                  | HO              |                    | 1000016670           |                              | 76 YR                    | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u>          | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                      |                      |                    |                    |                 |                                  |                                                            |                 |              |                |
|------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| Psychotic Disorder;<br>Suicide Attempt                                                               | Escitalopram Oxalate |                    | S                  | Oral            | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                                                            | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                          | 7739453              | EXPEDITED (15-DAY) | N                  | CA              | 1000016968                       |                                                            | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary<br>Valve Atresia; Maternal<br>Drugs Affecting Foetus;<br>Ventricular Hypoplasia | Lexapro              |                    |                    | S               | Transplacental                   | Transplacental                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Oct-2010                                                                                          | 7764850              | NON-EXPEDITED      | Y                  | OT              | DSA_41897_2009                   |                                                            | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hostility; Suicidal Ideation                                                                         | Wellbutrin           |                    |                    | S               | Oral                             | (150 Mg Every Morning<br>And 100 Mg Every<br>Evening Oral) |                 | Not Reported |                |
|                                                                                                      | Lexapro              |                    |                    | S               | Oral                             | (10 Mg Qd Oral)                                            |                 | Not Reported |                |
|                                                                                                      | Lyrica               |                    |                    | S               |                                  | (Df)                                                       |                 | Not Reported |                |
|                                                                                                      | Lunesta              |                    |                    | C               |                                  |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2010                                                                                          | 7461876              | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2010GB07270                  |                                                            | 26 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Maternal<br>Exposure During<br>Pregnancy                                               | Sertraline           |                    |                    | S               | Unknown                          | 100 Mg, Unk                                                |                 | Novartis     |                |
|                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Unknown                          | 20 Mg, Unk                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2010                                                                                          | 7582129              | EXPEDITED (15-DAY) | N                  |                 | 1000015922                       |                                                            | 55 YR           | Male         | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Delusion; Heart Rate Increased; Nausea; Nervousness; Panic Attack; Speech Disorder                                                                                                                                                                   | Escitalopram Oxalate                             |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Lorazepam                                        |                    |                    | C               |                      |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                      | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2010                                                                                                                                                                                                                                                   | 7649785                                          | EXPEDITED (15-DAY) | Y                  | DE              | GXKR2010US11935      |                                                            | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Cardiac Arrest; Cardiac Pacemaker Insertion; Cardioversion; Circulatory Collapse; Coma; Endotracheal Intubation; Long Qt Syndrome; Loss Of Consciousness; Malaise; Mechanical Ventilation; Sinus Rhythm; Torsade De Pointes; Ventricular Fibrillation | Fluoxetine                                       |                    |                    | S               | Unknown              |                                                            |                 | Novartis     |                |
|                                                                                                                                                                                                                                                               | Escitalopram Oxalate                             |                    |                    | S               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Trazodone                                        |                    |                    | S               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Buspirone                                        |                    |                    | C               | Unknown              |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               | Temazepam                                        |                    |                    | C               | Unknown              |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                      | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2010                                                                                                                                                                                                                                                   | 7684316                                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000016994           |                                                            | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                         | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anuria; Dysuria                                                                                                                                                                                                                                               | Escitalopram Oxalate                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                               |                                                  |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                                                                                               | Pariet (Rabeprazole Sodium) (Rabeprazole Sodium) |                    |                    | C               |                      |                                                            |                 | Not Reported |                |
| Xanax                                                                                                                                                                                                                                                         |                                                  |                    | C                  |                 |                      |                                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
| 29-Oct-2010                                                                                                                         | 7684321                                      | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000015734           |                                            | 41 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Condition Aggravated;<br>Depression                                                                           | Escitalopram Oxalate                         |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral           |                 | Not Reported |                |
|                                                                                                                                     | Imovane (Zopiclone) (Tablets)<br>(Zopiclone) |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                                                                                     | Lysanxia (Prazepam) (Tablets)<br>(Prazepam)  |                    |                    | C               |                      |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Oct-2010                                                                                                                         | 7839480                                      | EXPEDITED (15-DAY) | Y                  | OT              | 1000015996           |                                            | 152 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Foetal<br>Growth Restriction; Foetal<br>Heart Rate Deceleration<br>Abnormality; Maternal<br>Drugs Affecting Foetus | Escitalopram Oxalate                         |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Oct-2010                                                                                                                         | 7651036                                      | NON-EXPEDITED      | N                  |                 | US-WYE-H17330910     |                                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal<br>Syndrome; Headache                                                                                               | Pristiq Extended Release                     |                    |                    | S               |                      | Unspecified                                |                 | Wyeth        |                |
|                                                                                                                                     | Lexapro                                      |                    |                    | S               |                      | Unspecified                                |                 | Lundbeck     |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Nov-2010                                                                                                                         | 7238723                                      | EXPEDITED (15-DAY) | Y                  | DE              | 1000010771           |                                            | 29 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |                                                                       |   |      |                                                                |              |
|---------------------------------------------------------------|-----------------------------------------------------------------------|---|------|----------------------------------------------------------------|--------------|
| Completed Suicide;<br>Therapeutic Product Effect<br>Decreased | Lexapro                                                               | S | Oral | 5 Mg (5 Mg,1 In 1 D), Oral<br>; 10 Mg (10 Mg,1 In 1<br>D),Oral | Not Reported |
|                                                               |                                                                       |   | Oral | 5 Mg (5 Mg,1 In 1 D), Oral<br>; 10 Mg (10 Mg,1 In 1<br>D),Oral |              |
|                                                               | Effexor                                                               | S | Oral | See Image                                                      | Not Reported |
|                                                               |                                                                       |   | Oral | See Image                                                      |              |
|                                                               |                                                                       |   | Oral | See Image                                                      |              |
|                                                               | Zoloft (Sertraline) (Sertraline)                                      | C |      |                                                                | Not Reported |
|                                                               | Eryacne (Erythromycin) (Gel)<br>(Erythromycin)                        | C |      |                                                                | Not Reported |
|                                                               | Herbs (Herbals Nos W/Vitamins<br>Nos) (Herbals Nos W/Vitamins<br>Nos) | C |      |                                                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2010              | 7420487       | EXPEDITED (15-DAY) | Y                  |                 | 1000014312           |                      | 62 YR      | Female     | DNK            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Burning Sensation;<br>Paraesthesia | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 01-Nov-2010              | 7652661       | EXPEDITED (15-DAY) | Y                  | DE              | US-MYLANLABS-<br>2010S1019384 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Long Qt<br>Syndrome; Sinus<br>Tachycardia; Torsade De<br>Pointes | Trazodone            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Fluoxetine           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Temazepam            |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                  | Buspirone            |              |            | C           | Unknown      |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 01-Nov-2010              | 7674391        | DIRECT           | N                  | DE, OT          |                      |                                    |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Effexor        |                  |                    | S               |                      | Sample Capsules<br>Sample Capsules |                 | Not Reported |                |
|                          | Cymbalta       |                  |                    | S               |                      |                                    |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                      |                                    |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 02-Nov-2010                                                                                                                   | 7575852                                                    | EXPEDITED (15-DAY) | N                  | HO, OT          | 1000015338           |                               | 80 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Compulsive Shopping; Hostility; Mania; Paranoia; Refusal Of Treatment By Patient; Restlessness; Suicidal Ideation | Lexapro                                                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                               | Allopurinol                                                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Baby Aspirin (Acetylsalicylic Acid) (Acetylsalicylic Acid) |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Potassium (Potassium) (Potassium)                          |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                               | Amilonde (Amlodipine) (Amlodipine)                         |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 02-Nov-2010              | 7631871                               | EXPEDITED (15-DAY) | Y                  |                 | 1000016414           |                               | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Vomiting                 | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Practazin (Aldactazine) (Aldactazine) |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|---------------------------------|-----------------|--------------|----------------|
| 02-Nov-2010                                                                                                       | 7640373                 | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000016547                               |                                 | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Sounds Abnormal; Hypotension; Intentional Overdose; Seizure; Sopor; Suicide Attempt; Tachycardia | Escitalopram Oxalate    |                    |                    | S               | Oral                                     | (240 Mg,Once),Oral              |                 | Not Reported |                |
|                                                                                                                   | Seroquel                |                    |                    | S               | Oral                                     | (12000 Mg,Once),Oral            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2010                                                                                                       | 7653217                 | EXPEDITED (15-DAY) | Y                  | DE              | US-BRISTOL-MYERS SQUIBB COMPANY-15349954 |                                 | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Long Qt Syndrome; Torsade De Pointes                                                                              | Trazodone Hydrochloride |                    |                    | S               |                                          |                                 |                 | Apothecon    |                |
|                                                                                                                   | Buspirone               |                    |                    | S               |                                          |                                 |                 | Not Reported |                |
|                                                                                                                   | Fluoxetine              |                    |                    | S               |                                          |                                 |                 | Not Reported |                |
|                                                                                                                   | Escitalopram Oxalate    |                    |                    | S               |                                          |                                 |                 | Not Reported |                |
|                                                                                                                   | Temazepam               |                    |                    | S               |                                          |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2010                                                                                                       | 7653381                 | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010134762                 |                                 | 41 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Fatigue; Knee Arthroplasty; Somnolence; Suicidal Behaviour; Surgery                             | Zoloft                  |                    |                    | S               | Oral                                     | 100 Mg, Unk                     |                 | Pfizer       |                |
|                                                                                                                   | Lexapro                 |                    |                    | S               | Oral                                     | 20mg, One And A Half Pill Daily |                 | Not Reported |                |
|                                                                                                                   | Cymbalta                |                    |                    | S               | Oral                                     | 60 Mg, 1x/Day                   |                 | Not Reported |                |
|                                                                                                                   | Wellbutrin              |                    |                    | S               | Oral                                     | Unk                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2010                                                                                                       | 7653693                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-JNJFOC-20101006755                    |                                 | < 1 DAY         | Male         | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Apparent Death; Jaundice;<br>Neonatal Respiratory<br>Distress Syndrome;<br>Premature Baby | Haldol               |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Tegretol             |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Escitalopram Oxalate |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Tranxene T-Tab       |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Cyamemazine          |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Folic Acid           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                           | Aldomet              |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2010              | 7653694       | EXPEDITED (15-DAY) | Y                  | OT              | FR-JNJFOC-20101006733 |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Maternal Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Premature<br>Labour | Haldol               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                               | Tegretol             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                               | Tranxene T-Tab       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                               | Cyamemazine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                               | Folic Acid           |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Aldomet              |              |            | C           |              |                    |                 | Not Reported |
|                                                                               | Aldomet              |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2010              | 7653975       | EXPEDITED (15-DAY) | Y                  | HO, LT          | PHHY2010FR72790      |                      |            | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Apparent Death; Foetal<br>Arrhythmia; Foetal<br>Distress Syndrome;<br>Jaundice Neonatal;<br>Maternal Exposure During<br>Pregnancy; Neonatal | Tegretol Lp          |              |            | S           | Transplacental | 200 Mg/Day         |                 | Novartis     |
|                                                                                                                                             | Escitalopram Oxalate |              |            | S           | Transplacental | 5 Mg/Day           |                 | Not Reported |
|                                                                                                                                             | Tranxene T-Tab       |              |            | S           | Transplacental | 15 Mg/Day          |                 | Not Reported |
|                                                                                                                                             | Cyamemazine          |              |            | S           | Transplacental | 90 Mg/MI Daily     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                          |                    |                    |                 |                              |                      |                 |              |                |
|----------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Respiratory Distress Syndrome; Premature Baby; Respiratory Distress                          |                          |                    | Haldol             | S               | Transplacental               | 5 Mg/Day             | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2010                                                                                  | 7654182                  | NON-EXPEDITED      | N                  |                 | US-ABBOTT-10P-163-0654328-00 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Ear Infection; Fatigue                                                              | Biaxin                   |                    |                    | S               | Other                        |                      |                 | Not Reported |                |
|                                                                                              | Lexapro                  |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Nov-2010                                                                                  | 7678916                  | DIRECT             | N                  |                 |                              |                      | 25 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                                                                                        | Lexapro                  |                    |                    | S               | Oral                         | 20mg Qam Po          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2010                                                                                  | 7466287                  | EXPEDITED (15-DAY) | N                  | HO, OT          | GB-WATSON-2010-09064         |                      | 26 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death                                                                                 | Sertraline Hydrochloride |                    |                    | S               | Transplacental               | 100 Mg, Unk          |                 | Watson       |                |
|                                                                                              | Ciprallex                |                    |                    | S               | Transplacental               | 20 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Nov-2010                                                                                  | 7476863                  | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | GB-MYLANLABS-2010S1011808    |                      |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Breech Presentation; Encephalopathy; Foetal Death; Maternal Drugs Affecting Foetus; Maternal | Sertraline Hydrochloride |                    |                    | S               | Transplacental               |                      |                 | Genpharm     |                |
|                                                                                              | Ciprallex                |                    |                    | S               | Transplacental               |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During  
Pregnancy; Umbilical Cord  
Abnormality

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2010              | 7523670       | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2010AP001416         |                      |            | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Breech Presentation;<br>Foetal Death; Foetal<br>Disorder; Hypoxic-<br>Ischaemic<br>Encephalopathy; Maternal<br>Drugs Affecting Foetus | Sertraline Hydrochloride |              |            | S           | Transplacental | 100 Mg; Trpl       |                 | Not Reported |
|                                                                                                                                       | Cipralext                |              |            | S           | Transplacental | 20 Mg;Trpl         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2010              | 7619152       | EXPEDITED (15-DAY) | Y                  | DE              | 1000016294           |                      | 78 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u>                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Death                 | Memantine Hydrochloride                              |              |            | S           | Oral         | 20 Mg (20 Mg,2 In 1 D),Oral |                 | Not Reported |
|                       | Escitalopram Oxalate                                 |              |            | S           |              | 10 Mg (10 Mg,1 In 1 D)      |                 | Not Reported |
|                       | Amisulpride (Amisulpride)<br>(Tablets) (Amisulpride) |              |            | C           |              |                             |                 | Not Reported |
|                       | Travoprost (Travoprost)<br>(Travoprost)              |              |            | C           |              |                             |                 | Not Reported |
|                       | Dorzolamide/Timolol<br>(Dorzolamide, Timolol)        |              |            | C           |              |                             |                 | Not Reported |
|                       | (Dorzolamide, Timolol)                               |              |            |             |              |                             |                 |              |
|                       | Brinzolamide (Brinzolamide)<br>(Brinzolamide)        |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2010              | 7635535       | EXPEDITED (15-DAY) | N                  | HO              | 1000016469           |                      | 93 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                                                              |   |      |                               |              |
|-------------------------------------------------------------|--------------------------------------------------------------|---|------|-------------------------------|--------------|
| Anal Incontinence;<br>Dyspnoea; Malaise;<br>Nausea; Seizure | Lexapro                                                      | S | Oral | 2.5 Mg (2.5 Mg,1 In 1 D),Oral | Not Reported |
|                                                             | Temazepam                                                    | C |      |                               | Not Reported |
|                                                             | Pantoprazole Sodium                                          | C |      |                               | Not Reported |
|                                                             | Prochlorperazine<br>(Prochlorperazine)<br>(Prochlorperazine) | C |      |                               | Not Reported |
|                                                             | Perindopril (Perindopril)<br>(Perindopril)                   | C |      |                               | Not Reported |
|                                                             | Cranberry (Ascorbic Acid)<br>(Ascorbic Acid)                 | C |      |                               | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-----------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------|----------------|
| 03-Nov-2010                             | 7664659                                | EXPEDITED (15-DAY) | N                  | OT              | 1000012211           |                                                                                                                    | 63 YR           | Female                       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Retinal Detachment;<br>Weight Increased | Lexapro                                |                    |                    | S               | Oral                 | 520 Mg (20 Mg, 1 In 1 D)<br>Oral                                                                                   |                 | Not Reported                 |                |
|                                         | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                                                   |                 | Not Reported                 |                |
|                                         | Lexapro                                |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral<br>2.5 Mg (5 Mg, Qod), Oral<br>5 Mg (5 Mg, 1 In 1 D), Oral<br>2.5 Mg (5 Mg, Qod), Oral |                 | Not Reported                 |                |
|                                         | Lamictal<br>Simvastatin (10 Milligram) |                    |                    | C<br>C          |                      |                                                                                                                    |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 03-Nov-2010                                                              | 7688227              | EXPEDITED (15-DAY) | Y                  | DS              | 1000017014           |                                                              | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Neuralgia; Paraesthesia;<br>Trigeminal Neuralgia;<br>Withdrawal Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral ; (5 Mg,1 In 1 Wk),Oral<br>Oral ; (5 Mg,1 In 1 Wk),Oral |                 | Not Reported |                |
|                                                                          | Chlorphenamine       |                    |                    | C               |                      |                                                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |              |
|--------------------------------|---|--------------|
| (Chlorphenamine Maleate)       |   |              |
| (Chlorphenamine Maleate)       |   |              |
| Aspirin                        | C | Not Reported |
| Quinine (Quinine Sulphate)     | C | Not Reported |
| (Quinine Sulphate)             |   |              |
| Simvastatin                    | C | Not Reported |
| Ventolin (Salbutamol Sulphate) | C | Not Reported |
| (Salbutamol Sulphate)          |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2010              | 7690193       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2010-02633   |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt; Toxicity<br>To Various Agents | Zolpidem             |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                | Lamotrigine          |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                | Ibuprofen            |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                | Alprazolam           |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                | Ramelteon            |              |            | C           | Oral         | Oral               |                 | Not Reported |
|                                                | Zaleplon             |              |            | C           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Nov-2010              | 7733231       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000013743           |                      | 41 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                   | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Anxiety; Back Pain; Blood<br>Glucose Abnormal; Blood<br>Pressure Decreased; Drug<br>Ineffective; Fatigue; Hot<br>Flush; Hyperhidrosis;<br>Insomnia; Irritability;<br>Listless; Panic Attack;<br>Paraesthesia;<br>Restlessness;<br>Tachycardia; Tension; | Escitalopram Oxalate                          |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 15 Mg (15 Mg,1<br>In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Zopiclon (Zopiclone) (Tablets)<br>(Zopiclone) |              |            | C           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral ; 15 Mg (15 Mg,1<br>In 1 D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Thinking Abnormal;  
Tremor; Uterine  
Leiomyoma; Weight  
Increased; Yawning

| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------|-----------------|--------------|----------------|
| 04-Nov-2010                                                                                                                                   | 7418378                                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000014256               |                                  | 57 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Muscular Weakness; Off Label Use; Paraesthesia; Tremor                                                                             | Escitalopram Oxalate                              |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                                                               | Chondroprotective Drugs (Chondroprotective Drugs) |                    |                    | C               |                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2010                                                                                                                                   | 7472328                                           | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | GB-RANBAXY-2010RR-35623  |                                  |                 | Unknown      | GBR            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Thymus Disorder; Umbilical Cord Abnormality; Viral Infection | Sertraline Hydrochloride                          |                    |                    | S               | Transplacental           | 100 Mg, Unk                      |                 | Ranbaxy      |                |
|                                                                                                                                               | Cipralext                                         |                    |                    | S               | Transplacental           | 20 Mg, Unk                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2010                                                                                                                                   | 7613334                                           | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010119896 |                                  | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hypotension; Syncope                                                                                                        | Viagra                                            |                    |                    | S               | Oral                     | 100 Mg, As Needed                |                 | Pfizer       |                |
|                                                                                                                                               | Simvastatin                                       |                    |                    | C               |                          | 40 Mg, 1x/Day (At Night)         |                 | Not Reported |                |
|                                                                                                                                               | Plavix                                            |                    |                    | C               |                          | 75 Mg, 1x/Day (1 In The Morning) |                 | Not Reported |                |



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |      |                                         |              |
|--------------|---|------|-----------------------------------------|--------------|
| Lorazepam    | C |      | 1 Or 1.5 As Needed                      | Not Reported |
| Ranibizumab  | C |      | Unk In Each Eye                         | Not Reported |
| Vitamin C    | C |      | 500 Mg, 1x/Day (In The Morning)         | Not Reported |
| Vitamin D2   | C |      | 1000 Iu, 1x/Day                         | Not Reported |
| Selenium     | C |      | 200 Mg, 1x/Day (In The Morning)         | Not Reported |
| Vitamins Nos | C |      | Unk                                     | Not Reported |
| Magnesium    | C |      | Unk                                     | Not Reported |
| Viagra       | S | Oral | 50 Mg, As Needed                        | Pfizer       |
| Lisinopril   | S |      | 10 Mg (2 In The Morning And 1 At Night) | Not Reported |
| Lexapro      | S | Oral | 20 Mg, Daily                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2010              | 7656365       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2010FR72833      |                      |            | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Caesarean Section;<br>Hyperalbuminaemia;<br>Maternal Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Premature<br>Labour | Tegretol Lp          |              |            | S           | Oral         | 200 Mg/Day         |                 | Novartis     |
|                                                                                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg/Day           |                 | Not Reported |
|                                                                                                                           | Tranxene T-Tab       |              |            | S           | Oral         | 15 Mg/Day          |                 | Not Reported |
|                                                                                                                           | Cyamemazine          |              |            | S           |              | 90 Mg/MI Daily     |                 | Not Reported |
|                                                                                                                           | Haldol               |              |            | S           | Oral         | 5 Mg/Day           |                 | Not Reported |
|                                                                                                                           | Abilify              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                           | Folic Acid           |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2010              | 7688879       | EXPEDITED (15-DAY) | N                  | HO              | 1000016988           |                      | 93 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |                                        |   |      |                                    |              |
|-----------------|----------------------------------------|---|------|------------------------------------|--------------|
| Nausea; Seizure | Lexapro                                | S | Oral | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                 | Temazepam                              | C |      |                                    | Not Reported |
|                 | Pantoprazole Sodium                    | C |      |                                    | Not Reported |
|                 | Prochlorperazine<br>(Prochlorperazine) | C |      |                                    | Not Reported |
|                 | Perindopril (Perindopril)              | C |      |                                    | Not Reported |
|                 | Cranberry (Cranberry)                  | C |      |                                    | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                         | <u>Case #</u>                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------------|----------------|
| 04-Nov-2010                                                                                                                                                      | 7688945                                                             | EXPEDITED (15-DAY) | N                  | HO, RI, OT      | 1000017062           |                      | 25 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                            | <u>Product</u>                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Chest Discomfort; Death<br>Of Relative; Dizziness;<br>Fatigue; Job<br>Dissatisfaction; Motion<br>Sickness; Nausea;<br>Suicidal Ideation; Vitamin<br>D Deficiency | Escitalopram Oxalate<br>Gestiny! (Gestiny!) (Tablets)<br>(Gestiny!) |                    |                    | S<br>C          |                      |                      |                 | Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>                                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 04-Nov-2010                                                                               | 7688992                                                                               | EXPEDITED (15-DAY) | Y                  | HO              | 1000017009           |                                                                                     |                 | Female                                       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>                                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Discomfort; Intentional<br>Overdose; Product<br>Prescribing Error; Sense<br>Of Oppression | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Tercian 9cyamemazine<br>(Cyamemazine) |                    |                    | S<br>S<br>C     | Oral<br>Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral, 200 Mg, Once, Oral<br>5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2010              | 7498436       | EXPEDITED (15-DAY) | Y                  | OT              | 2010MA000442         |                      |            | Female     | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Foetal Death; Forceps Delivery; Induced Labour; Maternal Exposure During Pregnancy; Placental Disorder; Polyhydramnios; Postpartum Haemorrhage    | Sertraline Hydrochloride          |                    |                    | S               |                      | 100 Mg                                                                                    |                 | Not Reported |                |
|                                                                                                                                                   | Ciprallex                         |                    |                    | S               |                      | 20 Mg                                                                                     |                 | Not Reported |                |
|                                                                                                                                                   | Con Meds                          |                    |                    | C               |                      |                                                                                           |                 | Not Reported |                |
|                                                                                                                                                   | Prev Meds                         |                    |                    | C               |                      |                                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2010                                                                                                                                       | 7507528                           | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | AUR-APL-2010-01692   |                                                                                           | 238 DAY         | Female       |                |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death; Forceps Delivery; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Placental Disorder; Umbilical Cord Abnormality | Sertraline Hydrochloride          |                    |                    | S               | Transplacental       | 100mg, Transplacent                                                                       |                 | Not Reported |                |
|                                                                                                                                                   | Ciprallex                         |                    |                    | S               | Transplacental       | 20mg, Transplacent                                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Nov-2010                                                                                                                                       | 7610141                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000016178           |                                                                                           | 37 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Electrocardiogram Qt Prolonged; Mood Altered; Tachycardia; Thinking Abnormal                                                             | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral                                                               |                 | Not Reported |                |
|                                                                                                                                                   | Prazine (Promazine Hydrochloride) |                    |                    | S               | Oral                 | 150 Mg (150 Mg,1 In 1 D),Oral                                                             |                 | Not Reported |                |
|                                                                                                                                                   | Abilify                           |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D)                                                                    |                 | Not Reported |                |
|                                                                                                                                                   | Haldol                            |                    |                    | S               |                      | 9 Mg (3 Mg,3 In 1 D) ; 9 Mg (3 Mg,3 In 1 D) ; 9 Mg (3 Mg,3 In 1 D) ; 9 Mg (3 Mg,3 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                   | Risperdal                         |                    |                    | S               | Oral                 | 4 Mg (2 Mg,2 In 1 D),Oral ;                                                               |                 | Not Reported |                |

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|                                                 |      |                                                                                       |              |
|-------------------------------------------------|------|---------------------------------------------------------------------------------------|--------------|
|                                                 | Oral | 4 Mg (2 Mg,2 In 1 D),Oral<br>4 Mg (2 Mg,2 In 1 D),Oral ;<br>4 Mg (2 Mg,2 In 1 D),Oral |              |
| Stilnox (Zolpidem) (10 Milligram)<br>(Zolpidem) | C    |                                                                                       | Not Reported |
| Rivotril (Clonazepam) (Tablets)<br>(Clonazepam) | C    |                                                                                       | Not Reported |
| Entumin (Clotiapine) (Tablets)<br>(Clotiapine)  | C    |                                                                                       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2010              | 7644609       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000016539           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Depression; Drug Abuse;<br>Intentional Overdose;<br>Nausea; Poisoning;<br>Restlessness | Escitalopram Oxalate        |              |            | S           | Oral         | 40 Mg (40 Mg,Once),Oral ;<br>Oral |                 | Not Reported |
|                                                                                        |                             |              |            |             | Oral         | 40 Mg (40 Mg,Once),Oral ;<br>Oral |                 |              |
|                                                                                        | Levothyroxine Sodium        |              |            | S           | Oral         | (150-200 Mcg, Once),Oral          |                 | Not Reported |
|                                                                                        | Acetaminophen               |              |            | S           | Oral         | (1500 Mg,Once),Oral               |                 | Not Reported |
|                                                                                        | Dienogest\Ethinyl Estradiol |              |            | S           | Oral         | (1 Dosage<br>Forms,Once),Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2010              | 7657779       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2010139371 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract              | Toviaz         |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Xanax          |              |            | S           |              | Unk                |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                       | Levaquin       |              |            | S           |              | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
|-------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------|-----------------|--------------------------|----------------|
| 05-Nov-2010                                                                   | 7658413                                                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-WYE-G06901110     |                                                          | 31 YR           | Female                   | CHE            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>               |                |
| Anxiety; Condition Aggravated; Depression; Maternal Exposure During Pregnancy | Effexor                                                        |                    |                    | S               |                      |                                                          | 136 DAY         | Wyeth                    |                |
|                                                                               | Effexor                                                        |                    |                    | S               |                      |                                                          |                 | Wyeth                    |                |
|                                                                               | Seroquel                                                       |                    |                    | S               |                      |                                                          |                 | Zeneca                   |                |
|                                                                               | Fluctine                                                       |                    |                    | S               |                      | Dose And Frequency Unknown                               |                 | Eli Lilly And Co         |                |
|                                                                               | Zyprexa                                                        |                    |                    | S               |                      | Dose And Frequency Unknown                               |                 | Not Reported             |                |
|                                                                               | Zyprexa<br>Ciprallex                                           |                    |                    | S<br>S          |                      | Dose And Frequency Unknown                               |                 | Not Reported<br>Lundbeck |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 05-Nov-2010                                                                   | 7690686                                                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000016982           |                                                          | 40 YR           | Female                   | DNK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>               |                |
| Ataxia; Head Titubation; Overdose; Polyneuropathy; Serotonin Syndrome         | Escitalopram Oxalate                                           |                    |                    | S               | Oral                 | 30 Mg (30 Mg,1 In 1 D),Oral ;15 Mg (15 Mg,1 In 1 D),Oral |                 | Not Reported             |                |
|                                                                               |                                                                |                    |                    |                 | Oral                 | 30 Mg (30 Mg,1 In 1 D),Oral ;15 Mg (15 Mg,1 In 1 D),Oral |                 |                          |                |
|                                                                               | Venlafaxine                                                    |                    |                    | S               | Oral                 | 75 Mg (75 Mg,1 In 1 D),Oral                              |                 | Not Reported             |                |
|                                                                               | Omeprazol (Omeprazole)                                         |                    |                    | C               |                      |                                                          |                 | Not Reported             |                |
|                                                                               | Folacin (Folic Acid) (Tablets) (Folic Acid)                    |                    |                    | C               |                      |                                                          |                 | Not Reported             |                |
|                                                                               | Propavan (Propiomate Maleate) (Tablets) (Propiomazine Maleate) |                    |                    | C               |                      |                                                          |                 | Not Reported             |                |
|                                                                               | Theralen (Alimemazine Tartrate)                                |                    |                    | C               |                      |                                                          |                 | Not Reported             |                |
|                                                                               |                                                                |                    |                    |                 |                      |                                                          |                 |                          |                |

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|                                  |   |              |
|----------------------------------|---|--------------|
| (Tablets) (Alimemazine Tartrate) |   |              |
| Behepan (Cyanocobalamin)         | C | Not Reported |
| (Tablets) (Cyanocobalamin)       |   |              |
| Stesolid (Diazepam) (Tablets)    | C | Not Reported |
| (Diazepam)                       |   |              |
| Bricanyl (Terbutaline Sulfate)   | C | Not Reported |
| (Terbutaline Sulfate)            |   |              |
| Watan (Watan) (Watan)            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Nov-2010              | 7690819       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017008           |                      | 84 YR      | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Blood Alkaline            | Escitalopram Oxalate           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |
| Phosphatase Increased;    | Oxycodone Hydrochloride        |              |            | C           | Oral         | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |
| Confusional State; Fall;  |                                |              |            |             |              | Oral                     |                 |              |
| Gamma-                    |                                |              |            |             |              |                          |                 |              |
| Glutamyltransferase       | Oxycontin (Oxycodone           |              |            | C           |              |                          |                 | Not Reported |
| Increased; Haemoglobin    | Hydrochloride) (Oxycodone      |              |            |             |              |                          |                 |              |
| Decreased; Liver Function | Hydrochloride)                 |              |            |             |              |                          |                 |              |
| Test Abnormal;            | Omeprazol Sandoz               |              |            | C           |              |                          |                 | Not Reported |
| Subcutaneous              | (Omeprazole) (Omeprazole)      |              |            |             |              |                          |                 |              |
| Emphysema;                | Movicol (Nulytely) (Nulytely)  |              |            | C           |              |                          |                 | Not Reported |
| Transaminases Increased;  | Kalcipos Forte (Calcium        |              |            | C           |              |                          |                 | Not Reported |
| Urinary Tract Infection   | Carbonate) (Calcium Carbonate) |              |            |             |              |                          |                 |              |
|                           | Prednisolon Pfizer             |              |            | C           |              |                          |                 | Not Reported |
|                           | (Prednisolone) (Prednisolon)   |              |            |             |              |                          |                 |              |
|                           | Nitromex (Glycerol)            |              |            | C           |              |                          |                 | Not Reported |
|                           | Optimol (Timolol Maleate)      |              |            | C           |              |                          |                 | Not Reported |
|                           | Timolol Maleate)               |              |            |             |              |                          |                 |              |
|                           | Innohep (Tinzaparin Sodium)    |              |            | C           |              |                          |                 | Not Reported |
|                           | (Tinzaparin Sodium)            |              |            |             |              |                          |                 |              |
|                           | Trombyl (Acetylsalicylic Acid) |              |            | C           |              |                          |                 | Not Reported |
|                           | (Acetylsalicylic Acid)         |              |            |             |              |                          |                 |              |
|                           | Artelac (Hypromellose)         |              |            | C           |              |                          |                 | Not Reported |
|                           | (Hypromellose)                 |              |            |             |              |                          |                 |              |
|                           | Zopiclone Actavis (Zolpiclone) |              |            | C           |              |                          |                 | Not Reported |
|                           | (Zopiclone)                    |              |            |             |              |                          |                 |              |

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| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------------|-----------------|--------------|----------------|
| 05-Nov-2010                                                                                                                                  | 8538811                                                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000017131                 |                                         | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Sphincter Of Oddi Dysfunction                                                                                                                | Lexapro                                                 |                    |                    | S               | Oral                       | 10 Mg (10 Mg,1 In 1 D),Oral             |                 | Not Reported |                |
|                                                                                                                                              | Lexapro                                                 |                    |                    | S               | Oral                       | 15 Mg (15 Mg,1 In 1 D),Oral             |                 | Not Reported |                |
|                                                                                                                                              | Imitrex (Sumatriptan Succinate) (Sumatriptan Succinate) |                    |                    | C               |                            |                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2010                                                                                                                                  | 7521888                                                 | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | 1000015053                 |                                         |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Breech Presentation; Foetal Death; Hypoxic-Ischaemic Encephalopathy; Maternal Drugs Affecting Foetus; Thrombosis; Umbilical Cord Abnormality | Escitalopram Oxalate                                    |                    |                    | S               | Transplacental             | 20 Mg (20 Mg,1 In 1 D),Transplacental   |                 | Not Reported |                |
|                                                                                                                                              | Sertraline Hydrochloride                                |                    |                    | S               | Transplacental             | 100 Mg (100 Mg,1 In 1 D),Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                     | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Nov-2010                                                                                                                                  | 7659833                                                 | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-2010SE51641 |                                         | 73 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemolytic Anaemia                                                                                                                           | Nexium                                                  |                    |                    | S               | Oral                       |                                         |                 | Astrazeneca  |                |
|                                                                                                                                              | Cordarone                                               |                    |                    | S               | Oral                       |                                         |                 | Not Reported |                |
|                                                                                                                                              | Cipralext                                               |                    |                    | S               | Oral                       |                                         |                 | Not Reported |                |
|                                                                                                                                              | Diphenhydramine Hydrochloride\Lorazepam                 |                    |                    | C               |                            |                                         |                 | Not Reported |                |
|                                                                                                                                              | Crestor                                                 |                    |                    | C               |                            |                                         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 08-Nov-2010                                                                                                                                                             | 7690961                                    | EXPEDITED (15-DAY) | Y                  | OT              | 1000015684           |                                   | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Haemorrhage In<br>Pregnancy; Maternal<br>Exposure During<br>Pregnancy; Pregnancy                                                               | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2010                                                                                                                                                             | 7661955                                    | EXPEDITED (15-DAY) | Y                  | DE              | US-WATSON-2010-14485 |                                   | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Coma;<br>Long Qt Syndrome;<br>Torsade De Pointes                                                                                                        | Fluoxetine                                 |                    |                    | S               | Unknown              | Unk                               |                 | Watson       |                |
|                                                                                                                                                                         | Trazodone Hydrochloride                    |                    |                    | S               | Oral                 | Unk                               |                 | Watson       |                |
|                                                                                                                                                                         | Escitalopram Oxalate                       |                    |                    | S               | Unknown              | Unk                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2010                                                                                                                                                             | 7693625                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000017098           |                                   |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Albumin Increased;<br>Caesarean Section;<br>Gestational Hypertension;<br>Maternal Exposure During<br>Pregnancy; Pre-<br>Eclampsia; Pregnancy;<br>Premature Labour | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D) ,Oral       |                 | Not Reported |                |
|                                                                                                                                                                         | Tegretol                                   |                    |                    | S               | Oral                 | 200 Mg (200 Mg, 1in 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                         | Tranxene T-Tab                             |                    |                    | S               | Oral                 | 15 Mg (15mg, 1in 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                         | Cyamemazine                                |                    |                    | S               | Oral                 | 90 Mg (90 Mg, 1in 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                                                                                                                         | Haldol                                     |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1in 1 D), Oral        |                 | Not Reported |                |
|                                                                                                                                                                         | Abilify (Arip Iprazole )<br>(Aripiprazole) |                    |                    | C               |                      |                                   |                 | Not Reported |                |



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|  |                                      |   |  |  |  |  |  |  |              |
|--|--------------------------------------|---|--|--|--|--|--|--|--------------|
|  | Folic Acid (Folic Acid) (Folic Acid) | C |  |  |  |  |  |  | Not Reported |
|  | Aldomet                              | C |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Nov-2010              | 7745401       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000017099           |                      | < 1 DAY    | Female     | DEU            |

| <u>Preferred Term</u>                                                    | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|----------------|------------------------------------------|-----------------|--------------|
| Apgar Score Low;                                                         | Escitalopram Oxalate                    |              |            | S           | Oral           | 5 Mg (5 Mg, 1 In 1 D) ,Oral              |                 | Not Reported |
| Apparent Death;                                                          |                                         |              |            |             | Oral           | 5 Mg (5 Mg, 1 In 1 D) ,Oral              |                 |              |
| Caesarean Section; Foetal Distress Syndrome; Foetal Heart Rate Disorder; | Tegretol                                |              |            | S           | Transplacental | 200 Mg (200 Mg, 1 N 1 D), Transplacental |                 | Not Reported |
| Jaundice Neonatal;                                                       | Tranxene T-Tab                          |              |            | S           | Transplacental | 15 Mg (15 Mg, 1in 1 D),Transplacental    |                 | Not Reported |
| Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome  | Cyamemazine                             |              |            | S           | Transplacental | 90 Mg (90 Mg, 1 In 1 D), Transplacental  |                 | Not Reported |
|                                                                          | Haldol                                  |              |            | S           | Oral           | 5 Mg (5 Mg, 1in 1 D), Transplacental     |                 | Not Reported |
|                                                                          | Abilify (Arip Iprazole ) (Aripiprazole) |              |            | C           |                |                                          |                 | Not Reported |
|                                                                          | Folic Acid (Folic Acid) (Folic Acid)    |              |            | C           |                |                                          |                 | Not Reported |
|                                                                          | Aldomet                                 |              |            | C           |                |                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 09-Nov-2010              | 8268293       | NON-EXPEDITED    | N                  |                 | US-KINGPHARMUSA00001-K200801316 |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Increased;     | Skelaxin               |              |            | S           |              | Unk                |                 | King         |
| Hypoaesthesia; Mydriasis; | Lexapro                |              |            | S           | Oral         | 10 Mg, Single      | 1 DAY           | Not Reported |
| Panic Attack;             | Lexapro                |              |            | S           | Oral         | 5 Mg, Qd           | 2 DAY           | Not Reported |
| Paraesthesia              | Allegra-D              |              |            | S           |              | Unk                |                 | Not Reported |
|                           | Unspecified Ingredient |              |            | S           | Nasal        | Unk                |                 | Not Reported |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------------------|-----------------|-----------------|----------------|
| 10-Nov-2010                                                              | 7662980              | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2010SA066542 |                                  | 63 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Cholestasis; Hepatitis;<br>Lipase Increased;<br>Pancreatitis Acute       | Plavix               |                    |                    | S               | Oral                           |                                  |                 | Not Reported    |                |
|                                                                          | Perindopril          |                    |                    | S               | Oral                           |                                  | 3 WEEK          | Not Reported    |                |
|                                                                          | Tahor                |                    |                    | S               | Oral                           |                                  | 10 WEEK         | Not Reported    |                |
|                                                                          | Amitriptyline        |                    |                    | S               | Oral                           |                                  |                 | Not Reported    |                |
|                                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                           |                                  | 10 WEEK         | Not Reported    |                |
|                                                                          | Lioresal             |                    |                    | S               | Oral                           |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Nov-2010                                                              | 7663104              | EXPEDITED (15-DAY) | N                  | CA              | A0890306A                      |                                  |                 | Male            | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypoacusis; Maternal<br>Exposure During<br>Pregnancy                     | Lamictal             |                    |                    | S               |                                |                                  |                 | Glaxosmithkline |                |
|                                                                          | Wellbutrin XL        |                    |                    | S               |                                | 300mg Per Day                    |                 | Glaxosmithkline |                |
|                                                                          | Lexapro              |                    |                    | S               |                                | 20mg Per Day                     |                 | Not Reported    |                |
|                                                                          | Lexapro              |                    |                    | C               |                                |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Nov-2010                                                              | 7696453              | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000017174                     |                                  | 63 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Antidepressant Drug Level<br>Above Therapeutic;                          | Escitalopram Oxalate |                    |                    | S               | Oral                           | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported    |                |
| Antidepressant Drug Level<br>Below Therapeutic;                          | Olanzapine           |                    |                    | S               | Oral                           | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported    |                |
| Depressed Level Of<br>Consciousness; Muscle<br>Rigidity; Rhabdomyolysis; | Lithium              |                    |                    | S               |                                | 900 Mg (900 Mg, 1 In 1 D)        |                 | Not Reported    |                |
| Tremor                                                                   | Lorazepam            |                    |                    | C               |                                |                                  |                 | Not Reported    |                |
|                                                                          | Bisoprolol Fumarate  |                    |                    | C               |                                |                                  |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      |                        |                    |                    |                 |                                         |                                     |                 |              |                |
|--------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|-----------------------------------------|-------------------------------------|-----------------|--------------|----------------|
| Lanzoprazol (Lanzoprazol)<br>(Lanzoprazol)                                           |                        |                    | C                  |                 |                                         |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Nov-2010                                                                          | 7696554                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017157                              |                                     | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Palpitations;<br>Supraventricular<br>Tachycardia; Troponin I<br>Increased | Lexapro                |                    |                    | S               | Oral                                    | 10 Mg (10 Mg, 1 Mg In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                      | Unspecified Ingredient |                    |                    | S               |                                         |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Nov-2010                                                                          | 7693633                | DIRECT             | Y                  |                 |                                         |                                     | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Eruption; Rash<br>Pruritic                                                      | Abilify                |                    |                    | S               | Oral                                    | 2 Mg Q Qm Po                        |                 | Not Reported |                |
|                                                                                      | Lexapro                |                    |                    | S               | Oral                                    | 10 Mg Q Am Po                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2010                                                                          | 7354689                | NON-EXPEDITED      | N                  |                 | US-<br>KINGPHARMUSA00001<br>-K200901555 |                                     |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Discomfort;<br>Bladder Discomfort;<br>Malaise; Sleep Disorder              | Skelaxin               |                    |                    | S               |                                         | Unk                                 |                 | King         |                |
|                                                                                      | Lexapro                |                    |                    | S               |                                         | Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                    | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Nov-2010                                                                          | 7657169                | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2010137804            |                                     | 63 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                            | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Biliary Cyst; Cholestasis;<br>Faecaloma; Hepatitis;                                  | Tahor                  |                    |                    | S               | Oral                                    | 10 Mg, 1x/Day                       | 72 DAY          | Pfizer       |                |

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|                    |                             |   |      |               |        |              |
|--------------------|-----------------------------|---|------|---------------|--------|--------------|
| Pancreatitis Acute | Perindopril Erbumine        | S | Oral | 5 Mg, 1x/Day  | 25 DAY | Not Reported |
|                    | Plavix                      | S | Oral | 75 Mg, 1x/Day |        | Not Reported |
|                    | Amitriptyline Hydrochloride | S | Oral | 25 Mg, 1x/Day |        | Not Reported |
|                    | Escitalopram Oxalate        | S | Oral | 15 Mg, 1x/Day | 71 DAY | Not Reported |
|                    | Lioresal                    | S |      | 2 Df, 3x/Day  |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7665964       | EXPEDITED (15-DAY) | N                  | CA, HO, OT      | US-TEVA-254108USA    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                              | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cyanosis; Grunting;<br>Lethargy; Patent Ductus<br>Arteriosus; Persistent<br>Foetal Circulation;<br>Respiratory Distress;<br>Sepsis | Paroxetine Hydrochloride |              |            | S           | Transplacental |                    |                 | Teva         |
|                                                                                                                                    | Sertraline Hydrochloride |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                    | Fluoxetine Hydrochloride |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                    | Venlafaxine              |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                                                    | Escitalopram Oxalate     |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7666516       | EXPEDITED (15-DAY) | Y                  | OT              | IE-MYLANLABS-2010S1020320 |                      | 26 YR      | Female     | IRL            |

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Supraventricular<br>Tachycardia | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Alphapharm   |
|                                                      | Herbal Nos           |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7702697       | EXPEDITED (15-DAY) | Y                  | DS              | 1000017201           |                      | 42 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Blood Lactate<br>Dehydrogenase | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                              | Voltaren             |              |            | C           |              |                    |                 | Not Reported |

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Increased; Myalgia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7702857       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017191           |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Atrial Fibrillation; Loss Of Consciousness; Malaise | Escitalopram Oxalate |              |            | S           | Oral         | 0.5 Df (0.5 Dosage Forms,1 In 1 D),Oral |                 | Not Reported |
|                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 1 Df (1 Dosage Forms,1 In 1 D),Oral     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7704192       | EXPEDITED (15-DAY) | Y                  | CA              | DSA_44277_2010       |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|----------------------------|-----------------|--------------|
| Congenital Anomaly; Hypoacusis; Maternal Drugs Affecting Foetus | Wellbutrin XI  |              |            | S           | Transplacental | (300 Mg Qd Transplacental) |                 | Not Reported |
|                                                                 | Lamictal       |              |            | S           | Transplacental | (Df Transplacental)        |                 | Not Reported |
|                                                                 | Lexapro        |              |            | S           | Transplacental | (20 Mg Qd Transplacental)  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Nov-2010              | 7748000       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017192           |                      | 71 YR      | Female     | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Asthenia; Cardiac Failure; Iron Deficiency Anaemia | Escitalopram Oxalate                       |              |            | S           | Oral         | (15 Mg),Oral                 |                 | Not Reported |
|                                                    | Acenocoumarol                              |              |            | S           | Oral         | Oral                         |                 | Not Reported |
|                                                    | Alendronic Acid                            |              |            | S           | Oral         | 10 Mg (70 Mg,1 In 1 Wk),Oral |                 | Not Reported |
|                                                    | Durogesic                                  |              |            | C           |              |                              |                 | Not Reported |
|                                                    | Lyrica (Pregabalin) (Tablets) (Pregabalin) |              |            | C           |              |                              |                 | Not Reported |
|                                                    | Orfidal (Lorazepam) (Tablets) (Lorazepam)  |              |            | C           |              |                              |                 | Not Reported |

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|  |                                                                             |   |  |  |  |  |  |  |              |
|--|-----------------------------------------------------------------------------|---|--|--|--|--|--|--|--------------|
|  | Motilium (Domperidone)<br>(Tablets) (Domperidone)                           | C |  |  |  |  |  |  | Not Reported |
|  | Movicol                                                                     | C |  |  |  |  |  |  | Not Reported |
|  | Almax Comprimidos Masticables<br>(Almagate) (Chewable Tablet)<br>(Almagate) | C |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2010              | 7653073       | EXPEDITED (15-DAY) | N                  | HO, OT          | US-BAYER-201038418NA |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                    | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|------------------|--------------|------------------------|-----------------|-------------------------------------------------------|
| Bradycardia; Dehydration;<br>Ejection Fraction<br>Decreased; Hallucination;<br>Hyperhidrosis;<br>Hypotension; Influenza<br>Like Illness; Migraine;<br>Serotonin Syndrome | Betaseron<br>Avonex<br>Lexapro<br>Effexor Xr |              |            | S<br>C<br>S<br>S | Subcutaneous | Total Daily Dose: 3 Mg | 6 MTH           | Bayer<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2010              | 7701736       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017222           |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Electrocardiogram Qt<br>Prolonged | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2010              | 7636710       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | DE-ABBOTT-10P-062-0678483-00 |                      | 26 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>         | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>                                   |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------|------------|-------------|----------------------|-------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------|
| Acidosis; Intentional<br>Overdose; Loss Of<br>Consciousness;<br>Respiratory Depression;<br>Suicide Attempt | Clarithromycin<br>Escitalopram Oxalate<br>Paracetamol |              |            | S<br>S<br>S | Oral<br>Oral<br>Oral | Overdose: 3000mg(Single<br>Dosage),6 In 1 D<br>Unknown Single Dosage<br>Overdose: 8000mg(Single |                 | Not Reported<br>Not Reported<br>Not Reported |

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|            |   |      |                                                                |              |
|------------|---|------|----------------------------------------------------------------|--------------|
| Ibuprofen  | S | Oral | Dosage),16 In 1d<br>Overdose: 8000-12000 Mg<br>(Single Dosage) | Not Reported |
| Bromazepam | S | Oral | Overdose: 180mg(Single<br>Dosage),30 In 1d                     | Not Reported |
| Alcohol    | S |      | Overdose:Unknown<br>Amount(1.4 Per Mille)                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2010              | 7670446       | EXPEDITED (15-DAY) | Y                  | HO, LT          | GB-PERRIGO-<br>10GB014738 |                      | 87 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Naproxen Sodium |              |            | S           | Oral         | 250 Mg, Tid        |                 | Perrigo      |
|                       | Aspirin         |              |            | S           | Oral         | 75 Mg, Qd          |                 | Perrigo      |
|                       | Cipralex        |              |            | S           | Oral         | 15 Mg, Qd          |                 | Not Reported |
|                       | Omeprazole      |              |            | C           | Oral         | 200 Mg, Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 16-Nov-2010              | 7670944       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-01490RO |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Drug Ineffective; Ileus;<br>Overdose; Serotonin<br>Syndrome | Lithium Carbonate      |              |            | S           |                                          |                    |                 | Roxane       |
|                                                             | Risperidone            |              |            | S           |                                          |                    |                 | Roxane       |
|                                                             | Midazolam              |              |            | S           | Intravenous (not<br>otherwise specified) | 5 Mg               |                 | Roxane       |
|                                                             | Morphine               |              |            | S           | Intravenous (not<br>otherwise specified) |                    |                 | Roxane       |
|                                                             | Diazepam               |              |            | S           | Oral                                     |                    |                 | Roxane       |
|                                                             | Tramadol Hydrochloride |              |            | S           |                                          |                    |                 | Not Reported |
|                                                             | Quetiapine             |              |            | S           |                                          |                    |                 | Not Reported |
|                                                             | Escitalopram Oxalate   |              |            | S           |                                          |                    |                 | Not Reported |
|                                                             | Mirtazapine            |              |            | S           |                                          |                    |                 | Not Reported |
|                                                             | Fluoxetine             |              |            | S           |                                          |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |                                       |        |              |
|------------------------------|---|---------------------------------------|--------|--------------|
| Suxamethonium                | S | Intravenous (not otherwise specified) | 100 Mg | Not Reported |
| Cyproheptadine Hydrochloride | S |                                       | 12 Mg  | Not Reported |
| Olanzapine                   | S |                                       |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 17-Nov-2010              | 7623428       | EXPEDITED (15-DAY) | Y                  | HO              | SE-BAXTER-2010BH023718 |                      | 1 DAY      | Male       | SWE            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Abo Incompatibility;<br>Agitation Neonatal;<br>Maternal Drugs Affecting<br>Foetus; Melaena;<br>Necrotising Colitis; Off<br>Label Use; Premature<br>Baby | Gammagard Liquid |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                         | Gammagard Liquid |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
|                                                                                                                                                         | Cipralax         |              |            | S           | Intra-uterine                         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2010              | 7652436       | EXPEDITED (15-DAY) | Y                  | HO              | 1000016566           |                      | 80 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Electrolyte Imbalance;<br>Feeling Abnormal;<br>Hypernatraemia;<br>Hypokalaemia; Nausea;<br>Rhabdomyolysis;<br>Somnolence | Lexapro                           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                          | Hydrochlorothiazide               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                          | Seloken (Metoprolol Tartrate)     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                          | Lorazepam                         |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                          | Xalatan (Latanoprost) (Eye Drops) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Nov-2010              | 7672857       | EXPEDITED (15-DAY) | Y                  | HO              | BE-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>BL-00 |                      | 71 YR      | Female     | BEL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                        |   |      |         |                      |
|---------------------------------------|------------------------|---|------|---------|----------------------|
| Varicose Vein; Venous Thrombosis Limb | Pradaxa                | S | Oral | 220 Mg  | Boehringer Ingelheim |
|                                       | Escitalopram Oxalate   | S | Oral | 10 Mg   | Not Reported         |
|                                       | Dafalgan               | C | Oral | 4000 Mg | Not Reported         |
|                                       | Pravastatin Sodium     | C | Oral | 40 Mg   | Not Reported         |
|                                       | Asaflow                | C | Oral | 80 Mg   | Not Reported         |
|                                       | Otilonium Bromide      | C | Oral | 40 Mg   | Not Reported         |
|                                       | Zantac                 | C | Oral | 150 Mg  | Not Reported         |
|                                       | Indapamide\Perindopril | C | Oral | 2 Mg    | Not Reported         |
|                                       | Erbumine               |   |      |         |                      |
|                                       | Levothyroxine Sodium   | C | Oral | 50 Mcg  | Not Reported         |
|                                       | Lorazepam              | C | Oral | 1 Mg    | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Nov-2010              | 7713785       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017242           |                      | 73 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Asthenia; Erythema    | Nebivolol Hydrochloride        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported |
|                       | Escitalopram Oxalate           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                       | Iron\Minerals\Vitamins         |              |            | S           | Oral         | Oral                            |                 | Not Reported |
|                       | Amiodarone Hydrochloride       |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Lasix                          |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                       | Omeprazole                     |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                       | Enoxaparin Sodium              |              |            | S           | Subcutaneous | Subcutaneous                    |                 | Not Reported |
|                       | Kepra (Levetiracetam)          |              |            | C           |              |                                 |                 | Not Reported |
|                       | Normase (Lactulose)            |              |            | C           |              |                                 |                 | Not Reported |
|                       | Dexamethasone Sodium Phosphate |              |            | C           |              |                                 |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Nov-2010              | 7673498              | EXPEDITED (15-DAY) | Y                  | HO              | GB-TEVA-255386ISR    |                      | 87 YR           | Male         | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage     | Naproxen             |                    |                    | S               |                      |                      |                 | Teva         |                |
|                          | Acetylsalicylic Acid |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 18-Nov-2010                                                                              | 7702701                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000017077           |                                  | 63 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Increased;<br>Cholestasis; Faecaloma;<br>Hepatitis; Pancreatitis<br>Acute | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                          | Perindopril                 |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                          | Plavix                      |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                          | Atorvastatin Calcium        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                          | Amitriptyline Hydrochloride |                    |                    | S               | Oral                 | 25 Mg (25 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                          | Lioresal                    |                    |                    | S               | Oral                 | 60 Mg (20 Mg, 3 In 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 18-Nov-2010              | 7714380              | EXPEDITED (15-DAY) | Y                  | LT, OT          | 1000017320           |                                  | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Metrorrhagia             | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                          | Sedoxil (Mexazolam)  |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                              | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|------------------------------|----------------|
| 18-Nov-2010                                                                                                                                                                                                                           | 7717377                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000017301           |                                                                    | 35 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Haematemesis;<br>Headache; Nausea                                                                                                                                                                                            | Escitalopram Oxalate                       |                    |                    | S               |                      | 5 Mg (5 Mg, 1 In 1 D)                                              |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                              | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Nov-2010                                                                                                                                                                                                                           | 7654377                                    | EXPEDITED (15-DAY) | N                  | DE, OT          | 1000016561           |                                                                    | 65 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bipolar I Disorder;<br>Cardiomegaly; Completed<br>Suicide; Left Ventricular<br>Hypertrophy;<br>Nephrosclerosis;<br>Pneumoconiosis;<br>Pulmonary Congestion;<br>Self-Medication; Toxicity<br>To Various Agents;<br>Visceral Congestion | Lexapro                                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       |                                            |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |                              |                |
|                                                                                                                                                                                                                                       | Xanax                                      |                    |                    | S               | Oral                 | 1 Mg (1 Mg, 1 In 1 D), Oral                                        |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       | Saphris                                    |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                        |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       | Vicodin                                    |                    |                    | S               | Oral                 |                                                                    |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       | Triamterene (Triamterene)<br>(Triamterene) |                    |                    | C               |                      |                                                                    |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       | Atacand (Candesartan)<br>(Candesartan)     |                    |                    | C               |                      |                                                                    |                 | Not Reported                 |                |
|                                                                                                                                                                                                                                       | Simvastatin<br>Famotidine                  |                    |                    | C<br>C          |                      |                                                                    |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                              | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 19-Nov-2010                                                                                                                                                                                                                           | 7676191                                    | NON-EXPEDITED      | N                  |                 | A0879073A            |                                                                    | 54 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                 | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dry Mouth                                                                                                                                                                                                                             | Wellbutrin Sr                              |                    |                    | S               | Oral                 | 100mg Per Day                                                      |                 | Glaxosmithkline              |                |
|                                                                                                                                                                                                                                       | Lexapro                                    |                    |                    | S               | Oral                 | 20mg Per Day                                                       |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                 | Elavil                                                                   |                    | C                  | Oral            | 5mg As Required      |                                            | Glaxosmithkline |              |                |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
|                                                                                 | Valium                                                                   |                    | C                  | Oral            | 2.6mg As Required    |                                            | Glaxosmithkline |              |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2010                                                                     | 7690850                                                                  | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000017070           |                                            |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Psychiatric Evaluation<br>Abnormal; Suicide Attempt        | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | Oral                                       |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate                                                     |                    |                    | S               | Oral                 | Oral                                       |                 | Not Reported |                |
|                                                                                 | Analgesic Medications Nos<br>(Analgesics (Analgesics)                    |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                                 | Temesta (Lorazepam)<br>(Lorazepam)                                       |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                                 | Effexor Lp (Venlafaxine<br>Hydrochloride) (Venlafaxine<br>Hydrochloride) |                    |                    | C               |                      |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2010                                                                     | 7717260                                                                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017333           |                                            |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Distress Syndrome;<br>Maternal Drugs Affecting<br>Foetus; Premature Baby | Lexapro                                                                  |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
|                                                                                 | Abilify                                                                  |                    |                    | S               | Transplacental       | 30 Mg (30 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Nov-2010                                                                     | 7717277                                                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000017331           |                                            | 93 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence;<br>Dyspnoea; Malaise;<br>Nausea; Seizure                     | Lexapro                                                                  |                    |                    | S               | Oral                 | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral         |                 | Not Reported |                |
|                                                                                 | Pantoprazole (Antoprazole)                                               |                    |                    | C               |                      |                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |   |              |
|----------------------------|---|--------------|
| Cranberry (Vaccinium)      | C | Not Reported |
| Perindopril (Perindopril)  | C | Not Reported |
| (Perindopril)              |   |              |
| Prochlorperazine Maleate   | C | Not Reported |
| (Prochlorperazine Maleate) |   |              |
| (Prochlorperazine Maleate) |   |              |
| Temazepam                  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Nov-2010              | 7754136       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017321           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bone Density Decreased; | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Osteonecrosis; Tooth    | Effexor Xr     |              |            | S           | Oral         | 75 Mg, Oral        |                 | Not Reported |
| Extraction              |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2010              | 7377183       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000013334           |                      | 30 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Balance Disorder;     | Lexapro                            |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |
| Decreased Appetite;   |                                    |              |            |             |              | Oral                     |                 |              |
| Dizziness; Headache;  | Insulin Nos (Insulin Nos) (Insulin |              |            | C           |              |                          |                 | Not Reported |
| Pain In Extremity;    | Nos)                               |              |            |             |              |                          |                 |              |
| Sedation; Somnolence  |                                    |              |            |             |              |                          |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2010              | 7527650       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2010SA045342 |                      | 89 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated; | Xatral                 |              |            | S           | Oral         |                    |                 | Not Reported |
| Lichenoid Keratosis;  | Aspirin                |              |            | S           | Oral         |                    |                 | Not Reported |
| Prurigo               | Aerius (Desloratadine) |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Spironolactone         |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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|                      |   |      |              |
|----------------------|---|------|--------------|
| Escitalopram Oxalate | S | Oral | Not Reported |
| Atarax               | S | Oral | Not Reported |
| Pantoprazole         | C |      | Not Reported |

| <u>FDA Received Date</u>                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2010                                             | 7539891                | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2010100890 |                      | 89 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lichenoid Keratosis; Prurigo; Rash; Toxic Skin Eruption | Atarax                 |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                         | Spironolactone         |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                         | Escitalopram Oxalate   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                         | Aerius (Desloratadine) |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                         | Xatral                 |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                         | Aspirin                |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                         | Pantoprazole           |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2010                                        | 7677984              | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2010SA067985 |                      | 92 YR           | Male         | FRA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Prurigo; Toxic Skin Eruption | Xatral               |                    |                    | S               | Oral                           |                      | 3 YR            | Not Reported |                |
|                                                    | Aspirin              |                    |                    | S               | Oral                           |                      | 3 YR            | Not Reported |                |
|                                                    | Nitrofurantoin       |                    |                    | S               | Oral                           |                      | 14 DAY          | Not Reported |                |
|                                                    | Pantoprazole         |                    |                    | S               | Oral                           |                      | 4 MTH           | Not Reported |                |
|                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                           |                      | 1 YR            | Not Reported |                |
|                                                    | Spironolactone       |                    |                    | S               | Oral                           |                      | 2 YR            | Not Reported |                |
|                                                    | Bactrim Forte        |                    |                    | S               | Oral                           |                      | 11 DAY          | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2010              | 7722407       | DIRECT           | Y                  | HO, LT, RI      |                      |                      | 17 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Anxiety; Intentional Overdose; Suicide Attempt                         | Lexapro                 |                    |                    | S               | Oral                 | 10mg Qd Po                  |                 | Not Reported |                |
|                                                                        | Wellbutrin              |                    |                    | S               | Oral                 | 150 Qd Po                   |                 | Not Reported |                |
|                                                                        | Adderall Xr             |                    |                    | S               |                      | 15mg Qd                     | 18 MTH          | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2010                                                            | 7722568                 | DIRECT             | Y                  | LT, OT          |                      |                             | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Overdose                                                  | Lexapro                 |                    |                    | S               |                      | 25 Mg. 1x Daily             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Nov-2010                                                            | 7722728                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000017393           |                             | 67 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Generalised Exanthematous Pustulosis; Neutrophil Count Increased | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
|                                                                        | Alprazolam (Alprazolam) |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
|                                                                        | Fenofibrate             |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2010                                                            | 7498310                 | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000014945           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Metrorrhagia; Overdose                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 25 Mg (25 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                        | Tavor (Lorazepam)       |                    |                    | C               |                      |                             |                 | Not Reported |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------|---------------------------|--------------------|--------------------|-----------------|-----------------------|--------------------------|-----------------|-----------------|----------------|
| 23-Nov-2010                | 7679864                   | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20101105032 |                          |                 | Female          | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Cataract                   | Levaquin                  |                    |                    | S               | Unknown               |                          |                 | Not Reported    |                |
|                            | Toviaz                    |                    |                    | S               | Unknown               |                          |                 | Not Reported    |                |
|                            | Xanax                     |                    |                    | S               | Unknown               |                          |                 | Not Reported    |                |
|                            | Lexapro                   |                    |                    | S               | Unknown               |                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2010                | 7680078                   | EXPEDITED (15-DAY) | N                  | DE, OT          | CH-BAYER-201047514GPV |                          | 80 YR           | Female          | CHE            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Loss Anaemia;        | Aspirin Cardio            |                    |                    | S               | Oral                  | Total Daily Dose: 100 Mg |                 | Bayer           |                |
| Gastric Ulcer              | Oflen [Diclofenac Sodium] |                    |                    | S               | Oral                  |                          |                 | Not Reported    |                |
| Haemorrhage; Gastric       | Cipralext                 |                    |                    | S               |                       |                          |                 | Not Reported    |                |
| Ulcer Perforation;         | Sortis                    |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
| Melaena; Peritonitis;      | Stilnox                   |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
| Sepsis                     | Levothyroxine Sodium      |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
|                            | Beloc-Zok                 |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
|                            | Ramipril                  |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
|                            | Norvasc                   |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
|                            | Torem                     |                    |                    | C               | Oral                  |                          |                 | Not Reported    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 23-Nov-2010                | 7680422                   | EXPEDITED (15-DAY) | N                  | HO              | A0894413A             |                          | 43 YR           | Male            | USA            |
| <u>Preferred Term</u>      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Arthropathy; Depression;   | Wellbutrin                |                    |                    | S               | Oral                  |                          |                 | Glaxosmithkline |                |
| Drug Ineffective; Fatigue; |                           |                    |                    |                 |                       |                          |                 |                 |                |



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|                                                         |                         |   |      |               |                 |
|---------------------------------------------------------|-------------------------|---|------|---------------|-----------------|
| Knee Arthroplasty;<br>Somnolence; Suicidal<br>Behaviour | Zoloft                  | S | Oral | 100mg Unknown | Not Reported    |
|                                                         | Lexapro                 | S | Oral | 30mgd Per Day | Not Reported    |
|                                                         | Cymbalta                | S | Oral | 60mg Per Day  | Not Reported    |
|                                                         | Methadone Hydrochloride | C |      |               | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2010              | 7680523       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ROCHE-743107      |                      | 58 YR      | Female     | FRA            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Coma; Toxicity To Various<br>Agents | Rivotril             |              |            | S           | Oral         | Strength: 2.5 Mg/ML.<br>Solution In Drop. Taken In<br>The Evening |                 | Roche        |
|                                     | Escitalopram Oxalate |              |            | S           | Unknown      | Taken In The Evening                                              |                 | Not Reported |
|                                     | Dafalgan             |              |            | C           |              |                                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 23-Nov-2010              | 7680752       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-10P-056-<br>0686450-00 |                      | 67 YR      | Female     | FRA            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Generalised<br>Exanthematous Pustulosis | Fenofibrate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Alprazolam           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 23-Nov-2010              | 7681308       | EXPEDITED (15-DAY) | Y                  | HO, LT          | GB-MYLANLABS-<br>2010S1021053 |                      | 87 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Naproxen       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Aspirin        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cipralex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Omeprazole     |              |            | C           | Oral         |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------|-----------------|--------------|----------------|
| 23-Nov-2010                                                                                                                                                                                           | 7724367                 | EXPEDITED (15-DAY) | Y                  | DS, LT, OT      | 2010SP059735         |                                                                     | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Coordination Abnormal;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Product<br>Administration Error;<br>Product Prescribing Error;<br>Serum Serotonin<br>Increased; Speech<br>Disorder | Remeron                 |                    |                    | S               | Oral                 | 7.5 Mg;Qd;Po                                                        |                 | Not Reported |                |
|                                                                                                                                                                                                       | Imitrex                 |                    |                    | S               | Oral                 | 25 Mg;Prn;Po ; 25<br>Mg;Qd;Po                                       |                 | Not Reported |                |
|                                                                                                                                                                                                       |                         |                    |                    |                 | Oral                 | 25 Mg;Prn;Po ; 25<br>Mg;Qd;Po                                       |                 |              |                |
|                                                                                                                                                                                                       | Lexapro                 |                    |                    | S               | Oral                 | 20 Mg;Qd;Po                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Trazodone Hydrochloride |                    |                    | S               | Oral                 | 50 Mg;Qd;Po                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                       | Risperdal               |                    |                    | S               | Oral                 | .25 Mg;Po                                                           |                 | Not Reported |                |
|                                                                                                                                                                                                       | Keppra                  |                    |                    | C               |                      |                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2010                                                                                                                                                                                           | 7724638                 | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017353           |                                                                     | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Drug<br>Interaction; Fall;<br>Hypotension;<br>Parkinsonism; Syncope                                                                                                                        | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral                                      |                 | Not Reported |                |
|                                                                                                                                                                                                       | Taxilan (Perazine)      |                    |                    | S               | Oral                 | 400 Mg (400 Mg,1 In 1<br>D),Oral ; 350 Mg (350<br>Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                       |                         |                    |                    |                 | Oral                 | 400 Mg (400 Mg,1 In 1<br>D),Oral ; 350 Mg (350<br>Mg,1 In 1 D),Oral |                 |              |                |
|                                                                                                                                                                                                       | Haldol                  |                    |                    | S               | Oral                 | See Image                                                           |                 | Not Reported |                |
|                                                                                                                                                                                                       |                         |                    |                    |                 | Oral                 | See Image                                                           |                 |              |                |
|                                                                                                                                                                                                       |                         |                    |                    |                 | Oral                 | See Image                                                           |                 |              |                |
|                                                                                                                                                                                                       |                         |                    |                    |                 | Oral                 | See Image                                                           |                 |              |                |
|                                                                                                                                                                                                       | Haldol                  |                    |                    | S               | Oral                 | 0.5 Mg (0.5 Mg,1 In 1<br>D),Oral                                    |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 23-Nov-2010                                                                                                                      | 7748484                                             | EXPEDITED (15-DAY) | Y                  | DE, HO, RI, OT  | 2010AP002315         |                                 | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Cardiac Arrest;<br>Coma; Long Qt Syndrome;<br>Nervous System Disorder;<br>Sinus Tachycardia;<br>Ventricular Fibrillation | Fluoxetine Hydrochloride                            |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                  | Trazodone Hydrochloride                             |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                  | Escitalopram Oxalate                                |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                  | Buspirone                                           |                    |                    | S               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                  | Temazepam                                           |                    |                    | S               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2010                                                                                                                      | 7239707                                             | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000010858           |                                 | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Myelofibrosis;<br>Thrombocytopenia                                                                                               | Escitalopram Oxalate                                |                    |                    | S               |                      | 1 Df (1 Dosage Forms, 1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                  | Risperidon (Risperidone)<br>(Tablets) (Risperidone) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                         | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2010                                                                                                                      | 7566226                                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000015672           |                                 | 92 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Lichenoid Keratosis;<br>Prurigo; Toxic Skin<br>Eruption                                                                          | Escitalopram Oxalate                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral     |                 | Not Reported |                |
|                                                                                                                                  | Desloratadine                                       |                    |                    | S               | Oral                 | Oral                            |                 | Not Reported |                |
|                                                                                                                                  | Alfuzosin Hydrochloride                             |                    |                    | S               | Oral                 | 5 Mg (2.5 Mg,2 In 1 D),Oral     |                 | Not Reported |                |
|                                                                                                                                  | Kardegic (Acetylsalicylate Lysine)                  |                    |                    | S               | Oral                 | 75 Mg (75 Mg,1 In 1 ),Oral      |                 | Not Reported |                |
|                                                                                                                                  | Spironolactone                                      |                    |                    | S               | Oral                 | (1 In 1 D),Oral                 |                 | Not Reported |                |
|                                                                                                                                  | Atarax                                              |                    |                    | S               | Oral                 | Oral                            |                 | Not Reported |                |
|                                                                                                                                  | Pantoprazole Sodium                                 |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |   |      |                                      |              |
|---------------|---|------|--------------------------------------|--------------|
| Furadantine   | S |      | D),Oral                              |              |
| Bactrim Forte | S | Oral | 100 Mg (50 Mg,2 In 1 D)              | Not Reported |
|               |   |      | 1 Df (1 Dosage Forms, 1 In 1 D),Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2010              | 7662935       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000016673           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Ventricular Arrhythmia | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                      | Lamotrigine    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-Nov-2010              | 7670573       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2010144796 |                      | 76 YR      | Female     | FRA            |

| <u>Preferred Term</u>              | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Malaise;<br>Seizure | Atarax                     |              |            | S           | Oral         | 25 Mg, 3x/Day      | 57 DAY          | Pfizer       |
|                                    | Escitalopram Oxalate       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                    | Theralene                  |              |            | S           | Oral         | 15 Mg, Unk         | 43 DAY          | Not Reported |
|                                    | Dihydroergotamine Mesylate |              |            | S           | Oral         | Unk                | 31 DAY          | Not Reported |
|                                    | Mianserin Hydrochloride    |              |            | S           | Oral         | 30 Mg, 2x/Day      |                 | Not Reported |
|                                    | Pipamperone                |              |            | S           | Oral         | 90 Mg, 1x/Day      | 102 DAY         | Not Reported |
|                                    | Equanil                    |              |            | S           | Oral         | 400 Mg, 4x/Day     |                 | Not Reported |
|                                    | Aceprometazine\Meprobamate |              |            | S           | Oral         | 1 Df, 1x/Day       | 43 DAY          | Not Reported |
|                                    | Seretide                   |              |            | C           |              | 1 Unit, 2x/Day     |                 | Not Reported |
|                                    | Ditropan                   |              |            | C           |              | 5 Mg, 2x/Day       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Nov-2010              | 7670896       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 1000016837           |                      | 26 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                |                      |   |      |                                            |              |
|------------------------------------------------------------------------------------------------|----------------------|---|------|--------------------------------------------|--------------|
| Acidosis; Intentional Overdose; Loss Of Consciousness; Respiratory Depression; Suicide Attempt | Escitalopram Oxalate | S | Oral | Single Dosage,Oral                         | Not Reported |
|                                                                                                | Bromazepam           | S | Oral | (180 Mg,Once),Oral                         | Not Reported |
|                                                                                                | Ibuprofen            | S | Oral | 8000-12000 Mg (Once),Oral                  | Not Reported |
|                                                                                                | Clarithromycin       | S | Oral | (3000 Mg,Once),Oral                        | Not Reported |
|                                                                                                | Acetaminophen        | S | Oral | (8000 Mg,Once),Oral                        | Not Reported |
|                                                                                                | Alcohol (Ethanol)    | S | Oral | Unknown Single Amount (1.4 Per Mille),Oral | Not Reported |

| <u>FDA Received Date</u>                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 24-Nov-2010                                   | 7727858                                                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017404           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Burning Sensation; Diarrhoea                  | Lexapro                                                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                               | Antihypertensives (Antihypertensives) (Antihypertensives) |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2010                                   | 7736850                                                   | EXPEDITED (15-DAY) | Y                  | OT              | 1000017400           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma; Headache; Photophobia | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Nov-2010                                   | 7736851                                                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017399           |                             | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma                        | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------|----------------|
| 24-Nov-2010                                                                                   | 7736872                                                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017386           |                                                                                                                                              | 60 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Angle Closure Glaucoma                                                                        | Escitalopram Oxalate<br>Levothyrox (Levothyroxine Sodium) |                    |                    | S<br>C          |                      |                                                                                                                                              |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 24-Nov-2010                                                                                   | 7736905                                                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017414           |                                                                                                                                              | 22 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Balance Disorder;<br>Malaise; Muscle Spasms;<br>Nausea                                        | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                                                                             |                 | Not Reported                 |                |
|                                                                                               | Alprazolam                                                |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |
|                                                                                               | Diane 35 (Diane)                                          |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |
|                                                                                               | Oroperidys (Domperidone)                                  |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                         | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 26-Nov-2010                                                                                   | 7491391                                                   | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2010SP036628         |                                                                                                                                              | 66 YR           | Male                         | FRA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                           | <u>Duration</u> | <u>Mfr</u>                   |                |
| Agitation; Anxiety;<br>Hepatitis; Hypomania;<br>Logorrhoea; Major<br>Depression; Tachyphrenia | Mirtazapine                                               |                    |                    | S               | Oral                 | Po                                                                                                                                           |                 | Not Reported                 |                |
|                                                                                               | Escitalopram Oxalate                                      |                    |                    | S               | Oral                 | Po                                                                                                                                           |                 | Not Reported                 |                |
|                                                                                               |                                                           |                    |                    |                 |                      | 10 Mg Bid, Po; 10 Mg, Bid<br>Po; 5 Mg Qd Po;<br>10 Mg Bid, Po; 10 Mg, Bid<br>Po; 5 Mg Qd Po;<br>10 Mg Bid, Po; 10 Mg, Bid<br>Po; 5 Mg Qd Po; |                 |                              |                |
|                                                                                               | Fenofibrate                                               |                    |                    | S               | Oral                 | Po                                                                                                                                           |                 | Not Reported                 |                |
|                                                                                               | Teralithe                                                 |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |
|                                                                                               | Seresta                                                   |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |
|                                                                                               | Largactil                                                 |                    |                    | C               |                      |                                                                                                                                              |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                |                            |                    |                    |                 |                      |                                                  |                 |              |                |
|--------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|--------------|----------------|
| Imovane                                                                        |                            | C                  |                    | Not Reported    |                      |                                                  |                 |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2010                                                                    | 7693984                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017068           |                                                  | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depression; Drug<br>Ineffective; Unevaluable<br>Event | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Nov-2010                                                                    | 7702839                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000017083           |                                                  | 76 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                          | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure                                                         | Escitalopram Oxalate       |                    |                    | S               | Oral                 | Oral                                             |                 | Not Reported |                |
|                                                                                | Trimeprazine Tartrate      |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                                | Dihydroergotamine Mesylate |                    |                    | S               | Oral                 | Oral                                             |                 | Not Reported |                |
|                                                                                | Atarax                     |                    |                    | S               | Oral                 | 75 Mg (25 Mg, 3 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                                | Mianserin Hydrochloride    |                    |                    | S               | Oral                 | 60 Mg (20 Mg, 2 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                                | Pipamperone Hydrochloride  |                    |                    | S               | Oral                 | 90 Mg (90 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                                | Equanil                    |                    |                    | S               | Oral                 | 1600 Mg (400 Mg, 4 In 1<br>D), Oral              |                 | Not Reported |                |
|                                                                                | Equanil                    |                    |                    | S               | Oral                 | 1200 Mg (400 Mg, 3 In 1<br>D), Oral              |                 | Not Reported |                |
|                                                                                | Aceprometazine\Meprobamate |                    |                    | S               | Oral                 | 1 Dosage Form (1 Dosage<br>Forms 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate       |                    |                    | C               |                      |                                                  |                 | Not Reported |                |
|                                                                                | Trimeprazine Tartrate      |                    |                    | C               |                      |                                                  |                 | Not Reported |                |
|                                                                                | Ikaran (Dihydroergotamine  |                    |                    | C               |                      |                                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                              |   |              |
|----------------------------------------------|---|--------------|
| Mesilate)                                    |   |              |
| Atarax (Hydroxyzine)                         | C | Not Reported |
| Athylmil (Mianserin Hydrochloride)           | C | Not Reported |
| Dipiperon (Pipamperone Hydrochloride)        | C | Not Reported |
| Equanil                                      | C | Not Reported |
| Aceprometazine\Meprobamate                   | C | Not Reported |
| Seretide                                     | C | Not Reported |
| Ditropan (Oxybutynin) (Tablets) (Oxybutynin) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2010              | 7723221       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000017438           |                      | 87 YR      | Male       | DNK            |

| <u>Preferred Term</u>                    | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Fall; Traumatic Intracranial Haemorrhage | Escitalopram Oxalate           |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                          | Aspirin (Acetylsalicylic Acid) |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                          | Naproxen (Naproxen)            |              |            | S           | Oral         | 750 Mg (250 Mg, 3 In 1 D), Oral |                 | Not Reported |
|                                          | Omeprazole                     |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Nov-2010              | 7723291       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017432           |                      | 83 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                             | <u>Product</u>                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------|---------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|------------------------------|
| Gingival Bleeding; Hypocoagulable State; International Normalised Ratio Increased | Escitalopram Oxalate                                    |              |            | S           | Oral         | 1 Dosage Form (1 Dosage, Forms, 1 In 1 D), Oral |                 | Not Reported                 |
|                                                                                   | Coumadin                                                |              |            | S           | Oral         | (1 Dosage Forms, As Required), Oral             |                 | Not Reported                 |
|                                                                                   | Allopurinol<br>Esopral (Esomeprazole)<br>(Esomeprazole) |              |            | C<br>C<br>C |              |                                                 |                 | Not Reported<br>Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aspirin  
Rytmonorm (Propafenone)  
(Propafenone)

C  
C

Not Reported  
Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Nov-2010                       | 7733410                | EXPEDITED (15-DAY)        | Y                           | DE                       | 1000017441                    |                               |                     | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Acute Kidney Injury            | Lexapro                 |                       |                     | S                    | Oral                  | Oral                        |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Nov-2010                       | 7733431                | EXPEDITED (15-DAY)        | N                           | HO, RI, OT               | 1000017337                    |                               | 71 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>                                       | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|---------------------------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Seizure                        | Lexapro                                                       |                       |                     | S                    | Oral                  | See Image                   |                          | Not Reported        |
|                                |                                                               |                       |                     |                      | Oral                  | See Image                   |                          |                     |
|                                |                                                               |                       |                     |                      | Oral                  | See Image                   |                          |                     |
|                                |                                                               |                       |                     |                      | Oral                  | See Image                   |                          |                     |
|                                | Diltiazem (Diltiazem Hydrochloride) (Diltiazem Hydrochloride) |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Simvastatin                                                   |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Zyrtec (Cetirizine) (10 Milligram, Tablets) (Cetirizine)      |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Ramipril                                                      |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Nov-2010                       | 7733445                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000017390                    |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Cataract                       | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Toviaz                  |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Xanax                   |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                | Levaquin                |                       |                     | S                    |                       |                             |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|-----------------------|------------------------|-----------------|--------------|----------------|
| 29-Nov-2010                                                | 7673741                        | EXPEDITED (15-DAY) | Y                  | OT              | DE-JNJFOC-20101102433 |                        | 54 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hypotension;<br>Parkinsonism; Syncope;<br>Vertigo    | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Haldol                         |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Taxilan (Perazine)             |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Taxilan (Perazine)             |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
|                                                            | Ciprallex                      |                    |                    | S               | Oral                  |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2010                                                | 7685107                        | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20101106647 |                        |                 | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Breakthrough Pain;<br>Confusional State;<br>Encephalopathy | Fentanyl                       |                    |                    | S               | Transdermal           |                        |                 | Not Reported |                |
|                                                            | Xanax                          |                    |                    | S               | Unknown               |                        |                 | Not Reported |                |
|                                                            | Seroquel                       |                    |                    | S               | Unknown               |                        |                 | Not Reported |                |
|                                                            | Lexapro                        |                    |                    | S               | Unknown               |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Nov-2010                                                | 7739942                        | EXPEDITED (15-DAY) | Y                  | HO, LT          | GER/UKI/10/0016626    |                        | 87 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                      | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage;<br>Fall                              | Naproxen (Naproxen)            |                    |                    | S               | Oral                  | 250 Mg, 3 In 1 D, Oral |                 | Not Reported |                |
|                                                            | Aspirin (Acetylsalicylic Acid) |                    |                    | S               | Oral                  | 75 Mg, 1 In 1 D, Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                            | Cipralex                               |                    | S                  | Oral            | 15 Mg, 1 In 1 D, Oral    |                                  | Not Reported    |              |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                                                                                                                            | Omeprazole                             |                    | C                  |                 |                          |                                  | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Nov-2010                                                                                                                                                                                                                                                                                                | 7687630                                | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2010153602 |                                  | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Drug Interaction; Pain                                                                                                                                                                                                                                                        | Lyrica                                 |                    |                    | S               | Oral                     | 100mg                            |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                                            | Lyrica                                 |                    |                    | S               |                          |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                                            | Lexapro                                |                    |                    | S               | Oral                     | 60 Mg, Unk                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Lexapro                                |                    |                    | S               |                          |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2010                                                                                                                                                                                                                                                                                                | 7674606                                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016960               |                                  | 83 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                                                                                                                                                                                                                                                                           | Escitalopram Oxalate                   |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Dec-2010                                                                                                                                                                                                                                                                                                | 7741241                                | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000017498               |                                  | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Abnormal Dreams;<br>Arthralgia; Asthenia; Blood<br>Sodium Decreased;<br>Confusional State;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Depression; Diarrhoea;<br>Dry Mouth; Erectile<br>Dysfunction; Fall; Fatigue;<br>Heart Rate Decreased;<br>Hyperhidrosis; Hypotonia; | Escitalopram Oxalate                   |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Deniban (Amisulpride)<br>(Amisulpride) |                    |                    | C               |                          |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Esilgan (Estazolam) (Estazolam)        |                    |                    | C               |                          |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                            | Realsil (Realsil) (Realsil)            |                    |                    | C               |                          |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Liver Function Test  
Abnormal; Malaise;  
Myalgia; Pain; Product  
Dispensing Error;  
Somnolence; Tremor;  
Weight Decreased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2010              | 7741606       | EXPEDITED (15-DAY) | N                  | DE              | 1000017495           |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Renal Failure         | Lexapro        |              |            | S           | Oral         | (1 In 1 D),Oral    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2010              | 7741655       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017481           |                      | 19 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2010              | 7637178       | EXPEDITED (15-DAY) | Y                  | DS, OT          | GB-RANBAXY-2010R1-38864 |                      | 47 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure Increased; Condition Aggravated; Hyperreflexia; Hypertonia; Panic Attack; Phobia; Tachycardia; Tremor | Fluoxetine           |              |            | S           | Oral         | 20 Mg, Unk         | 10 DAY          | Ranbaxy      |
|                                                                                                                               | Fluoxetine           |              |            | S           |              |                    |                 | Ranbaxy      |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Unk         | 9 DAY           | Not Reported |
|                                                                                                                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                               | Citalopram           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                                                                                               | Citalopram           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 02-Dec-2010              | 7689439       | EXPEDITED (15-DAY) | Y                  | HO              | FR-RANBAXY-2010RR-39754 |                      | 67 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Acute Generalised Exanthematous Pustulosis                                | Fenofibrate                            |                    |                    | S               | Oral                 | Unk                         |                 | Ranbaxy      |                |
|                                                                           | Alprazolam                             |                    |                    | S               | Oral                 | Unk                         |                 | Not Reported |                |
|                                                                           | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | Unk                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2010                                                               | 7733158                                | EXPEDITED (15-DAY) | Y                  | HO, LT          | TIF2010A00131        |                             | 63 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Muscle Rigidity; Rhabdomyolysis; Tremor | Ciprallex                              |                    |                    | S               | Oral                 | 15 Mg (10 Mg) Oral          | 33 DAY          | Not Reported |                |
|                                                                           | Olanzapine (Olanzapine)                |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D) Oral | 64 DAY          | Not Reported |                |
|                                                                           | Bisoprolol                             |                    |                    | S               |                      | 1.25 Mg (1.25 Mg)           |                 | Not Reported |                |
|                                                                           | Lansoprazole (Lansoprazole)            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                           | Lorazepam                              |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2010                                                               | 7742865                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000016978           |                             | 33 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Suicide Attempt; Toxicity To Various Agents            | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2010                                                               | 7742867                                | EXPEDITED (15-DAY) | Y                  | DS              | 1000017507           |                             | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Lipoedema                                                                 | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                           | Carmen (Lercanidipine) (Lercanidipine) |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                                                                              |   |  |  |  |  |  |  |              |
|--|------------------------------------------------------------------------------|---|--|--|--|--|--|--|--------------|
|  | Amiloretik (Amiloride, Hydrochlorothiazide) (Amiloride, Hydrochlorothiazide) | C |  |  |  |  |  |  | Not Reported |
|  | Hormongel (Estradiol) (Estradiol)                                            | C |  |  |  |  |  |  | Not Reported |
|  | Doxepin (Doxepin) (Doxepin)                                                  | C |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|--------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 02-Dec-2010                                            | 7742882                                                      | EXPEDITED (15-DAY) | Y                  | HO              | 1000017502           |                             | 76 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Akinesia; Confusional State; Iatrogenic Injury; Tremor | Escitalopram Oxalate                                         |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate                                         |                    |                    | S               | Oral                 | 15 Mg (15 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                        | Oxazepam                                                     |                    |                    | S               | Oral                 | 20 Mg (10 Mg,2 In 1 D),Oral |                 | Not Reported |                |
|                                                        | Zolpidem Tartrate                                            |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                        | Furosemide (Furosemide)                                      |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                        | Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                        | Atorvastatin Calcium Bisoprolol Fumarate                     |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------|----------------|
| 02-Dec-2010                                        | 7743061        | DIRECT           | N                  | HO              |                      |                               | 33 YR           | Male       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Dissociative Amnesia; Loss Of Consciousness; Mania | Lexapro        |                  |                    | S               | Oral                 | 10 Mg Once Per Day Oral, Pill |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2010              | 7504309       | EXPEDITED (15-DAY) | Y                  | HO              | 1000014968           |                      | 66 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------|-----------------|--------------|----------------|
| Agitation; Hepatitis; Hypomania; Logorrhoea; Major Depression; Tachyphrenia  | Escitalopram Oxalate                              |                    |                    | S               | Oral                     | 20 Mg (10 Mg,2 In 1 D),Oral     |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate                              |                    |                    | S               | Oral                     | 20 Mg (10 Mg,2 In 1 D),Oral     |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate                              |                    |                    | S               | Oral                     | 10 Mg (10 Mg,1 In 1 D),Oral     |                 | Not Reported |                |
|                                                                              | Fenofibrate                                       |                    |                    | S               | Oral                     | Oral                            |                 | Not Reported |                |
|                                                                              | Mirtazapine                                       |                    |                    | S               | Oral                     | Oral                            |                 | Not Reported |                |
|                                                                              | Mirtazapine                                       |                    |                    | S               | Oral                     | Oral                            |                 | Not Reported |                |
|                                                                              | Imovane (Zopiclone) (Zopiclone)                   |                    |                    | C               |                          |                                 |                 | Not Reported |                |
|                                                                              | Largactil (Chlorpromazine) (Chlorpromazine)       |                    |                    | C               |                          |                                 |                 | Not Reported |                |
|                                                                              | Seresta (Oxazepam) (Oxazepam)                     |                    |                    | C               |                          |                                 |                 | Not Reported |                |
|                                                                              | Teralithe (Lithium Carbonate) (Lithium Carbonate) |                    |                    | C               |                          |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2010                                                                  | 7691629                                           | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2010161286 |                                 |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Ineffective                                                 | Pristiq Extended Release                          |                    |                    | S               |                          | 100 Mg, 1x/Day                  |                 | Pfizer       |                |
|                                                                              | Escitalopram Oxalate                              |                    |                    | S               |                          |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Dec-2010                                                                  | 7743895                                           | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000017489               |                                 | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Delirium; Depression; Poisoning Deliberate; Toxicity To Various Agents | Escitalopram Oxalate                              |                    |                    | S               | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                              | Clonazepam                                        |                    |                    | S               | Oral                     | 15 Gtt (15 Gtt, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dafalgan (Paracetamol)  
(Paracetamol)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Dec-2010              | 7744411       | EXPEDITED (15-DAY) | Y                  | DS, OT          | 2010MA004769         |                      | 47 YR      | Female     | GBR            |

| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure Increased; Condition Aggravated; Hypertonia; Panic Attack; Phobia; Reflexes Abnormal; Serotonin Syndrome; Tachycardia | Fluoxetine           |              |            | S           | Oral         | 20 Mg; Po          |                 | Alphapharm   |
|                                                                                                                                               | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg; Po          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Dec-2010              | 7723817       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017463           |                      | 45 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Metabolic Acidosis; Renal Failure; Respiratory Failure; Rhabdomyolysis; Serotonin Syndrome | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                              | Methylene Blue       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                              | Fentanyl             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Dec-2010              | 7729238       | EXPEDITED (15-DAY) | Y                  | DS, OT          | AUR-APL-2010-02547   |                      | 47 YR      | Female     |                |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Pressure Increased; Condition Aggravated; Hyperreflexia; Hypertonia; Panic Attack; Phobia; Serotonin Syndrome; Tachycardia | Fluoxetine           |              |            | S           | Oral         | 20mg-Oral          |                 | Not Reported |
|                                                                                                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 10mg-Oral          |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Dec-2010                                                                                                                                                                          | 7743755                                     | EXPEDITED (15-DAY) | N                  | CA              | 1000017521           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Persistent Foetal Circulation; Sepsis Neonatal | Lexapro                                     |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                                                                                                                                      | Paxil                                       |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                                                                                                                                      | Zoloft                                      |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                                                                                                                                      | Prozac                                      |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
|                                                                                                                                                                                      | Effexor                                     |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2010                                                                                                                                                                          | 7723061                                     | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2010MA004567         |                      | 87 YR           | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage; Fall                                                                                                                                                           | Naproxen                                    |                    |                    | S               | Oral                 | 250 Mg; Tid; Po      |                 | Purepac      |                |
|                                                                                                                                                                                      | Acetylsalicylic Acid (Acetylsalicylic Acid) |                    |                    | S               | Oral                 | 75 Mg; Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                      | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 15 Mg; Qd; Po        |                 | Not Reported |                |
|                                                                                                                                                                                      | Omeprazole                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Dec-2010                                                                                                                                                                          | 7756360                                     | DIRECT             |                    |                 |                      |                      | 36 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Akathisia; Anger                                                                                                                                                         | Lexapro                                     |                    |                    | S               | Oral                 | 10mg Daily Po        |                 | Forest       |                |
|                                                                                                                                                                                      | Clonazepam                                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2010                                                                                                                                                                          | 7696492                                     | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000017134           |                      | 28 YR           | Female       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| Abnormal Behaviour;<br>Bipolar Disorder;<br>Condition Aggravated;<br>Depression; Generalised<br>Anxiety Disorder; Mania;<br>Mental Disorder; Post-<br>Traumatic Stress Disorder;<br>Social Anxiety Disorder;<br>Suicidal Ideation | Escitalopram Oxalate                                       |                    |                    | S               | Oral                               | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                   |                                                            |                    |                    |                 | Oral                               | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 |              |                |
|                                                                                                                                                                                                                                   | Lamotrigin (Lamotrigine)<br>(Tablets) (Lamotrigine)        |                    |                    | C               |                                    |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Lithionit (Lithium Sulfate)<br>(Tablets) (Lithium Sulfate) |                    |                    | C               |                                    |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Sobril (Oxazepam) (Tablets)<br>(Oxazepam)                  |                    |                    | C               |                                    |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Atarax (Hydroxyzine) (Tablets)<br>(Hydroxyzine)            |                    |                    | C               |                                    |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2010                                                                                                                                                                                                                       | 7736907                                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000017383                         |                                                                    | 1 DAY           | Male         | SWE            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation Neonatal;<br>Haematochezia; Irritable<br>Bowel Syndrome;<br>Maternal Drugs Affecting<br>Foetus; Melaena;<br>Necrotising Colitis;<br>Premature Baby                                                                      | Escitalopram Oxalate                                       |                    |                    | S               | Transplacental                     | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                          | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Dec-2010                                                                                                                                                                                                                       | 7703184                                                    | EXPEDITED (15-DAY) | Y                  | HO              | DE-SANOFI-AVENTIS-<br>2010SA034202 |                                                                    | 77 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                             | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Epistaxis                                                                                                                                                                                                       | Plavix                                                     |                    |                    | S               | Oral                               |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Remergil                                                   |                    |                    | C               | Oral                               |                                                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                   | Remergil                                                   |                    |                    | C               | Oral                               |                                                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |              |
|----------------------|---|------|--------------|
| Dalteparin Sodium    | C | Oral | Not Reported |
| Simvastatin          | C | Oral | Not Reported |
| Metoprolol           | C | Oral | Not Reported |
| Acetylsalicylic Acid | S | Oral | Not Reported |
| Escitalopram Oxalate | S | Oral | Not Reported |
| Escitalopram Oxalate | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2010              | 7703555       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20101202533 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Somnolence; Suicidal Ideation; Weight Increased | Invega         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2010              | 7703741       | EXPEDITED (15-DAY) | N                  | OT              | US-BAYER-2010-003121 |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Dry Mouth; Urinary Tract Disorder; Vision Blurred | Acetylsalicylic Acid        |              | Y          | S           |              | Unk Unk, Q1mon     |                 | Bayer        |
|                                                                 | Fesoterodine                |              |            | S           | Oral         | 8 Mg, Unk          | 5 DAY           | Not Reported |
|                                                                 | Alprazolam                  |              |            | S           |              | Unk Unk, Prn       |                 | Not Reported |
|                                                                 | Simvastatin                 |              |            | S           |              | Unk Unk, Q1mon     |                 | Not Reported |
|                                                                 | Lexapro                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                 | Seroquel                    |              |            | S           |              | Unk Unk, Q1mon     |                 | Not Reported |
|                                                                 | Fish Oil                    |              |            | S           |              | Unk Unk, Q1mon     |                 | Bayer        |
|                                                                 | Vitamin D2 (Ergocalciferol) |              |            | S           |              | Unk Unk, Q1mon     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Dec-2010              | 7748719       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017565           |                      | 68 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                        |                      |   |      |                                 |              |
|----------------------------------------|----------------------|---|------|---------------------------------|--------------|
| Ocular Hypertension;<br>Vision Blurred | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D)<br>Oral | Not Reported |
|----------------------------------------|----------------------|---|------|---------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2010              | 7567132       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000015705           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Agitation; Blood Glucose Decreased; Erectile Dysfunction; Loss Of Libido; Polydipsia; Polyuria; Thirst | Escitalopram Oxalate                    |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D, Oral |                 | Not Reported |
|                                                                                                        | Temesta (Lorazepam) (Lorazepam)         |              |            | C           |              |                            |                 | Not Reported |
|                                                                                                        | Stilnox (Zolpidem) (Tablets) (Zolpidem) |              |            | C           |              |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Dec-2010              | 7749099       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000017596           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Fatigue; Suicidal Ideation; Thinking Abnormal | Escitalopram Oxalate |              |            | S           | Oral         | See Image: Oral    | 1 WEEK          | Not Reported |
|                                                          |                      |              |            |             | Oral         | See Image: Oral    |                 |              |
|                                                          |                      |              |            |             | Oral         | See Image: Oral    | 1 WEEK          |              |
|                                                          | Insulin Nos          |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Altace               |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Chemotherapy         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2010              | 6362231       | EXPEDITED (15-DAY) | Y                  | RI, OT          | S07-GER-02887-01     |                      | 49 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------|-----------------|--------------|
| Affect Lability; Agitation; Alcoholism; Depression; Disease Recurrence; Nervousness; Panic Disorder; Restlessness; Sleep Disorder; Suicidal Ideation; Tension; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral                                  |                 | Not Reported |
|                                                                                                                                                                | Trimipramine Maleate |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                                |                      |              |            |             | Oral         | 100 Mg (100 Mg, 1 In 1 D),                                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Withdrawal Syndrome

Oral; 75 Mg (75 Mg, 1 In 1 D),Oral

Bisoprolol Fumarate

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2010              | 7755028       | EXPEDITED (15-DAY) | Y                  | HO, LT          | IPC201012-000313     |                      | 73 YR      | Female     | ESP            |

| <u>Preferred Term</u>                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Activated Partial Thromboplastin Time | Metformin Hydrochloride |              |            | S           |              | 850 Mg 3 Times Daily | 2 WEEK          | Not Reported |
| Prolonged; Anaemia;                   | Acenocoumarol           |              |            | S           |              |                      |                 | Not Reported |
| Arrhythmia; Blood Glucose             | Bisoprolol              |              |            | S           |              |                      |                 | Not Reported |
| Increased; Cardiac                    | Torsemide               |              |            | S           |              |                      |                 | Not Reported |
| Failure; Continuous                   | Digoxin                 |              |            | S           |              |                      |                 | Not Reported |
| Haemodiafiltration; Heart             | Escitalopram Oxalate    |              |            | S           |              |                      |                 | Not Reported |
| Rate Decreased; Hepatic               | Lormetazepam            |              |            | S           |              |                      |                 | Not Reported |
| Failure; International                | Terbutaline Sulfate     |              |            | S           |              |                      |                 | Not Reported |
| Normalised Ratio                      | Tiotropium Bromide      |              |            | S           |              |                      |                 | Not Reported |
| Increased; Lactic Acidosis;           | Insulin Glargine        |              |            | S           |              |                      |                 | Not Reported |
| Leukocytosis; Liver Injury;           |                         |              |            |             |              |                      |                 |              |
| Neutrophilia; Pancreatitis;           |                         |              |            |             |              |                      |                 |              |
| Pleural Effusion;                     |                         |              |            |             |              |                      |                 |              |
| Polydipsia; Polyuria;                 |                         |              |            |             |              |                      |                 |              |
| Prothrombin Time                      |                         |              |            |             |              |                      |                 |              |
| Prolonged; Renal Failure;             |                         |              |            |             |              |                      |                 |              |
| Thrombocytopenia                      |                         |              |            |             |              |                      |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2010              | 7198579       | EXPEDITED (15-DAY) | Y                  | OT              | DK-PFIZER INC-2009280745 |                      |            | Male       | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased; | Lyrica              |              |            | S           |              | 300 Mg, 2x/Day     | 1156 DAY        | Pfizer       |
| Dizziness; Fatigue      | Ciprallex           |              |            | S           |              | Unk                |                 | Not Reported |
|                         | Bendroflumethiazide |              |            | S           |              | Unk                |                 | Not Reported |
|                         | Amitriptyline       |              |            | C           |              | 50 Mg, 1x/Day      |                 | Not Reported |
|                         | Morphine            |              |            | C           |              | 10 Mg, As Needed   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |   |                 |              |
|-------------------------------------------------------------------------|---|-----------------|--------------|
| Gabapentin                                                              | C | 1200 Mg, 3x/Day | Not Reported |
| Tramadol                                                                | C | 200 Mg, 2x/Day  | Not Reported |
| Ammonium<br>Bromide\Caffeine\Phenobarbital\<br>Phenytoin\Sodium Bromide | C | 300 Mg, 2x/Day  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2010              | 7222984       | EXPEDITED (15-DAY) | Y                  | HO              | ES-PFIZER INC-<br>2009309733 |                      | 84 YR      | Female     | ESP            |

| <u>Preferred Term</u>                                    | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depressed Level Of<br>Consciousness; Drug<br>Interaction | Lyrica                                      |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Pfizer       |
|                                                          | Omeprazole                                  |              |            | C           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                          | Nitrendipine                                |              |            | C           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                          | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         | Unk                | 4 DAY           | Not Reported |
|                                                          | Escitalopram Oxalate                        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                          | Diazepam                                    |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2010              | 7339797       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2010026726 |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Drug<br>Ineffective; Fibromyalgia;<br>General Physical<br>Condition Abnormal;<br>Insomnia; Mania;<br>Micturition Frequency<br>Decreased; Neuralgia;<br>Oedema Peripheral; Pain<br>In Extremity; Suicidal<br>Ideation; Thyroid Disorder;<br>Weight Increased | Lyrica         |              |            | S           |              | 50 Mg, 3x/Day      |                 | Pfizer       |
|                                                                                                                                                                                                                                                                           | Lyrica         |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                           | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Lithium        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Elavil         |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Clonazepam     |              |            | C           |              | 1 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                                                                                                                           | Klonopin       |              |            | C           | Oral         | Unk                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Dec-2010                                                                             | 7342698                   | EXPEDITED (15-DAY) | Y                  | OT              | GB-PFIZER INC-2010036118 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy; Pregnancy Of<br>Partner | Pregabalin                |                    |                    | S               | Other                    | Unk                  |                 | Pfizer       |                |
|                                                                                         | Trazodone                 |                    |                    | S               | Other                    | Unk                  |                 | Not Reported |                |
|                                                                                         | Cipralelex                |                    |                    | S               | Other                    | 20 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2010                                                                             | 7387232                   | EXPEDITED (15-DAY) | Y                  | HO              | ES-PFIZER INC-2010050324 |                      | 77 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                                                      | Lyrica                    |                    |                    | S               | Oral                     | 150 Mg, 1x/Day       | 12 DAY          | Pfizer       |                |
|                                                                                         | Ciprofloxacin             |                    |                    | C               | Oral                     | 500 Mg, 1x/Day       | 9 DAY           | Not Reported |                |
|                                                                                         | Trazodone                 |                    |                    | C               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                         | Captopril                 |                    |                    | C               | Oral                     | 50 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                         | Amoxicillin & Clavulanate |                    |                    | C               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                         | Potassium<br>Cipralelex   |                    |                    | S               | Oral                     | 15 Mg, 1x/Day        | 12 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2010                                                                             | 7407576                   | EXPEDITED (15-DAY) | Y                  | HO, OT          | DK-PFIZER INC-2010063884 |                      | 31 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Rhabdomyolysis;<br>Urinary Retention               | Lyrica                    |                    |                    | S               | Oral                     | 75 Mg, 2x/Day        | 7 DAY           | Pfizer       |                |
|                                                                                         | Cipralelex                |                    |                    | S               |                          | 20 Mg, 1x/Day        | 13 DAY          | Not Reported |                |
|                                                                                         | Oxycontin                 |                    |                    | S               | Oral                     | 10 Mg, 2x/Day        |                 | Not Reported |                |
|                                                                                         | Tramadol                  |                    |                    | S               | Oral                     | 100 Mg, 4x/Day       | 391 DAY         | Not Reported |                |
|                                                                                         | Seroquel                  |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       | 3 DAY           | Not Reported |                |
|                                                                                         | Seroquel                  |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       | 170 DAY         | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 15-Dec-2010                       | 7414848                 | EXPEDITED (15-DAY)        | Y                           | OT                       | CH-PFIZER INC-2010067812      |                               | 19 YR                    | Female              | CHE                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abortion; Abortion                | Lyrica                  |                           |                             | S                        |                               | 200 Mg, 1x/Day                |                          | Pfizer              |                         |
| Spontaneous; Maternal             | Lyrica                  |                           |                             | S                        |                               | 125 Mg, 1x/Day                | 9 DAY                    | Pfizer              |                         |
| Exposure During                   | Neurontin               |                           |                             | S                        |                               | 200 Mg, 1x/Day                | 41 DAY                   | Pfizer              |                         |
| Pregnancy; Pregnancy              | Ciprallex               |                           |                             | S                        |                               | 2 Df, 1x/Day                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2010                       | 7454553                 | EXPEDITED (15-DAY)        | N                           | OT                       | US-PFIZER INC-2007014600      |                               | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Distension;             | Lyrica                  |                           |                             | S                        |                               | 50 Mg, 3x/Day                 |                          | Pfizer              |                         |
| Abdominal Pain; Bladder           | Lexapro                 |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
| Disorder; Eye Pain; Vision        |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Blurred; Visual                   |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Impairment; Weight                |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| Increased                         |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2010                       | 7487741                 | EXPEDITED (15-DAY)        | Y                           | HO                       | DE-PFIZER INC-2010084293      |                               | 59 YR                    | Male                | DEU                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatic Enzyme                    | Lyrica                  |                           |                             | S                        |                               | 50 Mg, 3x/Day                 |                          | Pfizer              |                         |
| Increased; Hepatitis;             | Ciprallex               |                           |                             | S                        |                               | 20/0/0 (Units Not Provided)   | 20 DAY                   | Not Reported        |                         |
| Jaundice                          |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2010                       | 7617187                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000016228                    |                               | 91 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |                                                                 |   |      |                                  |              |
|------------------------------------------------------------|-----------------------------------------------------------------|---|------|----------------------------------|--------------|
| Confusional State;<br>Disturbance In Attention;<br>Fatigue | Escitalopram Oxalate                                            | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                            | Kardegic (Acetylsalicylate<br>Lysine) (Acetylsalicylate Lysine) | C |      |                                  | Not Reported |
|                                                            | Corvasal (Molsidomine)                                          | C |      |                                  | Not Reported |
|                                                            | Crestor (Rosuvastatin)                                          | C |      |                                  | Not Reported |
|                                                            | Rosuvastatin)                                                   |   |      |                                  |              |
|                                                            | Fosavance (Alendronate<br>Sodium, Colecalciferol)               | C |      |                                  | Not Reported |
|                                                            | (Alendronate Sodium),<br>Colecalciferol)                        |   |      |                                  |              |
|                                                            | Vastarel                                                        | C |      |                                  | Not Reported |
|                                                            | Xatrel (Alfusion) (Alfusion)                                    | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 15-Dec-2010              | 7712462       | EXPEDITED (15-DAY) | N                  | OT              | US-PURDUE-USA-<br>2010-0058201 |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Detoxification;<br>Intentional Product<br>Misuse; Lethargy;<br>Overdose; Pain;<br>Somnolence | Oxycontin        |              |            | S           |              | 80 Mg, See Text    |                 | Purdue       |
|                                                                                                   | Morphine Sulfate |              |            | S           |              | Unk Unk, See Text  |                 | Purdue       |
|                                                                                                   | Diazepam         |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Vicodin Es       |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Soma             |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Parafon Forte    |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Zanaflex         |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Klonopin         |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Ativan           |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Phenergan        |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Lexapro          |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Relafen          |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Neurontin        |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Lidoderm         |              |            | S           |              | Unk Unk, See Text  |                 | Not Reported |
|                                                                                                   | Morphine Sulfate |              |            | C           |              | Unk Unk, See Text  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |   |                   |              |
|------------------|---|-------------------|--------------|
| Reglan           | C | Unk Unk, See Text | Not Reported |
| Morphine Sulfate | C | Unk Unk, See Text | Purdue       |
| Lovastatin       | C | Unk, See Text     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2010              | 7777335       | EXPEDITED (15-DAY) | Y                  | HO              | 100017301            |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Anxiety; Decreased      | Escitalopram Oxalate         |              |            | S           | Oral         | 5 Mg, (5mg, 1 In 1 D),Oral |                 | Not Reported |
| Appetite; Dysaesthesia; | Advil                        |              |            | S           | Oral         | 200 TO 800 Mg, Oral        |                 | Not Reported |
| Haematemesis;           | Seresta (Oxazepam) (Tablets) |              |            | C           |              |                            |                 | Not Reported |
| Headache; Malaise;      | (Oxazepam)                   |              |            |             |              |                            |                 |              |
| Nausea; Vomiting        |                              |              |            |             |              |                            |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Dec-2010              | 7463048       | EXPEDITED (15-DAY) | N                  | HO              | FR-ABBOTT-10P-056-0654575-00 |                      | 66 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; Hypomania  | Lipanthyl                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Mirtazapine                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Mirtazapine                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lithium Carbonate             |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Oxazepam                      |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Chlorpromazine\Chlorpromazine |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Hydrochloride                 |              |            |             |              |                    |                 |              |
|                       | Zopiclone                     |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Dec-2010              | 7759388       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017691           |                      | 36 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Aggression; Condition Aggravated; Drug Withdrawal Syndrome; Intentional Overdose; Treatment Noncompliance | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                           | Bromazepam                                                                     |                    |                    | S               |                      | (150 Mg, Once)<br>(150 Mg, Once) |                 | Not Reported |                |
|                                                                                                           | Risperidone                                                                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2010                                                                                               | 7759393                                                                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000017682           |                                  | 83 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Drug Interaction; Hallucination; Incoherent; Nervous System Disorder; Tremor                     | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                                           | Topalgic [Tramadol Hydrochloride]                                              |                    |                    | S               |                      | 200 Mg (100 Mg, 2 In 1 D)        |                 | Not Reported |                |
|                                                                                                           | Sinemet Lp (Carbidopa, Levodopa) (25 Milligram, Tablets) (Carbidopa, Levodopa) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2010                                                                                               | 7759833                                                                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000017713           |                                  | 22 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Poisoning Deliberate; Somnolence                                                                          | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                           | Oxazepam                                                                       |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                                                           | Abilify                                                                        |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                  | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Dec-2010                                                                                               | 7760193                                                                        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017660           |                                  | 18 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                     | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Poisoning; Drug Abuse                                                                             | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                 | 10 Mg, Once, Oral                |                 | Not Reported |                |

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|                                                                                       | Fluoxetine           |                    | S                  | Oral            |                          | 1 Dosage Forms, Once, Oral |                 |            | Not Reported   |
|---------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|------------|----------------|
|                                                                                       | Alcohol (Ethanol)    |                    | S                  | Oral            |                          | Oral                       |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Dec-2010                                                                           | 7790582              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017646               |                            | 19 YR           | Male       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Alcohol Poisoning; Alcohol Use; Drug Abuse                                            | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg Once, Oral           |                 |            | Not Reported   |
|                                                                                       | Fluoxetine           |                    |                    | S               | Oral                     | 1 Dosage Forms, Once, Oral |                 |            | Not Reported   |
|                                                                                       | Alcohol (Ethanol)    |                    |                    | S               | Oral                     | Oral                       |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Dec-2010                                                                           | 7723121              | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2010173852 |                            | 44 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Detoxification; Intentional Product Misuse; Lethargy; Overdose; Pain; Somnolence | Neurontin            |                    |                    | S               |                          | 600 Mg, (12 Pills)         |                 |            | Pfizer         |
|                                                                                       | Morphine Sulfate     |                    |                    | S               |                          | 20 Mg/MI                   |                 |            | Unknown        |
|                                                                                       | Oxycontin            |                    |                    | S               |                          | 80 Mg, Unk                 |                 |            | Not Reported   |
|                                                                                       | Diazepam             |                    |                    | S               |                          | 10 Mg, Unk                 |                 |            | Not Reported   |
|                                                                                       | Vicodin              |                    |                    | S               |                          | Unk                        |                 |            | Not Reported   |
|                                                                                       | Soma                 |                    |                    | S               |                          | 350 Mg, Unk                |                 |            | Not Reported   |
|                                                                                       | Parafon Forte        |                    |                    | S               |                          | Unk                        |                 |            | Not Reported   |
|                                                                                       | Zanaflex             |                    |                    | S               |                          | 4 Mg, Unk                  |                 |            | Not Reported   |
|                                                                                       | Klonopin             |                    |                    | S               |                          | 1 Mg, Unk                  |                 |            | Not Reported   |
|                                                                                       | Ativan               |                    |                    | S               |                          | 1 Mg, Unk                  |                 |            | Not Reported   |
|                                                                                       | Promethazine         |                    |                    | S               |                          | Unk                        |                 |            | Not Reported   |
|                                                                                       | Lexapro              |                    |                    | S               |                          | 40 Mg, Unk                 |                 |            | Not Reported   |
|                                                                                       | Relafen              |                    |                    | S               |                          | 750 Mg, Unk                |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

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|                  |   |            |              |
|------------------|---|------------|--------------|
| Lidoderm         | S | 5 %        | Not Reported |
| Morphine Sulfate | C | Unk        | Not Reported |
| Reglan           | C | 10 Mg, Unk | Not Reported |
| Msir             | C | Unk        | Not Reported |
| Lovastatin       | C | 20 Mg, Unk | Not Reported |

| <u>FDA Received Date</u>       | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 21-Dec-2010                    | 7619521                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016319           |                         | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>          | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Personality Change | Escitalopram Oxalate      |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                | Anxiolytics (Anxiolytics) |                    |                    | C               |                      |                         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2010              | 7753188        | EXPEDITED (15-DAY) | Y                  | OT              | 2010SP062320         |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania; Oedema Peripheral | Saphris        |                    |                    | S               | Sublingual           | 20 Mg; Hs; SI        |                 | Not Reported |                |
|                          | Wellbutrin     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Maxzide        |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                          | Alprazolam     |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 21-Dec-2010                                            | 7764961                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017734           |                               |                 | Male         | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Hypersensitivity; Tubulointerstitial Nephritis | Escitalopram Oxalate             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                        | Inexium (Esomeprazole Magnesium) |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                        | Lexomil (Bromazepam)             |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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(Bromazepam)

| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 21-Dec-2010                                                                                                           | 7766111              | DIRECT             | N                  | HO              |                      |                           | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Adverse Drug Reaction;<br>Balance Disorder;<br>Confusional State;<br>Overdose; Physical<br>Assault; Suicidal Ideation | Lexapro              |                    |                    | S               | Oral                 | 15mg Every Day Po         |                 | Walgreen     |                |
|                                                                                                                       | Geodon               |                    |                    | S               | Oral                 | 40mg Every Day Po         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2010                                                                                                           | 7794836              | EXPEDITED (15-DAY) | Y                  | OT              | AE-1210-401          |                           | 44 YR           | Female       | SGP            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Incorrect Dose<br>Administered; Lethargy;<br>Overdose; Pain;<br>Somnolence                                            | Lidoderm             |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Oxycontin            |                    |                    | S               |                      | 80 Mg                     |                 | Not Reported |                |
|                                                                                                                       | Morphine Sulfate     |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Diazepam             |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Vicodin Es           |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Soma                 |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Parafon Forte        |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Zanaflex             |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Klonopin             |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Ativan               |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Phenergan            |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Lexapro              |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Relafen              |                    |                    | S               |                      |                           |                 | Not Reported |                |
|                                                                                                                       | Neurontin            |                    |                    | S               |                      |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2010                                                                                                           | 7629976              | EXPEDITED (15-DAY) | Y                  | OT              | 1000016392           |                           | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Insomnia;                                                                                                  | Escitalopram Oxalate |                    |                    | S               |                      | 2.5 Mg (2.5 Mg, 1 In 1 D) |                 | Not Reported |                |

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|                                       |                                                              |   |                         |  |              |
|---------------------------------------|--------------------------------------------------------------|---|-------------------------|--|--------------|
| Logorrhoea; Paradoxical Drug Reaction | Escitalopram Oxalate                                         | S | 10 Mg (10 Mg, 1 In 1 D) |  | Not Reported |
|                                       | Levothyroxine Sodium                                         | C |                         |  | Not Reported |
|                                       | Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine) | C |                         |  | Not Reported |
|                                       | Microval (Levonorgestrel) (Levonorgestrel)                   | C |                         |  | Not Reported |
|                                       | Myolastan (Tetrazepam) (Tetrazepam)                          | C |                         |  | Not Reported |
|                                       | Inexium (Esomeprazole Magnesium)                             | C |                         |  | Not Reported |
|                                       | Tramadol Hydrochloride And Acetaminophen                     | C |                         |  | Not Reported |
|                                       |                                                              |   |                         |  |              |

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2010                                                                                   | 7727985        | EXPEDITED (15-DAY) | Y                  | HO, OT          | FI-ASTRAZENECA-2010SE38024 |                      |                 | Female       | FIN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Leukopenia; Potentiating Drug Interaction; Psychotic Disorder | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                               | Abilify        |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                               | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                               | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                               | Seroquel       |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                               | Ciprallex      |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Dec-2010              | 7730043        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010176017 |                      | 12 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ejaculation Delayed      | Zoloft         |                  |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 22-Dec-2010              | 7731189       | EXPEDITED (15-DAY) | Y                  | HO              | IN-MYLANLABS-2010S1022934 |                      | 23 YR      | Female     | IND            |

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| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Dystonia;<br>Temporomandibular Joint<br>Syndrome                                                                                        | Escitalopram Oxalate                                            |                    |                    | S               | Unknown              |                                       |                 | Alphapharm   |                |
|                                                                                                                                                           | Clonazepam                                                      |                    |                    | C               | Unknown              |                                       |                 | Not Reported |                |
|                                                                                                                                                           | Aripiprazole                                                    |                    |                    | S               | Unknown              |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2010                                                                                                                                               | 7765225                                                         | EXPEDITED (15-DAY) |                    | LT              | 1000017780           |                                       |                 | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression                                                                                                                                                | Lexapro                                                         |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Dec-2010                                                                                                                                               | 7765942                                                         | EXPEDITED (15-DAY) |                    | OT              | ACO_20790_2010       |                                       | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue;<br>Feeling Abnormal;<br>Hemiparesis;<br>Inappropriate Schedule Of<br>Product Administration;<br>Multiple Sclerosis; Vision<br>Blurred | Ampyra                                                          |                    |                    | S               | Oral                 | 10 Mg, Qd, Oral, 10 Mg,<br>Bid, Oral, |                 | Not Reported |                |
|                                                                                                                                                           |                                                                 |                    |                    |                 | Oral                 | 10 Mg, Qd, Oral, 10 Mg,<br>Bid, Oral, |                 |              |                |
|                                                                                                                                                           | Lexapro                                                         |                    |                    | S               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                           | Valium /00017001/ (Diazepam)                                    |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                           | Antihypertensives                                               |                    |                    | C               |                      |                                       |                 | Not Reported |                |
|                                                                                                                                                           | Copaxone /03175301/<br>(Glatiramer Acetate, Mannitol<br>Lipitor |                    |                    | C               |                      |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2010                                                                                                                                               | 4170801                                                         | EXPEDITED (15-DAY) | Y                  | DS, RI, OT      | S04-TUR-02785-01     |                                       | 38 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract; Corneal Opacity                                                                                                                                 | Ciprallex                                                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral      |                 | Not Reported |                |



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| Sleeping Pills (Sleeping Pills)<br>(Sleeping Pills)                                                                                                                                                                                                                                                                                                                                     |                                         |                           | C                           |                          | Not Reported                  |                                  |                          |                     |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|---------------------|-------------------------|
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                                                                       | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Dec-2010                                                                                                                                                                                                                                                                                                                                                                             | 7676787                                 | EXPEDITED (15-DAY)        | N                           | RI, OT                   | 1000016976                    |                                  | 45 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                                                                          | <a href="#">Product</a>                 | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Glucose Increased;<br>Cataract Subcapsular; Dry<br>Mouth; Fatigue; Glucose<br>Tolerance Test Abnormal;<br>Pollakiuria; Polydipsia                                                                                                                                                                                                                                                 | Escitalopram Oxalate                    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         | Supradyn (Supradyn)<br>(Supradyn)       |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         | Lansor (Lansoprazole)<br>(Lansoprazole) |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                                                                       | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Dec-2010                                                                                                                                                                                                                                                                                                                                                                             | 7766926                                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000017582                    |                                  | 56 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                                                                                                                                                                                                                                                                                                          | <a href="#">Product</a>                 | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Dreams;<br>Agitation; Crying;<br>Depersonalisation/Dereali<br>sation Disorder;<br>Discomfort; Disturbance In<br>Attention; Dizziness; Drug<br>Withdrawal Syndrome;<br>Headache; Hyperhidrosis;<br>Hypoaesthesia; Influenza<br>Like Illness; Irritability;<br>Muscle Tightness;<br>Nausea; Overdose;<br>Paraesthesia; Salivary<br>Hypersecretion; Suicidal<br>Ideation; Vertigo | Lexapro                                 |                           |                             | S                        | Oral                          | See Image                        |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                           |                             |                          | Oral                          | See Image                        |                          |                     |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                           |                             |                          | Oral                          | See Image                        |                          |                     |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                           |                             |                          | Oral                          | See Image                        |                          |                     |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         | Cymbalta                                |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         | Xanax                                   |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
|                                                                                                                                                                                                                                                                                                                                                                                         | Propranolol                             |                           |                             | C                        |                               |                                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                                                                                                                                                                                                                                                                                       | <a href="#">Case #</a>                  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Dec-2010                                                                                                                                                                                                                                                                                                                                                                             | 7768223                                 | DIRECT                    | N                           | HO                       |                               |                                  | 81 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| Diarrhoea; Dizziness; Loss Of Consciousness; Malaise; Nausea                                          | Lexapro              |                    |                    | S               | Oral                                     | 5 Mg 1 Time Only Oral         |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Dec-2010                                                                                           | 7768356              | DIRECT             |                    | OT              |                                          |                               | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Balance Disorder; Decreased Appetite; Diarrhoea; Nausea; Urticaria; Vertigo; Vomiting | Lexapro              |                    |                    | S               | Oral                                     | 10 Mg Once Daily Mouth        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2010                                                                                           | 7682181              | EXPEDITED (15-DAY) | Y                  | HO              | 1000016997                               |                               | 39 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Extrasystoles                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Dec-2010                                                                                           | 7740337              | EXPEDITED (15-DAY) | N                  | HO              | IN-BRISTOL-MYERS SQUIBB COMPANY-15451370 |                               | 23 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Joint Dislocation; Salivary Hypersecretion; Sedation                                        | Clonazepam           |                    |                    | S               |                                          |                               |                 | Sandoz       |                |
|                                                                                                       | Aripiprazole         |                    |                    | S               |                                          |                               |                 | Not Reported |                |
|                                                                                                       | Aripiprazole         |                    |                    | S               |                                          |                               |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate |                    |                    | S               |                                          |                               |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------|--------------------|------------------|------------------------------|---------------------------------------------------------|-----------------|--------------------------------------------------------------|----------------|
| 27-Dec-2010                                                                                                                                                                          | 7759853                                                           | EXPEDITED (15-DAY) | Y                  | HO               | 1000017714                   |                                                         | 52 YR           | Male                                                         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Clavicle Fracture;<br>Dizziness; Fall; Fatigue;<br>Gastrointestinal Disorder;<br>Generalised Tonic-Clonic<br>Seizure; Somnolence;<br>Spinal Column Injury;<br>Temporal Lobe Epilepsy | Escitalopram Oxalate<br>Zolpidem                                  |                    |                    | S<br>C           |                              | 15 Mg (15 Mg, 1 In 1 D)                                 |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 27-Dec-2010                                                                                                                                                                          | 7766140                                                           | EXPEDITED (15-DAY) | Y                  | HO, RI, OT       | 1000017833                   |                                                         | 68 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Gastrointestinal Sounds<br>Abnormal; Intentional<br>Overdose; Sopor; Suicide<br>Attempt                                                                                              | Escitalopram Oxalate<br>Tavor (Lorazepam)<br>Diazepam<br>Seroquel |                    |                    | S<br>S<br>S<br>S | Oral<br>Oral<br>Oral<br>Oral | Oral<br>50 Mg, Once, Oral<br>250 Mg, Once, Oral<br>Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 27-Dec-2010                                                                                                                                                                          | 7766764                                                           | EXPEDITED (15-DAY) | Y                  | RI, OT           | 1000017803                   |                                                         |                 | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Hepatic Failure                                                                                                                                                                      | Lexapro                                                           |                    |                    | S                | Oral                         | Oral                                                    |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>         | <u>503B Facility</u>                                    | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 27-Dec-2010                                                                                                                                                                          | 7767675                                                           | EXPEDITED (15-DAY) | Y                  | HO, OT           | 20100556                     |                                                         | 45 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>                 | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Post Procedural                                                                                                                                                                      | Methylene Blue                                                    |                    |                    | S                |                              |                                                         |                 | Not Reported                                                 |                |

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|                                                 |                      |   |              |
|-------------------------------------------------|----------------------|---|--------------|
| Complication; Renal Failure; Serotonin Syndrome | Escitalopram Oxalate | S | Not Reported |
|-------------------------------------------------|----------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2010              | 7770465       | DIRECT           | N                  | HO, LT, RI      |                      |                      | 16 YR      | Female     | USA            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicide Attempt; Visual Impairment | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2010              | 7799038       | EXPEDITED (15-DAY) | N                  | DE              | 1000017830           |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Cerebrovascular Accident; Chest Pain; Drug Abuse; Incorrect Route Of Product Administration; Loss Of Consciousness; Wrong Technique In Product Usage Process | Lexapro                     |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral    |                 | Not Reported |
|                                                                                                                                                              | Soma                        |              |            | S           | Oral         | 1000 Mg (250 Mg, 4 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                              | Percocet                    |              |            | S           | Oral         | 5/325 Mg Tablets, Oral           |                 | Not Reported |
|                                                                                                                                                              | Valium                      |              |            | S           |              |                                  |                 | Not Reported |
|                                                                                                                                                              | Fentora                     |              |            | S           | Buccal       | 400 Mg (400 Mg, 1 In 1 D), Bu    |                 | Not Reported |
|                                                                                                                                                              | Fentanyl Transdermal System |              |            | S           | Transdermal  | Transdermal                      |                 | Not Reported |
|                                                                                                                                                              | Zipor                       |              |            | S           | Oral         | (25 Mg), Oral                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2010              | 8538826       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017835           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Blindness Transient   | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 29-Dec-2010              | 7742655       | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-2010SE60174 |                      | 50 YR      | Male       | CHE            |

| <u>Preferred Term</u>     | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Drug Interaction; Seizure | Seroquel Xr                          |              |            | S           | Oral         |                            |                 | Astrazeneca  |
|                           | Oxazepam                             |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Oxazepam                             |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Campral                              |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Magnesium Carbonate\Potassium Iodide |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Thiamine Hydrochloride               |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Ferrous Sulfate                      |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Allopurinol                          |              |            | C           | Oral         |                            |                 | Not Reported |
|                           | Seroquel Xr                          |              |            | S           | Oral         | 1-4 X 50 Mg/Day In Reserve |                 | Astrazeneca  |
|                           | Seroquel Xr                          |              |            | S           | Oral         |                            |                 | Astrazeneca  |
|                           | Seroquel Xr                          |              |            | S           | Oral         |                            |                 | Astrazeneca  |
|                           | Seroquel Xr                          |              |            | S           | Oral         |                            |                 | Astrazeneca  |
|                           | Remeron                              |              |            | S           | Oral         |                            |                 | Not Reported |
|                           | Remeron                              |              |            | S           | Oral         |                            |                 | Not Reported |
|                           | Remeron                              |              |            | S           | Oral         |                            |                 | Not Reported |
|                           | Ciprallex                            |              |            | S           | Oral         |                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2010              | 7772864       | EXPEDITED (15-DAY) | Y                  | HO              | 2010SP065684         |                      | 50 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------|-----------------|--------------|
| Convulsive Threshold Lowered; Drug Interaction; Generalised Tonic-Clonic Seizure | Remeron        |              |            | S           | Oral         | 15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po |                 | Not Reported |
|                                                                                  |                |              |            |             | Oral         | 15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po |                 |              |

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|                                                                      |   |      |                                                            |              |
|----------------------------------------------------------------------|---|------|------------------------------------------------------------|--------------|
| Seroquel Xr                                                          | S | Oral | 15 Mg; Qd;Po, 30 Mg; Qd;Po, 45 Mg; Qd; Po                  | Not Reported |
|                                                                      |   | Oral | 300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd |              |
|                                                                      |   | Oral | 300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd |              |
|                                                                      |   | Oral | 300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd |              |
|                                                                      |   | Oral | 300 Mg; Qd; Po, 500 Mg; Qd; Po, 600 Mg; Qd; Po, 200 Mg; Qd |              |
| Cipralex                                                             | S | Oral | 20 Mg; Qd; Po                                              | Not Reported |
| Oxazepam                                                             | S | Oral | 15 Mg; Qid; Po, 15 Mg; Bid; Po                             | Not Reported |
|                                                                      |   | Oral | 15 Mg; Qid; Po, 15 Mg; Bid; Po                             |              |
| Campral                                                              | C |      |                                                            | Not Reported |
| Becozyme (Pyridoxine Hydrochloride/Biotin/Cyanocobalamin/Riboflavin) | C |      |                                                            | Not Reported |
| Benerva                                                              | C |      |                                                            | Not Reported |
| Ferr0 Gradumet                                                       | C |      |                                                            | Not Reported |
| Zyloric                                                              | C |      |                                                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Dec-2010              | 7772938       | EXPEDITED (15-DAY) | Y                  | OT              | 2010SP066041         |                      | 69 YR      | Female     | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Varicophlebitis       | Remeron        |              |            | S           |              | 15 Mg; Qd, 30 Mg; Qd<br>15 Mg; Qd, 30 Mg; Qd |                 | Not Reported |
|                       | Cipralex       |              |            | S           | Oral<br>Oral | 10 Mg; Po, 10 Mg<br>10 Mg; Po, 10 Mg         |                 | Not Reported |
|                       | Simvastatin    |              |            | C           |              |                                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------------|-----------------|--------------|----------------|
| 29-Dec-2010                                                                                                                                                            | 7792255                                                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000017678                   |                                          | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Galactorrhoea;<br>Menstruation Irregular                                                                                                                               | Escitalopram Oxalate                                                      |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 N 1 D),Oral              |                 | Not Reported |                |
|                                                                                                                                                                        | Escitalopram Oxalate                                                      |                    |                    | C               | Oral                         | Oral                                     |                 | Not Reported |                |
|                                                                                                                                                                        | Strattera (Atomoxetine Hydrochloride)(Tablets)(Atomoxetine Hydrochloride) |                    |                    | C               |                              |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2010                                                                                                                                                            | 7359111                                                                   | EXPEDITED (15-DAY) | Y                  | CA, RI, OT      | 1000012796                   |                                          | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Abnormal;<br>Cardiac Murmur; Maternal<br>Drugs Affecting Foetus;<br>Premature Baby;<br>Transposition Of The<br>Great Vessels; Ventricular<br>Septal Defect | Lexapro                                                                   |                    |                    | S               | Transplacental               | Transplacental                           |                 | Not Reported |                |
|                                                                                                                                                                        | Modafinil                                                                 |                    |                    | S               | Transplacental               | 200 Mg (200 Mg, 1 In 1 D),Transplacental |                 | Not Reported |                |
|                                                                                                                                                                        | Levothyroxine (Levothyroxine Sodium)(Levothyroxine Sodium)                |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        | Metformin Hydrochloride                                                   |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        | Buspar (Buspirone Hydrochloride)(Buspirone Hydrochloride)                 |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        | Nasonex (Mometasone Furoate) (Mometasone Furoate)                         |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        | Ob Natal (Ob Natal) (Ob Natal)                                            |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        | Xyrem (Oxybate Sodium) (Oxybate Sodium)                                   |                    |                    | C               |                              |                                          |                 | Not Reported |                |
|                                                                                                                                                                        |                                                                           |                    |                    |                 |                              |                                          |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Dec-2010                                                                                                                                                            | 7744447                                                                   | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-10P-163-0693390-00 |                                          | 44 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                  |       |              |
|----------|------------------|-------|--------------|
| Overdose | Vicodin Es       | S     | Not Reported |
|          | Lexapro          | S     | Not Reported |
|          | Neurontin        | S     | Not Reported |
|          | Oxycontin        | C     | Not Reported |
|          | Morphine Sulfate | C     | Not Reported |
|          | Diazepam         | C     | Not Reported |
|          | Soma             | C     | Not Reported |
|          | Parafon Forte    | C     | Not Reported |
|          | Zanaflex         | C     | Not Reported |
|          | Klonopin         | C     | Not Reported |
|          | Ativan           | C     | Not Reported |
|          | Phenergan        | C     | Not Reported |
|          | Lexapro          | C     | Not Reported |
|          | Relafen          | C     | Not Reported |
|          | Lidoderm         | C     | Not Reported |
|          |                  | Patch | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2010              | 7771661       | EXPEDITED (15-DAY) | N                  | DE              | 1000017884           |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Asphyxia; Completed Suicide; Depression | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 31-Dec-2010              | 7388216       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2010056903 |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;                         | Celebrex       |              |            | S           |              | Unk                |                 | Pfizer       |
| Anxiety; Drug Ineffective;                    | Effexor        |              |            | S           |              | Unk                |                 | Pfizer       |
| Insomnia; Meniscus Injury;                    | Lexapro        |              |            | S           |              | 20 Mg, 1x/Day      |                 | Not Reported |
| Nausea; Panic Attack;                         | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
| Thoracic Vertebral Fracture; Thyroid Disorder | Seroquel       |              |            | S           |              | 600 Mg, 1x/Day     |                 | Not Reported |
|                                               | Seroquel       |              |            | S           |              |                    |                 | Not Reported |
|                                               | Tegretol       |              |            | C           |              | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |   |                |              |
|---------------------------------------------|---|----------------|--------------|
| Lopresor                                    | C | 50 Mg, 2x/Day  | Not Reported |
| Neurontin                                   | C | 300 Mg, 3x/Day | Not Reported |
| Glucophage                                  | C | 850 Mg, 2x/Day | Not Reported |
| Prilosec                                    | C | 20 Mg, 1x/Day  | Not Reported |
| Dichloralphenazone\Isomethepte<br>ne Mucate | C | Unk            | Not Reported |
| Lorcet                                      | C | 10mg/650mg     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2011              | 6953712       | EXPEDITED (15-DAY) | Y                  | HO              | 1000005134           |                      | 89 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Generalised<br>Exanthematous<br>Pustulosis; Acute Kidney<br>Injury; Band Neutrophil<br>Count Increased; Cheilitis;<br>Inflammation;<br>Leukocytosis;<br>Lymphadenopathy; Rash | Escitalopram Oxalate                              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                                                     | Tetrazepam (Tetrazepam)<br>(Tablets) (Tetrazepam) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2011              | 7580319       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000015872           |                      | 42 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Drug Withdrawal<br>Syndrome; Fatigue;<br>Hypoaesthesia; Insomnia;<br>Pollakiuria; Speech<br>Disorder; Syncope;<br>Thyroid Function Test<br>Abnormal | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral; 25 Mg (25 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                                                                                                                     |                      |              |            |             | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral; 25 Mg (25 Mg, 1 In 1<br>D), Oral |                 |              |
|                                                                                                                                                     |                      |              |            |             | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral; 25 Mg (25 Mg, 1 In 1<br>D), Oral |                 |              |
|                                                                                                                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),                                           |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Oral; 20 Mg (20 Mg, 1 In 1 D), Oral  
15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral

| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|---------------------------|-----------------|--------------|----------------|
| 03-Jan-2011                                                                                                                                                           | 7746856              | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-JNJFOC-20101208167 |                           | 85 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anger; Anxiety; Disorientation; Dysphagia; Gait Disturbance; General Physical Health Deterioration; Hypercalcaemia; Parkinsonism; Salivary Hypersecretion; Somnolence | Risperdal            |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Calcimagon-D3        |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Cipralelex           |                    |                    | S               | Unknown               |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Cipralelex           |                    |                    | S               | Unknown               | Augmentation 5mg And 10mg |                 | Not Reported |                |
|                                                                                                                                                                       | Aspirin Cardio       |                    |                    | C               |                       |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Fosamax              |                    |                    | C               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Fluorometholone      |                    |                    | C               | Ophthalmic            |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Omeprazole           |                    |                    | C               |                       |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Perindopril Erbumine |                    |                    | C               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Lyrica               |                    |                    | C               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Dafalgan             |                    |                    | C               |                       |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Magnesium Aspartate  |                    |                    | C               |                       |                           |                 | Not Reported |                |
|                                                                                                                                                                       | Unknown Medication   |                    |                    | C               |                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2011                                                                                                                                                           | 7774475              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017915            |                           | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse; Intentional Overdose                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                  | (60 Mg,Once), Oral        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                     | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| 03-Jan-2011                                                                                                                                                  | 7774650                                                                                              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017921           |                                                        | 86 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Activated Partial Thromboplastin Time Prolonged; Haematuria; International Normalised Ratio Increased; Phimosis; Pulmonary Embolism; Urinary Tract Infection | Escitalopram Oxalate                                                                                 |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Fluindione                                                                                           |                    |                    | S               | Oral                 | 1 Dosage Form (1 Dosage Forms,1 In 1 D), Oral          |                 | Not Reported |                |
|                                                                                                                                                              | Fluindione                                                                                           |                    |                    | S               | Oral                 | 0.75 Dosage Form (0.75 Dosage Forms, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                              | Lovenox                                                                                              |                    |                    | S               | Subcutaneous         | 12000 Iu (6000 Iu,2 In 1 D),Subcutaneous, Subcutaneous |                 | Not Reported |                |
|                                                                                                                                                              | Vastarel                                                                                             |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Tarka (Trandolapril, Verapamil)                                                                      |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Trandolapril, Verapamil)                                                                            |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Lipanthyl (Fenofibrate)                                                                              |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Fenofibrate)                                                                                        |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Allopurinol                                                                                          |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Piascledine (Glycine Max Seed Oil, Persea Americana Oil)(Glycine Max Seed Oil, Persea Americana Oil) |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Chibro-Proscar (Finasteride)                                                                         |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Finasteride)                                                                                        |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Omexel (Tamsulosin Hydrochloride) (Tamsulosin Hydrochloride)                                         |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Temesta (Lorazepam)                                                                                  |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Lorazepam)                                                                                          |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Laroxyl (Amitriptyline Hydrochloride)(Amitriptyline Hydrochloride)                                   |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | Dafalgan (Paracetamol)                                                                               |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Paracetamol)                                                                                        |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Duphalac (Lactulose)                                                                                 |                    |                    | C               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                              | (Lactulose)                                                                                          |                    |                    |                 |                      |                                                        |                 |              |                |
|                                                                                                                                                              | Peristaltine (Rhamnus Purshiana)                                                                     |                    |                    | C               |                      |                                                        |                 | Not Reported |                |

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Dry Extract) (Rhamnus  
Purshiana Dry Extract)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jan-2011              | 7774710       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017949           |                      | 83 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abnormal Dreams;<br>Alopecia; Decreased<br>Appetite; Dizziness;<br>Dysgeusia; Insomnia; Lip<br>Swelling; Myalgia; Optic<br>Nerve Disorder;<br>Oropharyngeal Blistering;<br>Pruritus; Rash;<br>Rhinorrhoea; Swollen<br>Tongue; Weight<br>Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Jan-2011              | 7550069       | EXPEDITED (15-DAY) | Y                  | HO              | IT-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2010-<br>DE-04 |                      | 68 YR      | Female     | ITA            |

| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Abdominal Pain;<br>Peritoneal Disorder;<br>Pyrexia | Telmisartan    |              |            | S           | Oral         | 80 Mg              |                 | Boehringer Ingelheim |
|                                                    | Ciprallex      |              |            | S           | Oral         | 5 Mg               |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 04-Jan-2011              | 7747752       | EXPEDITED (15-DAY) | Y                  | HO, OT          | IN-ROXANE<br>LABORATORIES, INC.-<br>2010-RO-01730RO |                      | 62 YR      | Male       | IND            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Delirium; Drug<br>Dependence | Zolpidem       |              |            | S           |              | 10 Mg              |                 | Roxane     |
|                              | Zolpidem       |              |            | S           |              | 40 Mg              |                 | Roxane     |
|                              | Zolpidem       |              |            | S           |              |                    |                 | Roxane     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |                         | Escitalopram Oxalate |                    | S               |                              | 10 Mg                            |                 | Not Reported |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                    |                         | Domperidone Maleate  |                    | S               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2011                                                                                                                                        | 7748032                 | EXPEDITED (15-DAY)   | Y                  | DE              | US-ASTRAZENECA-2011SE00052   |                                  | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                                                                   | Quetiapine              |                      |                    | S               | Oral                         |                                  |                 | Zeneca       |                |
|                                                                                                                                                    | Escitalopram Oxalate    |                      |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                                                                                    | Gabapentin              |                      |                    | S               | Oral                         |                                  |                 | Not Reported |                |
|                                                                                                                                                    | Clonazepam              |                      |                    | S               | Oral                         |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2011                                                                                                                                        | 7766498                 | EXPEDITED (15-DAY)   | Y                  | RI, OT          | 1000011597                   |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Labour;<br>Maternal Exposure During<br>Pregnancy; Pregnancy;<br>Prolonged Labour;<br>Vacuum Extractor<br>Delivery; Vaginal<br>Perforation | Escitalopram Oxalate    |                      |                    | S               | Oral                         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2011                                                                                                                                        | 7342962                 | EXPEDITED (15-DAY)   | N                  | CA              | US-ABBOTT-10P-163-0634234-00 |                                  | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Murmur; Maternal<br>Exposure During<br>Pregnancy; Transposition<br>Of The Great Vessels;<br>Ventricular Septal Defect                      | Lexapro                 |                      |                    | S               | Transplacental               |                                  |                 | Not Reported |                |
|                                                                                                                                                    | Provigil                |                      |                    | S               | Transplacental               |                                  |                 | Not Reported |                |
|                                                                                                                                                    | Levothyroxine           |                      |                    | C               | Transplacental               |                                  |                 | Not Reported |                |
|                                                                                                                                                    | Metformin Hydrochloride |                      |                    | C               | Transplacental               |                                  |                 | Not Reported |                |

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|  |          |   |                |              |
|--|----------|---|----------------|--------------|
|  | Buspar   | C | Transplacental | Not Reported |
|  | Nasonex  | C | Transplacental | Not Reported |
|  | Ob Natal | C | Transplacental | Not Reported |

| <u>FDA Received Date</u>          | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
| 05-Jan-2011                       | 7747060                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-ASTRAZENECA-2010SE54938 |                                                           | < 1 DAY         | Male         | AUS            |
| <u>Preferred Term</u>             | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome Neonatal | Seroquel Xr                |                    |                    | S               | Transplacental             | 50 Mg Daily Started Pre-Pregnancy Stopped At 39/40 Weeks  |                 | Not Reported |                |
|                                   | Lamotrigine                |                    |                    | S               | Transplacental             | 200 Mg Daily Started At 11/40 Week                        |                 | Not Reported |                |
|                                   | Lexapro                    |                    |                    | S               | Transplacental             | 10 Mg Daily Started Pre-Pregnancy Stopped At 10/40 Week   |                 | Not Reported |                |
|                                   | Valproate Sodium           |                    |                    | S               | Transplacental             | 1000 Mg Daily Started Pre-Pregnancy Stopped At 10/40 Week |                 | Not Reported |                |
|                                   | Ferrous Sulfate\Folic Acid |                    |                    | C               | Transplacental             | 1 Tablet Daily From The First Trimester                   |                 | Not Reported |                |
|                                   | Ferrous Sulfate\Folic Acid |                    |                    | C               | Transplacental             | 1 Tablet Daily From The First Trimester                   |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2011                                   | 7749342              | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE00267 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents | Quetiapine           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                               | Metoprolol           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                               | Duloxetine           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                               | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            | Metoclopramide         |                    | S                  | Oral            |                            |                                                                                             |                 | Not Reported |                |
|----------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                            | Clonazepam             |                    | S                  | Oral            |                            |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2011                                                                | 7749381                | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE00275 |                                                                                             | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                              | Lisinopril             |                    |                    | S               | Oral                       |                                                                                             |                 | Zeneca       |                |
|                                                                            | Venlafaxine            |                    |                    | S               | Oral                       |                                                                                             |                 | Not Reported |                |
|                                                                            | Cocaine                |                    |                    | S               | Oral                       |                                                                                             |                 | Not Reported |                |
|                                                                            | Diphenhydramine        |                    |                    | S               | Oral                       |                                                                                             |                 | Not Reported |                |
|                                                                            | Escitalopram Oxalate   |                    |                    | S               | Oral                       |                                                                                             |                 | Not Reported |                |
|                                                                            | Unspecified Ingredient |                    |                    | S               | Oral                       |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2011                                                                | 7777527                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017938                 |                                                                                             | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma; Intraocular Pressure Increased                     | Escitalopram Oxalate   |                    |                    | S               |                            |                                                                                             |                 | Not Reported |                |
|                                                                            | Lithium                |                    |                    | C               |                            |                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2011                                                                | 7777628                | EXPEDITED (15-DAY) | Y                  | HO              | 1000017960                 |                                                                                             | 50 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Generalised Tonic-Clonic Seizure; Head Injury; Loss Of Consciousness | Escitalopram Oxalate   |                    |                    | S               | Oral                       | 20 Mg (20 Mg, 1 In 1 D), Oral                                                               |                 | Not Reported |                |
|                                                                            | Remeron                |                    |                    | S               | Oral                       | 15 Mg (15 Mg, 1 In 1 D), Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |      |                                                                                                |                                                              |
|-----------------------------------------------------------|------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
|                                                           | Oral | 15 Mg (15 Mg, 1 In 1 D),<br>Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                                                              |
|                                                           | Oral | 15 Mg (15 Mg, 1 In 1 D),<br>Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                                                              |
| Seroquel Xr                                               | S    | Oral<br>Oral<br>Oral<br>Oral                                                                   | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
| Anxiolit (Oxazepam)<br>(Oxazepam)                         | C    |                                                                                                | Not Reported                                                 |
| Acamprosate Calcium                                       | C    |                                                                                                | Not Reported                                                 |
| Becozyne (B-Complex) (B-Complex)                          | C    |                                                                                                | Not Reported                                                 |
| Benerva (Thiamine Hydrochloride) (Thiamine Hydrochloride) | C    |                                                                                                | Not Reported                                                 |
| Ferro Gradumet (Ferrous Sulfate) (Ferrous Sulfate)        | C    |                                                                                                | Not Reported                                                 |
| Allopurinol                                               | C    |                                                                                                | Not Reported                                                 |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2011              | 7777718       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000017961           |                      | 81 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Drug Interaction;<br>International Normalised<br>Ratio Increased;<br>Intraventricular<br>Haemorrhage | Escitalopram Oxalate                             |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                      | Phenprocoumon                                    |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                                                                                                      | Sortis (Atorvastatin)<br>(Atorvastatin)          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                      | Coversum Combi (Bi<br>Predonium) (Bi Predonium)  |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                      | Mephanol-100 (Allopurinol)<br>(Allopurinol)      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                      | Pradif (Tamsulosin<br>Hydrochloride) (Tamsulosin |              |            | C           |              |                                  |                 | Not Reported |



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Hydrochloride)

| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------|-----------------|--------------|----------------|
| 05-Jan-2011                                                                                                                                                            | 7777744                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017962           |                                                                | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Overdose;<br>Premature Menopause                                                                                                                          | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D),<br>Oral                               |                 | Not Reported |                |
|                                                                                                                                                                        | Mirena                    |                    |                    | S               | Intra-uterine        | (52 Mg), Intrauterine                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2011                                                                                                                                                            | 7790027                   | EXPEDITED (15-DAY) | Y                  | CA, DS, HO      | 1000017906           |                                                                | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Disability; Drug<br>Withdrawal Syndrome;<br>Macrosomia; Maternal<br>Drugs Affecting Foetus;<br>Overdose; Serotonin<br>Syndrome; Talipes;<br>Toxicity To Various Agents | Escitalopram Oxalate      |                    |                    | S               | Transplacental       | 40 Mg (40 Mg, 1 In 1 D),<br>Transplacental                     |                 | Not Reported |                |
|                                                                                                                                                                        | Zyprexa                   |                    |                    | S               | Transplacental       | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
|                                                                                                                                                                        | Depakote                  |                    |                    | S               | Transplacental       | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2011                                                                                                                                                            | 7742699                   | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000017513           |                                                                | 80 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury;<br>Arrhythmia; Atrial<br>Fibrillation; Blood Loss<br>Anaemia; Candida<br>Infection; Cardiac Failure;<br>Gastric Ulcer<br>Haemorrhage; Gastric     | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),<br>Oral                                |                 | Not Reported |                |
|                                                                                                                                                                        | Olfen (Diclofenac Sodium) |                    |                    | S               | Oral                 | 150 Mg (75 Mg,2 In 1 D),<br>Oral                               |                 | Not Reported |                |
|                                                                                                                                                                        | Aspirin                   |                    |                    | S               | Oral                 | 100 Mg (100mg,1 In 1 D),<br>Oral                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                                                                   |   |              |
|----------------------------------------------------|-------------------------------------------------------------------|---|--------------|
| Ulcer Perforation; General Physical Health         | Sortis (Atorvastatin) (Tablets0 (Atorvastatin)                    | C | Not Reported |
| Deterioration; Melaena; Peritonitis; Procalcitonin | Stilnox (Zolpidem) (Tabelts) (Zolpidem)                           | C | Not Reported |
| Increased; Respiratory Failure; Sepsis             | Eltroxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium)  | C | Not Reported |
|                                                    | Belco Zok (Metoprolol Succinate) (Tablets) (Metoprolol Succinate) | C | Not Reported |
|                                                    | Ramipril (Ramipril) (Tablets) (Ramipril)                          | C | Not Reported |
|                                                    | Norvasc (Amlodipine Besilate) (Tablets) (Amlodipine Besilate)     | C | Not Reported |
|                                                    | Torem (Torasemide) (Tablets) (Torasemide)                         | C | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2011                      | 7749975        | EXPEDITED (15-DAY) | Y                  | OT              | CH-BAYER-2010-007653 |                      | 39 YR           | Female       | CHE            |
| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Premature Menopause | Mirena         |                    |                    | S               | Intra-uterine        | Unk                  | 2141 DAY        | Bayer        |                |
|                                  | Cipraxel       |                    |                    | S               | Oral                 | Daily Dose 40 Mg     |                 | Not Reported |                |
|                                  | Cipraxel       |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 06-Jan-2011                                                                                       | 7750536                            | EXPEDITED (15-DAY) | N                  | HO              | B0691140A            |                      | 41 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Bradypnoea; Coma; Hypotension; Hypothermia; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents | Valacyclovir Hydrochloride         |                    |                    | S               | Unknown              |                      | 1 DAY           | Glaxosmithkline |                |
|                                                                                                   | Aceprometazine Maleate\Meprobamate |                    |                    | S               | Unknown              | 39tab Per Day        | 1 DAY           | Unknown         |                |
|                                                                                                   | Zopiclone                          |                    |                    | S               | Unknown              | 42tab Per Day        | 1 DAY           | Unknown         |                |
|                                                                                                   | Inexium                            |                    |                    | S               |                      |                      | 1 DAY           | Unknown         |                |
|                                                                                                   | Escitalopram Oxalate               |                    |                    | S               |                      |                      | 1 DAY           | Unknown         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                         | Depakote             |                    | S                  |                 |                              |                                                                                              | 1 DAY           |              | Unknown        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                         | Tiaprider            |                    | S                  |                 |                              |                                                                                              | 1 DAY           |              | Unknown        |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2011                                                                                                                                                             | 7750766              | EXPEDITED (15-DAY) | Y                  | CA, DS, HO      | FR-ABBOTT-10P-056-0694228-00 |                                                                                              |                 | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Macrosomia; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Overdose; Serotonin Syndrome; Talipes; Toxicity To Various Agents; Withdrawal Syndrome | Depakote             |                    |                    | S               | Transplacental               |                                                                                              |                 | Not Reported |                |
|                                                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Transplacental               |                                                                                              |                 | Not Reported |                |
|                                                                                                                                                                         | Zyprexa              |                    |                    | S               | Transplacental               |                                                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2011                                                                                                                                                             | 7790733              | EXPEDITED (15-DAY) | N                  | CA              | 1000018004                   |                                                                                              | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Multiple Congenital Abnormalities; Patent Ductus Arteriosus; Ventricular Septal Defect                                                 | Lexapro              |                    |                    | S               | Transplacental               | Transplacental                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2011                                                                                                                                                             | 7792227              | EXPEDITED (15-DAY) | Y                  | LT              | 1000018040                   |                                                                                              | 55 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling Abnormal; Insomnia; Nausea; Restlessness; Suicidal Ideation                                                                                            | Escitalopram Oxalate |                    |                    | S               | Oral                         | 2.5 Mg (2.5 Mg, 1 In 1 D), Oral;3.75 Mg (3.75 Mg, 1 In 1 D),Oral; 5 Mg (5 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                         |                      |                    |                    |                 | Oral                         | 2.5 Mg (2.5 Mg, 1 In 1 D),                                                                   |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                        |        |      |                                                                                                                                                                                  |                              |
|--------------------------------------------------------------------------------------------------------|--------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Sobril (Oxazepam) (Oxazepam)<br>Propavan (Propiomazine<br>Maleate) (Tablets)<br>(Propiomazine Maleate) | C<br>C | Oral | Oral;3.75 Mg (3.75 Mg, 1<br>In 1 D),Oral; 5 Mg (5 Mg, 1<br>In 1 D),Oral<br>2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral;3.75 Mg (3.75 Mg, 1<br>In 1 D),Oral; 5 Mg (5 Mg, 1<br>In 1 D),Oral | Not Reported<br>Not Reported |
|                                                                                                        |        |      |                                                                                                                                                                                  |                              |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 06-Jan-2011              | 7795699        | DIRECT           | N                  | HO              |                      |                      | 62 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Suicidal Ideation        | Lexapro        |                  |                    | S               | Oral                 | 10mg Daily Po        |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Jan-2011              | 7796929        | DIRECT           | Y                  |                 |                      |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Contusion                | Lexapro        |                  |                    | S               | Oral                 | 5 Mg Daily Po        |                 | Not Reported |                |

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------|-----------------|--------------|----------------|
| 07-Jan-2011                 | 7299597              | EXPEDITED (15-DAY) | Y                  | HO              | 1000011593           |                                                  | 59 YR           | Female       | DNK            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Fibrosis; Hepatitis | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),<br>Oral                  |                 | Not Reported |                |
|                             | Furadantin           |                    |                    | S               | Oral                 | 21.4286 Mg (50 Mg, 3 In 1<br>Wk), Oral           |                 | Not Reported |                |
|                             | Ibuprofen            |                    |                    | S               |                      | 0.25 Dosage Form (0.5<br>Dosage Forms, 1 In 2 D) |                 | Not Reported |                |

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|                                                   |   |      |                                              |              |
|---------------------------------------------------|---|------|----------------------------------------------|--------------|
| Acetaminophen                                     | S |      | 0.25 Dosage Form (0.5 Dosage Forms,1 In 2 D) | Not Reported |
| Crestor                                           | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral                  | Not Reported |
| Prorofan (Propofan, Caffeine, Dextropropoxyphene) | C |      |                                              | Not Reported |

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 07-Jan-2011                                                                                                             | 7752835                            | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-11P-056-0694770-00 |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Coma; Hypotension; Hypothermia; Intentional Overdose; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents | Depakote                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                         | Escitalopram Oxalate               |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                         | Aceprometazine Maleate\Meprobamate |                    |                    | S               | Oral                         | 400 Mg Coated        |                 | Not Reported |                |
|                                                                                                                         | Zopiclone                          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                         | Inexium                            |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                         | Zelitrex                           |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                                                         | Tiapridal                          |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 07-Jan-2011                                                                                                                                                                    | 7756748              | EXPEDITED (15-DAY) | Y                  | HO              | 1000017760           |                        | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Ataxia; Chest Discomfort; Chills; Confusional State; Drug Interaction; Electrocardiogram St-T Change; Hyperhidrosis; Mydriasis; Serotonin Syndrome; Tremor | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                | Selegiline           |                    |                    | S               |                      | 5 Mg (5 Mg,1 In 1 D)   |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 07-Jan-2011                                                                                                                                      | 7788304                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000015832           |                                 | 68 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Peritonitis; Pyrexia                                                                                                          | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral      |                 | Not Reported |                |
|                                                                                                                                                  | Telmisartan                         |                    |                    | S               | Oral                 | 80 Mg (80 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2011                                                                                                                                      | 7789871                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000017992           |                                 | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradypnoea; Coma;<br>Hypotension;<br>Hypothermia; Mydriasis;<br>Oxygen Saturation<br>Decreased;<br>Rhabdomyolysis; Toxicity<br>To Various Agents | Escitalopram Oxalate                |                    |                    | S               |                      | (Once)                          |                 | Not Reported |                |
|                                                                                                                                                  | Aceprometazine/Meprobamate          |                    |                    | S               |                      | (39 Dosage Forms,Once)          |                 | Not Reported |                |
|                                                                                                                                                  | Zopiclone                           |                    |                    | S               |                      | (42 Dosage Forms, Once)         |                 | Not Reported |                |
|                                                                                                                                                  | Inexium (Esomeprazole<br>Magnesium) |                    |                    | S               |                      | (Once)                          |                 | Not Reported |                |
|                                                                                                                                                  | Depakote                            |                    |                    | S               |                      | (Once)                          |                 | Not Reported |                |
|                                                                                                                                                  | Valacyclovir Hydrochloride          |                    |                    | S               |                      | (Once)                          |                 | Not Reported |                |
|                                                                                                                                                  | Tiaprider                           |                    |                    | S               |                      | (Once)                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jan-2011                                                                                                                                      | 7795437                             | DIRECT             | Y                  | OT              |                      |                                 | 11 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Depressive Symptom;<br>Product Quality Issue;<br>Suicidal Ideation                                                      | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg Qhs Po                    |                 | Forest       |                |
|                                                                                                                                                  | Abilify                             |                    |                    | C               |                      |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 10-Jan-2011                                                                                                                                                                                                                          | 7324758               | EXPEDITED (15-DAY) | N                  | HO, OT          | US-ROCHE-687974      |                                                                               | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Bronchitis;<br>Constipation; Decreased<br>Appetite; Dyspnoea;<br>Exostosis; Haemorrhage;<br>Infection; Nerve Injury;<br>Obstruction; Oedema<br>Peripheral; Vascular Stent<br>Insertion; White Blood Cell<br>Count Decreased | Peginterferon Alfa-2a |                    |                    | S               | Unknown              | Form: Pre-Filled Syringe;                                                     |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Peginterferon Alfa-2a |                    |                    | S               | Unknown              |                                                                               |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Peginterferon Alfa-2a |                    |                    | S               | Unknown              |                                                                               |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Peginterferon Alfa-2a |                    |                    | S               | Unknown              | Patient In Week 30 Of<br>Treatment                                            |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Peginterferon Alfa-2a |                    |                    | S               | Unknown              | Week 33                                                                       |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Peginterferon Alfa-2a |                    |                    | S               | Unknown              | Week 55                                                                       |                 | Roche        |                |
|                                                                                                                                                                                                                                      | Ribavarin             |                    |                    | S               | Unknown              | Note: Divided Doses;<br>Patient Received<br>Ribasphere And Ribavirin<br>(Par) |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Ribavarin             |                    |                    | S               | Unknown              | Dosage Reduced. In<br>Divided Doses; Week 55                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro               |                    |                    | S               | Oral                 |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lyrica                |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Fluticasone           |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Seretide              |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Skelaxin              |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Vitamin B12           |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Combivent             |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Oxycodone             |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lamotrigine           |                    |                    | C               |                      | Frequency: At Bedtime                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Morphine              |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Trazodone             |                    |                    | C               |                      | Frequency: At Bed Time                                                        |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lisinopril            |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Promethazine          |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Fentanyl Patch        |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Oxycodone             |                    |                    | C               |                      |                                                                               |                 | Not Reported |                |

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### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 10-Jan-2011                                                   | 7753716                      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2011002893 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                             | Venlafaxine Hcl              |                    |                    | S               | Oral                     |                      |                 | Pfizer       |                |
|                                                               | Lisinopril                   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                               | Escitalopram Oxalate         |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                               | Cocaine                      |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                               | Diphenhydramine              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2011                                                   | 7753717                      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2011002383 |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                         | Escitalopram Oxalate         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                               | Alprazolam                   |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                               | Cyclobenzaprine              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                               | Zolpidem                     |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                               | Desogestrel/Ethinylestradiol |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2011                                                   | 7790538                      | EXPEDITED (15-DAY) | Y                  | HO              | 1000018041               |                      | 73 YR           | Female       | LTU            |
| <u>Preferred Term</u>                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Somnolence; Suicide Attempt | Escitalopram Oxalate         |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                               | Diazepam                     |                    |                    | S               |                          | (5 Mg)               |                 | Not Reported |                |
|                                                               | Xanax                        |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2011                                                   | 7755326                      | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20110101571    |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                         | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |



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|       |                               |   |      |              |
|-------|-------------------------------|---|------|--------------|
| Death | Cyclobenzaprine Hydrochloride | S | Oral | Not Reported |
|       | Escitalopram Oxalate          | S | Oral | Not Reported |
|       | Zolpidem                      | S | Oral | Not Reported |
|       | Alprazolam                    | S | Oral | Not Reported |
|       | Desogestrel/Ethinyl Estradiol | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2011              | 7755359       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-20110101661 |                      | 61 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents | Cyclobenzaprine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                           | Verapamil Hydrochloride       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                           | Escitalopram Oxalate          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                           | Doxepin                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                           | Alprazolam                    |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jan-2011              | 7755740       | EXPEDITED (15-DAY) | N                  | OT              | A0904404A            |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Depression; Drug Interaction; Suicidal Ideation | Wellbutrin     |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                                                 | Tikosyn        |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                 | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 11-Jan-2011              | 7755937       | EXPEDITED (15-DAY) | N                  | DE, OT          | US-CEPHALON-2011000113 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident; Chest Pain; Drug Abuse; Product Prescribing Error | Fentora        |              |            | S           | Buccal       |                    |                 | Not Reported |
|                                                                             | Fentora        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |             |  |  |         |              |
|--|----------|---|-------------|--|--|---------|--------------|
|  | Lexapro  | S |             |  |  | 176 DAY | Not Reported |
|  | Soma     | S |             |  |  |         | Not Reported |
|  | Soma     | S |             |  |  |         | Not Reported |
|  | Percocet | S |             |  |  |         | Not Reported |
|  | Percocet | S |             |  |  |         | Not Reported |
|  | Valium   | S |             |  |  |         | Not Reported |
|  | Fentanyl | S | Transdermal |  |  |         | Not Reported |
|  | Fentanyl | S |             |  |  |         | Not Reported |
|  | Zipsor   | S |             |  |  |         | Not Reported |
|  | Zipsor   | S |             |  |  |         | Not Reported |

| <u>FDA Received Date</u>                 | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 11-Jan-2011                              | 7793802                                           | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018078           |                         |                 | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Pain; Intraocular Pressure Increased | Escitalopram Oxalate                              |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                          | Teralithe (Lithium Carbonate) (Lithium Carbonate) |                    |                    | C               |                      |                         |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 12-Jan-2011              | 5837874        | EXPEDITED (15-DAY) | Y                  | RI, OT          | S05-USA-03295-01     |                                 | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia       | Lexapro        |                    |                    | S               | Oral                 | 30 Mg (30 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
|                          | Clozapine      |                    |                    | S               | Oral                 | 300 Mg (300 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Clozapine      |                    |                    | S               | Oral                 | 50 Mg, (150 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 12-Jan-2011                                                           | 7756565                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011005057 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Night Sweats                                                          | Pristiq Extended Release |                  |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                       | Zoloft                   |                  |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                       | Zoloft                   |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                       | Lexapro                  |                  |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                       | Lexapro                  |                  |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2011                                                           | 7756604                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011005070 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Ineffective; Increased Appetite; Weight Increased       | Pristiq Extended Release |                  |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                       | Lexapro                  |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2011                                                           | 7756655                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011004027 |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea; Off Label Use; Panic Attack                                   | Pristiq Extended Release |                  |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                       | Lexapro                  |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2011                                                           | 7800580                  | DIRECT           | N                  | HO              |                          |                      | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety; Insomnia; Irritability; Suicidal Ideation; Weight | Lexapro                  |                  |                    | S               | Oral                     | 10 Mg Once Daily Po  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Increased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2011              | 7759520       | EXPEDITED (15-DAY) | N                  | OT              | US-ROCHE-752271      |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Cerebral Disorder; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Hypophagia; Insomnia; Post-Traumatic Stress Disorder; Product Dose Omission; Psychomotor Hyperactivity; Suffocation Feeling; Wrong Technique In Product Usage Process | Valium                 |              |            | S           | Oral         | At Night                                                          |                 | Roche        |
|                                                                                                                                                                                                                                                         | Effexor                |              |            | S           | Oral         | Other Indication: Panic Disorder; Form: Prolonged Release Capsule |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Effexor                |              |            | S           | Oral         | Dose Increased                                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Effexor                |              |            | S           | Oral         |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Prozac                 |              |            | S           | Oral         |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Prozac                 |              |            | S           | Oral         | Dose Decreased                                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Prozac                 |              |            | S           | Oral         | Dose Decreased                                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Zyprexa                |              |            | S           | Oral         |                                                                   | 2 DAY           | Not Reported |
|                                                                                                                                                                                                                                                         | Lexapro                |              |            | S           | Oral         |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Calcium                |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Ergocalciferol         |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Folic Acid             |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Niacinamide            |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Panthenol              |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Retinol                |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Riboflavin             |              |            | C           |              |                                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                         | Thiamine Hydrochloride |              |            | C           |              |                                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2011              | 7759532       | EXPEDITED (15-DAY) | Y                  | DE, HO          | US-ROCHE-752292      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident; Chest Pain; Loss Of Consciousness | Valium         |              |            | S           | Unknown      |                    |                 | Roche        |
|                                                             | Percocet       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                             | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |             |              |
|----------|---|-------------|--------------|
| Soma     | S | Oral        | Not Reported |
| Fentora  | S | Unknown     | Not Reported |
| Fentanyl | S | Transdermal | Not Reported |
| Zipsor   | S | Oral        | Not Reported |

| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------|-----------------|--------------|----------------|
| 13-Jan-2011                                                                                     | 7759592                 | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR002470 |                                     | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                                                        | Verapamil Hydrochloride |                    |                    | S               | Oral                                            | Unk                                 |                 | Par          |                |
|                                                                                                 | Doxepin                 |                    |                    | S               | Oral                                            | Unk                                 |                 | Par          |                |
|                                                                                                 | Alprazolam              |                    |                    | S               | Oral                                            | Unk                                 |                 | Par          |                |
|                                                                                                 | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | Unk                                 |                 | Not Reported |                |
|                                                                                                 | Cyclobenzaprine         |                    |                    | S               | Oral                                            | Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2011                                                                                     | 7759887                 | EXPEDITED (15-DAY) | N                  | CA, HO          | US-ABBOTT-11P-163-<br>0695775-00                |                                     | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Multiple Congenital<br>Abnormalities; Patent<br>Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro                 |                    |                    | S               | Transplacental                                  |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2011                                                                                     | 7794355                 | EXPEDITED (15-DAY) | N                  | DE, HO          | 2011010001                                      |                                     | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Chest Pain; Incorrect<br>Route Of Product                          | Soma                    |                    |                    | S               | Oral                                            | 1000 Mg 9250 Mg, 4 In 1<br>D), Oral |                 | Not Reported |                |
| Administration; Intentional                                                                     | Lexapro                 |                    |                    | S               | Oral                                            | 20 Mg (20 Mg, 1 In 1 D),            |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                     |   |             |                            |              |
|---------------------------------------|---------------------|---|-------------|----------------------------|--------------|
| Product Misuse; Loss Of Consciousness | Percocet            | S | Oral        | Oral                       | Not Reported |
|                                       | Valium              | S |             | 5/325 Mg, Oral             | Not Reported |
|                                       | Fentora             | S |             |                            | Not Reported |
|                                       | Fentanyl (Fentanyl) | S | Transdermal | 400 Mg (400 Mg, 1 In 1 D)  | Not Reported |
|                                       | Zipsor              | S | Oral        | Transdermal (25 Mg) , Oral | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Jan-2011                       | 7794668                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000018070                    |                               | 86 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                         | <a href="#">Product</a>         | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------|---------------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coma; Drug Interaction; Hypomagnesaemia; Hyponatraemia | Escitalopram Oxalate            |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral |                          | Not Reported        |
|                                                        | Omeprazole                      |                       |                     | S                    | Oral                  | Oral                        |                          | Not Reported        |
|                                                        | Perindopril Erbumine            |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                                        | Imovane (Zopiclone) (Zopiclone) |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Jan-2011                       | 7795783                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000018096                    |                               |                     | Female              | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Thermal Burn                   | Escitalopram Oxalate    |                       |                     | S                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Jan-2011                       | 7757951                | EXPEDITED (15-DAY)        | Y                           | HO                       | FR-ASTRAZENECA-2011SE00390    |                               | 41 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a>                                                                    | <a href="#">Product</a>    | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------------------------|----------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Bradypnoea; Coma; Hypotension; Hypothermia; Mydriasis; Rhabdomyolysis; Toxicity To Various Agents | Inexium                    |                       |                     | S                    | Oral                  |                             | 1 DAY                    | Not Reported        |
|                                                                                                   | Aceprometazine\Meprobamate |                       |                     | S                    | Oral                  | Intake Of 39 Tablets Once   | 1 DAY                    | Not Reported        |
|                                                                                                   | Zopiclone                  |                       |                     | S                    | Oral                  | Intake Of 42 Tablets Once   | 1 DAY                    | Not Reported        |
|                                                                                                   | Escitalopram Oxalate       |                       |                     | S                    | Oral                  |                             | 1 DAY                    | Not Reported        |
|                                                                                                   | Depakote                   |                       |                     | S                    |                       |                             | 1 DAY                    | Not Reported        |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                             |                           | Tiaprider          |                    | S               | Oral                                      |                      | 1 DAY           | Not Reported |                |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                             |                           | Valacyclovir       |                    | S               | Oral                                      |                      | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2011                                                                                                                                 | 7761748                   | EXPEDITED (15-DAY) | N                  | HO, OT          | US-PFIZER INC-2011006758                  |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Bipolar Disorder; Breast Cancer; Depressed Mood; Drug Ineffective; Drug Interaction; Endometrial Hypertrophy; Thyroid Neoplasm | Zoloft                    |                    |                    | S               |                                           |                      |                 | Pfizer       |                |
|                                                                                                                                             | Lexapro                   |                    |                    | S               |                                           |                      |                 | Not Reported |                |
|                                                                                                                                             | Tamoxifen Citrate         |                    |                    | S               |                                           |                      |                 | Not Reported |                |
|                                                                                                                                             | Cymbalta                  |                    |                    | S               |                                           |                      |                 | Not Reported |                |
|                                                                                                                                             | Femara                    |                    |                    | S               |                                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Jan-2011                                                                                                                                 | 7813935                   | EXPEDITED (15-DAY) | Y                  | OT              | DSA_44637_2011                            |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Drug Interaction; Suicidal Ideation                                                                                             | Bupropion Hydrochloride   |                    |                    | S               | Oral                                      | (Df Oral)            |                 | Not Reported |                |
|                                                                                                                                             | Tikosyn                   |                    |                    | S               |                                           |                      |                 | Not Reported |                |
|                                                                                                                                             | Lexapro                   |                    |                    | S               |                                           | (Df)                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                    | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                 | 7763410                   | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR PHARMACEUTICAL, INC-2011SCPR002501 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                       | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                                                                                                    | Diazepam                  |                    |                    | S               | Oral                                      | Unk                  |                 | Par          |                |
|                                                                                                                                             | Escitalopram Oxalate      |                    |                    | S               | Oral                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                             | Acetaminophen\Hydrocodone |                    |                    | S               | Oral                                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                             | Morphine                  |                    |                    | S               | Oral                                      | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 18-Jan-2011                                                                                                                                                                                                                         | 7763482              | EXPEDITED (15-DAY) | N                  |                 | US-JNJFOC-20101202625                 |                                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Sexual Dysfunction;<br>Somnolence                                                                                                                                                                                                   | Invega               |                    |                    | S               | Oral                                  |                                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Lexapro              |                    |                    | S               |                                       |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                                                                                                         | 7775896              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017909                            |                                               | 46 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Lactate Dehydrogenase Increased; Gamma-Glutamyltransferase Increased; Hepatic Function Abnormal; Pancytopenia | Escitalopram Oxalate |                    |                    | S               | Oral                                  | 20 Mg (20 Mg,1 In 1 D), Oral                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Fotemustine          |                    |                    | S               | Intravenous (not otherwise specified) | 10/5 MI, Intravenous (Not Otherwise Specified |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Acetaminophen        |                    |                    | S               | Oral                                  | 3000 Mg (1000 Mg, 3in 1 D), Oral              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                                                                                                         | 7799568              | EXPEDITED (15-DAY) | Y                  | HO              | 1000018126                            |                                               | 1 YR            | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To Product By Child                                                                                                                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                                  | (10 Mg,Once), Oral                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                                                                                                         | 7801141              | EXPEDITED (15-DAY) | Y                  | HO              | 1000018127                            |                                               | 36 YR           | Male         | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------|-----------------|--------------|----------------|
| Blood Blister; Cough; Haemoglobin Decreased; Haemoptysis; Immune Thrombocytopenic Purpura; Iron Deficiency; Oropharyngeal Blistering; White Blood Cell Count Decreased | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D), Oral                        |                 | Not Reported |                |
|                                                                                                                                                                        | Lansoprazole (Lansoprazole)                 |                    |                    | S               | Oral                 | 1 Df (1 Dosage Forms, 1 In 1 D), Oral               |                 | Not Reported |                |
|                                                                                                                                                                        | Amoxicillin                                 |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                                                                                                                                        | Solupred (Prednisolone Sodium Metazoate)    |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                                                                                                                                        | Levothyrox (Levothyroxine Sodium) (Tablets) |                    |                    | C               |                      |                                                     |                 | Not Reported |                |
|                                                                                                                                                                        | (Levothyroxine Sodium)                      |                    |                    |                 |                      |                                                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                                            | 7801144                                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018106           |                                                     | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Arterial Hypertension; Renal Failure; Systemic Lupus Erythematosus                                                                                           | Escitalopram Oxalate                        |                    |                    | S               |                      |                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2011                                                                                                                                                            | 7822472                                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018143           |                                                     | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Retinal Vein Thrombosis                                                                                                                                                | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D), Oral                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                               | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jan-2011                                                                                                                                                            | 7449988                                     | EXPEDITED (15-DAY) | Y                  | OT              | 1000014565           |                                                     | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Deafness Unilateral; Depression;                                                                                                                               | Lexapro                                     |                    |                    | S               | Oral                 | (10 Mg (10 Mg, 1 In 1 D), Oral) (5 Mg (5 Mg, 1 In 1 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dry Mouth; Exaggerated  
Startle Response; Night  
Sweats; Panic Attack;  
Paraesthesia;  
Temporomandibular Joint  
Syndrome; Tinnitus; Vision  
Blurred

Oral

Oral

Oral

Oral

Oral

Oral

Oral

D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10  
(10 Mg (10 Mg, 1 In 1 D),  
Oral) (5 Mg (5 Mg, 1 In 1  
D), Oral) (2.5 Mg (2.5 Mg,  
1 In 1 D), Oral) (10

Lyrica  
Nasacort (Triamcinolone  
Acetonide) (Triamcinolone  
Acetonide)  
Prozac

C

C

C

Not Reported

Not Reported

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 19-Jan-2011              | 7764972        | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR002547 |                      | 72 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                      |   |      |     |              |
|--------------------------|----------------------|---|------|-----|--------------|
| Completed Suicide; Death | Clonazepam           | S | Oral | Unk | Par          |
|                          | Quetiapine           | S | Oral | Unk | Not Reported |
|                          | Escitalopram Oxalate | S | Oral | Unk | Not Reported |
|                          | Gabapentin           | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2011              | 7764974       | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR002539 |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Death | Clonazepam           |              |            | S           | Oral         | Unk                |                 | Par          |
|                          | Quetiapine           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                          | Metoclopramide       |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                          | Metoprolol           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                          | Duloxetine           |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                          | Escitalopram Oxalate |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2011              | 7765243       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJCH-2011000951  |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Diphenhydramine        |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                                                  | Venlafaxine            |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                                                  | Cocaine                |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                                                  | Lisinopril             |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                                                  | Escitalopram Oxalate   |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |
|                                                  | Unspecified Ingredient |              |            | S           | Oral         | Text:Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2011              | 7805127       | DIRECT           | N                  | OT              |                      |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Anxiety; Depression; Nightmare; Withdrawal Syndrome                    | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Daily Po                | 4 YR                     | Not Reported        |                         |
|                                                                        | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg Daily Po                | 5 YR                     | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jan-2011                                                            | 7767631                 | EXPEDITED (15-DAY)        | Y                           | OT                       | FR-PFIZER INC-2010159144      |                               | 24 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Alcohol Abuse; Gamma-Glutamyltransferase Increased                     | Xanax                   |                           |                             | S                        |                               | 0.25 Mg, 4x/Day               |                          | Pfizer              |                         |
|                                                                        | Stilnox                 |                           |                             | S                        |                               | Unk                           |                          | Not Reported        |                         |
|                                                                        | Escitalopram Oxalate    |                           |                             | S                        |                               | Unk                           |                          | Not Reported        |                         |
|                                                                        | Alcohol                 |                           |                             | S                        |                               | Unknown; Excessive Dose       |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jan-2011                                                            | 7797290                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000018055                    |                               | 46 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Diarrhoea; Muscle Spasms; Nausea; Tonic Clonic Movements; Vomiting     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jan-2011                                                            | 7805762                 | DIRECT                    | N                           | HO                       |                               |                               | 20 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abnormal Behaviour; Delusion; Euphoric Mood; Psychomotor Hyperactivity | Lexapro                 |                           |                             | S                        | Oral                          | 20mg 1 Per Day Po             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jan-2011                                                            | 7806657                 | DIRECT                    | N                           |                          |                               |                               | 47 YR                    | Female              | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| Amnesia                                                                                                                        | Lexapro        |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2011                                                                                                                    | 7806730        | DIRECT             | N                  | DS, OT          |                              |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia                                                                                                                        | Lexapro        |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jan-2011                                                                                                                    | 7825209        | EXPEDITED (15-DAY) | N                  | DE, HO          | 2011S1000004                 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>Chest Pain; Drug Abuse;<br>Incorrect Route Of Product<br>Administration; Loss Of<br>Consciousness | Zipsor         |                    |                    | S               |                              | 25 Mg                |                 | Not Reported |                |
|                                                                                                                                | Lexapro        |                    |                    | S               | Oral                         | 20 Mg; Qd; Po        |                 | Not Reported |                |
|                                                                                                                                | Soma           |                    |                    | S               | Oral                         | 250 Mg; Qid; Po      |                 | Not Reported |                |
|                                                                                                                                | Percocet       |                    |                    | S               | Oral                         | 1625 Mg; Qd; Po      |                 | Not Reported |                |
|                                                                                                                                | Valium         |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                | Fentora        |                    |                    | S               |                              | 400 Mg; Qd           |                 | Not Reported |                |
|                                                                                                                                | Fentanyl       |                    |                    | S               | Transdermal                  | 400 Mg; Qd; Tder     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2011                                                                                                                    | 7422233        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2010070738 |                      | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Attention                                                                                                                      | Geodon         |                    |                    | S               | Oral                         | 20 Mg Daily          |                 | Pfizer       |                |
| Deficit/Hyperactivity                                                                                                          | Geodon         |                    |                    | S               |                              | 80 Mg, Unk           |                 | Pfizer       |                |
| Disorder; Bipolar Disorder;                                                                                                    | Geodon         |                    |                    | S               |                              | 100 Mg, Unk          |                 | Pfizer       |                |
| Blood Pressure                                                                                                                 | Geodon         |                    |                    | S               |                              | 60 Mg, Unk           |                 | Pfizer       |                |
| Decreased; Blood                                                                                                               | Geodon         |                    |                    | S               |                              | 80 Mg, 3x/Day        |                 | Pfizer       |                |
| Pressure Fluctuation;                                                                                                          |                |                    |                    |                 |                              |                      |                 |              |                |
| Major Depression;                                                                                                              |                |                    |                    |                 |                              |                      |                 |              |                |
| Personality Disorder                                                                                                           |                |                    |                    |                 |                              |                      |                 |              |                |

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|          |   |      |                               |              |
|----------|---|------|-------------------------------|--------------|
| Geodon   | S |      | 40 Mg, 2x/Day                 | Pfizer       |
| Geodon   | S |      | 40 Mg, Unk                    | Pfizer       |
| Geodon   | S |      | 60 Mg, Unk                    | Pfizer       |
| Geodon   | S |      | 40 Mg, 2x/Day                 | Pfizer       |
| Zoloft   | S |      | Unk                           | Pfizer       |
| Effexor  | S | Oral | 75 Mg, Daily                  | Pfizer       |
| Effexor  | S |      | 37.5 Mg, In The Morning 7 DAY | Pfizer       |
| Effexor  | S |      | 75 Mg, Unk                    | Pfizer       |
| Effexor  | S |      | 150 Mg, In The Morning        | Pfizer       |
| Effexor  | S |      | 75 Mg, 2x/Day                 | Pfizer       |
| Effexor  | S |      | 40 Mg, 2x/Day                 | Pfizer       |
| Lithium  | S |      | Unk                           | Not Reported |
| Klonopin | S |      | Unk                           | Not Reported |
| Klonopin | S |      | 1 Mg, 2x/Day                  | Not Reported |
| Klonopin | S |      | 0.5 Mg, 3x/Day                | Not Reported |
| Klonopin | S |      | 1 Mg, 3x/Day, As Needed       | Not Reported |
| Klonopin | S |      | 0.5 Mg, 3x/Day                | Not Reported |
| Lexapro  | S |      | Unk                           | Not Reported |
| Seroquel | S |      | 100 Mg At Bedtime             | Not Reported |
| Seroquel | S |      | 50 Mg, At Bedtime As Needed   | Not Reported |
| Seroquel | S |      | 100 Mg, As Needed             | Not Reported |
| Seroquel | S |      | 200 Mg, At Night              | Not Reported |
| Seroquel | S |      | 300 Mg, Unk                   | Not Reported |
| Seroquel | S |      | 200 Mg, At 6 And 9 At Night   | Not Reported |
| Seroquel | S |      | 200 Mg, At Night              | Not Reported |
| Paxil    | S |      | Unk                           | Not Reported |

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| <u>FDA Received Date</u>                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Jan-2011                                                         | 7769506                                 | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR002601 |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death; Intentional Product<br>Misuse; Toxicity To<br>Various Agents | Alprazolam                              |                    |                    | S               | Oral                                            | Unk                  |                 | Par          |                |
|                                                                     | Cyclobenzaprine                         |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate                    |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported |                |
|                                                                     | Zolpidem                                |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported |                |
|                                                                     | Desogestrel\Ethinyl Estradiol           |                    |                    | S               | Oral                                            | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2011                                                         | 7769580                                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-11P-163-<br>0698445-00                |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                   | Acetaminophen\Hydrocodone<br>Bitartrate |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate                    |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Tricyclic Antidepressants               |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Alcohol                                 |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     |                                         |                    |                    |                 |                                                 |                      |                 |              |                |
| <u>FDA Received Date</u>                                            | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2011                                                         | 7769731                                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-11P-163-<br>0698443-00                |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                               | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                   | Acetaminophen\Hydrocodone<br>Bitartrate |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Escitalopram Oxalate                    |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Morphine                                |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     | Diazepam                                |                    |                    | S               |                                                 | Ingestion            |                 | Not Reported |                |
|                                                                     |                                         |                    |                    |                 |                                                 |                      |                 |              |                |

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| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 21-Jan-2011                                                                                                                                                                                                                            | 7807010              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017503           |                                  | 46 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Disorientation;<br>Hallucination;<br>Hyperhidrosis; Pyrexia                                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                        | Risperidone          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2011                                                                                                                                                                                                                            | 7807092              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018214           |                                  | 23 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Arthralgia; Drug<br>Interaction; Dysphagia;<br>Dystonia; Irritability; Joint<br>Dislocation; Muscle<br>Spasms; Salivary<br>Hypersecretion; Speech<br>Disorder; Tremor                                                       | Escitalopram Oxalate |                    |                    | S               |                      | (10 Mg)                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                        | Aripiprazole         |                    |                    | S               |                      | (10 Mg,Once), (10 Mg)            |                 | Not Reported |                |
|                                                                                                                                                                                                                                        | Clonazepam           |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jan-2011                                                                                                                                                                                                                            | 7809468              | DIRECT             |                    |                 |                      |                                  | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Balance Disorder;<br>Chest Discomfort;<br>Confusional State;<br>Fatigue; Feeling<br>Abnormal; Hyperhidrosis;<br>Memory Impairment; Pain;<br>Palpitations; Panic Attack;<br>Paraesthesia; Poor Quality<br>Sleep; Rebound Effect | Lexapro              |                    |                    | S               |                      |                                  |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                                                                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------|---------------------------|-----------------|-----------------|----------------|
| 24-Jan-2011                                                                                                                                                                                                                                    | 7771565                     | EXPEDITED (15-DAY) | N                  | DS, HO, LT, OT  | B0693617A                             |                           | 77 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Kidney Injury;<br>Anterograde Amnesia;<br>Clonus; Delirium;<br>Disturbance In Attention;<br>Drug Interaction;<br>Echolalia; Epilepsy;<br>Metabolic<br>Encephalopathy;<br>Myoclonus; Perseveration;<br>Visual Acuity Reduced;<br>Vomiting | Fortum                      |                    |                    | S               | Intravenous (not otherwise specified) |                           |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Amitriptyline Hydrochloride |                    |                    | S               | Oral                                  | 10drop Per Day            |                 | Unknown         |                |
|                                                                                                                                                                                                                                                | Escitalopram Oxalate        |                    |                    | S               | Oral                                  | 10mg Per Day              |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Primperan                   |                    |                    | S               | Intravenous (not otherwise specified) | 1unit Three Times Per Day |                 | Unknown         |                |
|                                                                                                                                                                                                                                                | Ramipril                    |                    |                    | S               | Oral                                  | 2.5mg Per Day             |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Lasix                       |                    |                    | S               | Oral                                  |                           |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Dalacine                    |                    |                    | C               | Intravenous (not otherwise specified) | 600mg Three Times Per Day | 4 MTH           | Not Reported    |                |
|                                                                                                                                                                                                                                                | Rifadine                    |                    |                    | C               | Oral                                  | 200mg Three Times Per Day | 4 MTH           | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Lyrice                      |                    |                    | C               | Oral                                  | 100mg Twice Per Day       |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                | Inexium                     |                    |                    | C               | Oral                                  | 20mg Per Day              |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                | Kardegic                    |                    |                    | C               | Oral                                  | 75mg Per Day              |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                | Innohep                     |                    |                    | C               | Subcutaneous                          | .6ml Per Day              |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                | Doliprane                   |                    |                    | C               | Oral                                  | 1g Four Times Per Day     |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Bromazepam                  |                    |                    | C               | Oral                                  |                           |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Bisoprolol Fumarate         |                    |                    | C               | Oral                                  | 1.25mg Per Day            |                 | Not Reported    |                |
|                                                                                                                                                                                                                                                | Tramadol Hydrochloride      |                    |                    | C               | Oral                                  | 50mg Four Times Per Day   |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Pravastatin Sodium          |                    |                    | C               | Oral                                  | 20mg Per Day              |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Bromazepam                  |                    |                    | C               | Oral                                  | .75tab Per Day            |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                | Amikacin                    |                    |                    | C               |                                       |                           | 3 DAY           | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Jan-2011                                                                                                                                                                                                                                    | 7771783                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | GR-ASTRAZENECA-2011SE02761            |                           | 72 YR           | Female          | GRC            |

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| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Acute Pulmonary        | Omeprazole           |              |            | S           | Oral                                  |                    |                 | Not Reported |
| Oedema; Blood Pressure | Aspirin              |              |            | C           | Oral                                  |                    |                 | Not Reported |
| Abnormal; Drug         | Omeprazole           |              |            | S           | Intravenous (not otherwise specified) |                    |                 | Not Reported |
| Interaction;           |                      |              |            |             |                                       |                    |                 |              |
| Electrocardiogram Qt   | Escitalopram Oxalate |              |            | S           |                                       | Chronic Use        |                 | Not Reported |
| Prolonged; Ergot       | Dihydroergocristine  |              |            | S           |                                       | Chronic Use        |                 | Not Reported |
| Poisoning; Prinzmetal  | Carvedilol           |              |            | S           | Oral                                  |                    |                 | Not Reported |
| Angina; Ventricular    | Carvedilol           |              |            | S           |                                       |                    |                 | Not Reported |
| Tachycardia            | Carvedilol           |              |            | S           |                                       | Increased Dose     |                 | Not Reported |

  

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2011              | 7807960       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018269           |                      | 52 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Arthralgia; Cyst; Feeling | Escitalopram Oxalate           |              |            | S           | Oral         | See Image, Oral               |                 | Not Reported |
| Drunk; Muscle             |                                |              |            |             | Oral         | See Image, Oral               |                 |              |
| Contractions Involuntary; |                                |              |            |             | Oral         | See Image, Oral               |                 |              |
| Myalgia; Nausea;          |                                |              |            |             | Oral         | See Image, Oral               |                 |              |
| Paraesthesia;             | Escitalopram Oxalate           |              |            | S           | Oral         | See Image, Oral               |                 | Not Reported |
| Tachycardia; Tendon       |                                |              |            |             | Oral         | See Image, Oral               |                 |              |
| Pain; Tendonitis          |                                |              |            |             | Oral         | See Image, Oral               |                 |              |
|                           | Escitalopram Oxalate           |              |            | S           | Oral         | Oral, 3 Gtt (3 Gtt, 1 In 1 D) |                 | Not Reported |
|                           |                                |              |            |             | Oral         | Oral, 3 Gtt (3 Gtt, 1 In 1 D) |                 |              |
|                           | Zolpidem Tartrate              |              |            | C           |              |                               |                 | Not Reported |
|                           | Lexomil (Bromazepam)           |              |            | C           |              |                               |                 | Not Reported |
|                           | (Bromazepam)                   |              |            |             |              |                               |                 |              |
|                           | Nozinan (Levomepromazine)      |              |            | C           |              |                               |                 | Not Reported |
|                           | (Levome Promazine)             |              |            |             |              |                               |                 |              |
|                           | Rivotril (Clonazepam)          |              |            | C           |              |                               |                 | Not Reported |
|                           | (Clonazepam)                   |              |            |             |              |                               |                 |              |
|                           | Renutryl (Renutryl) (Renutryl) |              |            | C           |              |                               |                 | Not Reported |

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| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------------|-----------------|--------------|----------------|
| 24-Jan-2011                                                                                             | 7808404              | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-00132           |                                           | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                        | Lisinopril           |                    |                    | S               | Oral                         | Oral                                      |                 | Not Reported |                |
|                                                                                                         | Venlafaxine          |                    |                    | S               | Oral                         | Oral                                      |                 | Not Reported |                |
|                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                         | Oral                                      |                 | Not Reported |                |
|                                                                                                         | Cocaine              |                    |                    | S               |                              |                                           |                 | Not Reported |                |
|                                                                                                         | Diphenhydramine      |                    |                    | S               | Oral                         | Oral                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011                                                                                             | 7765595              | EXPEDITED (15-DAY) | Y                  | CA, LT          | 1000017827                   |                                           | < 1 DAY         | Male         | FRA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Epidermolysis;<br>Hypoglycaemia Neonatal;<br>Maternal Drugs Affecting<br>Foetus; Traumatic<br>Haematoma | Escitalopram Oxalate |                    |                    | S               | Transplacental               | 10 Mg (10 Mg, 1 N 1 D),<br>Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011                                                                                             | 7765766              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2011007677 |                                           | 90 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dizziness;<br>Insomnia                                                                         | Cardura              |                    |                    | S               |                              | Unk                                       |                 | Pfizer       |                |
|                                                                                                         | Lexapro              |                    |                    | S               |                              | Unk                                       |                 | Not Reported |                |
|                                                                                                         | Lasix                |                    |                    | S               |                              | Unk                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011                                                                                             | 7773452              | EXPEDITED (15-DAY) | Y                  | OT              | D0070046A                    |                                           | 78 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                 |                |   |      |                       |                 |
|-----------------------------------------------------------------|----------------|---|------|-----------------------|-----------------|
| Accidental Overdose;<br>Hypotension; Intellectual<br>Disability | Lamictal       | S | Oral | 50mg See Dosage Text  | Glaxosmithkline |
|                                                                 | Seroquel       | S | Oral | 350mg See Dosage Text | Glaxosmithkline |
|                                                                 | Cipralex       | S | Oral | 20mg See Dosage Text  | Not Reported    |
|                                                                 | Ramipril       | S | Oral |                       | Glaxosmithkline |
|                                                                 | Spironolactone | S | Oral |                       | Glaxosmithkline |
|                                                                 | Madopar        | S | Oral |                       | Not Reported    |

| <u>FDA Received Date</u>     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------|-----------------|--------------|----------------|
| 25-Jan-2011                  | 7777061              | EXPEDITED (15-DAY) | Y                  |                 | 1000017950           |                                | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Oedema; Lip<br>Oedema | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2011              | 7809028              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018218           |                      |                 | Unknown      | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Facial Paralysis         | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                          | Mirtazapine          |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-Jan-2011                                                                                             | 7809789                     | EXPEDITED (15-DAY) | Y                  | HO              | 2011SP002123         |                      | 61 YR           | Male         | CHE            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiovascular Disorder;<br>Deep Vein Thrombosis;<br>Fatigue; Immobile;<br>Peripheral Venous<br>Disease | Remeron                     |                    |                    | S               |                      | 15 Mg                |                 | Not Reported |                |
|                                                                                                         | Depakine (Valproate Sodium) |                    |                    | S               |                      | (1000 Mg) (1500 Mg)  |                 | Not Reported |                |
|                                                                                                         |                             |                    |                    |                 |                      | (1000 Mg)            |                 |              |                |
|                                                                                                         |                             |                    |                    |                 |                      | (1000 Mg) (1500 Mg)  |                 |              |                |
|                                                                                                         |                             |                    |                    |                 |                      | (1000 Mg)            |                 |              |                |
|                                                                                                         |                             |                    |                    |                 |                      | (1000 Mg) (1500 Mg)  |                 |              |                |

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|                          |                                   |                          |                    |                 |                                       | (1000 Mg)<br>(1000 Mg) (1500 Mg)<br>(1000 Mg) |                 |              |                |
|--------------------------|-----------------------------------|--------------------------|--------------------|-----------------|---------------------------------------|-----------------------------------------------|-----------------|--------------|----------------|
|                          |                                   | Cipralext                |                    | S               |                                       | 10 Mg                                         |                 |              | Not Reported   |
|                          |                                   | Tamsulosin Hydrochloride |                    | C               |                                       |                                               |                 |              | Not Reported   |
|                          |                                   | Pantozol                 |                    | C               |                                       |                                               |                 |              | Not Reported   |
|                          |                                   | Ciproxine                |                    | C               |                                       |                                               |                 |              | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>                     | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011              | 7809989                           | DIRECT                   | N                  |                 |                                       |                                               | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                    | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased         | Lexapro                           |                          |                    | S               | Oral                                  | 10mg Once A Day Po                            |                 | Forest       |                |
| <u>FDA Received Date</u> | <u>Case #</u>                     | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011              | 7810011                           | DIRECT                   | Y                  | OT              |                                       |                                               | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                    | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Dystonia      | Lexapro                           |                          |                    | S               | Oral                                  | 10mg Qam Po                                   |                 | Not Reported |                |
|                          | Haloperidol                       |                          |                    | S               | Intravenous (not otherwise specified) | 5mg, Stat,lv                                  |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                     | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Jan-2011              | 7822218                           | EXPEDITED (15-DAY)       | Y                  | DE              | 025450                                |                                               | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                    | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Abuse               | Alprazolam                        |                          |                    | S               | Oral                                  | Oral                                          |                 | Not Reported |                |
|                          | Cyclobenzaprine                   |                          |                    | S               | Oral                                  | Oral                                          |                 | Not Reported |                |
|                          | Escitalopram Oxalate              |                          |                    | S               | Oral                                  | Oral                                          |                 | Not Reported |                |
|                          | Zolpidem                          |                          |                    | S               | Oral                                  | Oral                                          |                 | Not Reported |                |
|                          | Desogestrel And Ethinyl Estradiol |                          |                    | S               | Oral                                  | Oral                                          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                   | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 25-Jan-2011                                | 7831267                                            | EXPEDITED (15-DAY) | Y                  | DE              | 025516                             |                                                                                                    | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                          | Alprazolam                                         |                    |                    | S               | Oral                               | (Oral)                                                                                             |                 | Not Reported |                |
|                                            | Verapamil Hydrochloride                            |                    |                    | S               | Oral                               | (Oral)                                                                                             |                 | Not Reported |                |
|                                            | Escitalopram Oxalate                               |                    |                    | S               | Oral                               | (Oral)                                                                                             |                 | Not Reported |                |
|                                            | Cyclobenzaprine                                    |                    |                    | S               | Oral                               | (Oral)                                                                                             |                 | Not Reported |                |
|                                            | Doxepin                                            |                    |                    | S               | Oral                               | (Oral)                                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2011                                | 7294744                                            | EXPEDITED (15-DAY) | Y                  | DE              | 1000011581                         |                                                                                                    | 26 YR           | Male         | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Overdose | Escitalopram Oxalate                               |                    |                    | S               |                                    | 10 Mg (10 Mg, 1 In 1 D), 2<br>Or 3 Boxes (Once)<br>10 Mg (10 Mg, 1 In 1 D), 2<br>Or 3 Boxes (Once) |                 | Not Reported |                |
|                                            | Paroxetine Hydrochloride                           |                    |                    | S               |                                    |                                                                                                    |                 | Not Reported |                |
|                                            | Morphine                                           |                    |                    | S               |                                    | (Once)                                                                                             |                 | Not Reported |                |
|                                            | Alcohol (Ethanol)                                  |                    |                    | S               |                                    | (Once)                                                                                             |                 | Not Reported |                |
|                                            | Xanax (Alprazolam) (0.5<br>Milligram) (Alprazolam) |                    |                    | C               |                                    |                                                                                                    |                 | Not Reported |                |
|                                            | Olmifon (Adrafinil)(Adrafinil)                     |                    |                    | C               |                                    |                                                                                                    |                 | Not Reported |                |
|                                            | Cymbalta                                           |                    |                    | C               |                                    |                                                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2011                                | 7724624                                            | EXPEDITED (15-DAY) | Y                  | DS, OT          | FR-SANOFI-AVENTIS-<br>2010SA075838 |                                                                                                    | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                      | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract                                   | Plaquenil                                          |                    |                    | S               | Oral                               |                                                                                                    |                 | Not Reported |                |

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|                            |   |      |                                                          |              |
|----------------------------|---|------|----------------------------------------------------------|--------------|
| Plaquenil                  | S | Oral |                                                          | Not Reported |
| Folic Acid                 | S | Oral | Every Day Excepted Monday                                | Not Reported |
| Cortancyl                  | S | Oral |                                                          | Not Reported |
| Femara                     | S | Oral |                                                          | Not Reported |
| Methotrexate               | S |      | 10 Mg Every Monday<br>Dose:10<br>Milligram(S)/Millilitre | Not Reported |
| Inipomp                    | S | Oral |                                                          | Not Reported |
| Calcium Carbonate          | S | Oral |                                                          | Not Reported |
| Fosamax                    | S | Oral | 70 Mg On Friday                                          | Not Reported |
| Valacyclovir Hydrochloride | S | Oral |                                                          | Not Reported |
| Escitalopram Oxalate       | S | Oral |                                                          | Not Reported |
| Aprovel                    | S | Oral |                                                          | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 26-Jan-2011                                      | 7811044              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018243           |                                 |                 | Male         | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal<br>Haemorrhage;<br>Haematemesis | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1in 1 D),<br>Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 27-Jan-2011                                 | 7417094              | EXPEDITED (15-DAY) | Y                  | LT              | DK-TEVA-236928ISR    |                      | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased;<br>Drug Interaction | Mirtazapine          |                    |                    | S               | Oral                 |                      |                 | Teva         |                |
|                                             | Quetiapine           |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                             | Bendroflumethiazide  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                             | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Jan-2011              | 7776745       | EXPEDITED (15-DAY) | Y                  | HO, OT          | SE-PFIZER INC-2011016171 |                      | 82 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                    | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gastric Ulcer;<br>Haemoglobin Decreased;<br>Haemorrhoids | Prednisolone                 |              |            | S           | Oral         | 2.5 Mg/24h, Unk    | 68 DAY          | Pfizer       |
|                                                          | Cipralax                     |              |            | S           | Oral         | 10 Mg/24h, Unk     |                 | Not Reported |
|                                                          | Diclofenac                   |              |            | S           | Oral         | 75 Mg/24h, Unk     |                 | Not Reported |
|                                                          | Heminevrin                   |              |            | C           |              | 300 Mg, Unk        |                 | Not Reported |
|                                                          | Vagifem                      |              |            | C           |              | 25 Ug, Unk         |                 | Not Reported |
|                                                          | Calcium Carbonate            |              |            | C           |              | 500 Mg/400iu       |                 | Not Reported |
|                                                          | Omeprazole                   |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Metoprolol                   |              |            | C           |              |                    |                 | Not Reported |
|                                                          | Calcium Phosphate\Folic Acid |              |            | C           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                          | Acetaminophen                |              |            | C           |              | 500 Mg, Unk        |                 | Not Reported |
|                                                          | Cyanocobalamin               |              |            | C           |              | 1 Mg, Unk          |                 | Not Reported |
|                                                          | Nitromex                     |              |            | C           | Sublingual   | 0.25 Mg, Unk       |                 | Not Reported |
|                                                          | Duphalac                     |              |            | C           | Oral         | 670 Mg/MI, Unk     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7730363       | EXPEDITED (15-DAY) | N                  | OT              | B0689678A            |                      | 77 YR      | Female     | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------|----------------------------|--------------|------------|-------------|---------------------------------------|---------------------|-----------------|-----------------|
| Cataract; Photophobia;<br>Vision Blurred | Valacyclovir Hydrochloride |              |            | S           | Oral                                  |                     |                 | Glaxosmithkline |
|                                          | Cortancyl                  |              |            | S           | Oral                                  | 70mg Per Day        |                 | Unknown         |
|                                          | Femara                     |              |            | S           | Oral                                  | 2.5mg Unknown       |                 | Unknown         |
|                                          | Plaquenil                  |              |            | S           | Oral                                  | 200mg Twice Per Day |                 | Unknown         |
|                                          | Methotrexate               |              |            | S           | Intravenous (not otherwise specified) | 10mg Weekly         |                 | Unknown         |
|                                          | Folic Acid                 |              |            | S           | Oral                                  |                     |                 | Unknown         |
|                                          | Inipomp                    |              |            | S           | Oral                                  | 40mg Per Day        |                 | Unknown         |



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|                      |   |      |             |         |
|----------------------|---|------|-------------|---------|
| Cacit Vitamine D3    | S | Oral |             | Unknown |
| Fosamax              | S | Oral | 70mg Weekly | Unknown |
| Escitalopram Oxalate | S | Oral |             | Unknown |
| Aprovel              | S | Oral |             | Unknown |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7774466       | EXPEDITED (15-DAY) | Y                  | DE              | 1000017910           |                      | 76 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                | <u>Product</u>                                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Apathy; Arteriosclerosis; Azotaemia; Carotid Arteriosclerosis; Cerebral Atrophy; Cerebral Small Vessel Ischaemic Disease; Coma; Constipation; Electrocardiogram Qt Prolonged; Fatigue; Hypercreatinaemia; Hyperglycaemia; Hypernatraemia; Hyperosmolar State; Hypotension; Psychomotor Retardation; Tonic Clonic Movements; Vomiting | Escitalopram Oxalate                                                                    |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                      | Agomelatine                                                                             |              |            | S           | Oral         | 25 Mg (25 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                      | Lansoprazole                                                                            |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                      | Karvezide (Irbesartan, Hydrochlorothiazide) (Tablets) (Irbesartan, Hydrochlorothiazide) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7777965       | NON-EXPEDITED    | N                  |                 | A0860715A            |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction; Panic Attack | Wellbutrin     |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                | Lexapro        |              |            | S           |              |                    | 3 DAY           | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|-----------------|----------------|
| 28-Jan-2011                                                                                                                                             | 7777992                     | NON-EXPEDITED      | N                  |                 | A0866793A            |                                         |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>      |                |
| Benign Neoplasm Of Thyroid Gland; Goitre                                                                                                                | Wellbutrin                  |                    |                    | S               | Unknown              |                                         |                 | Glaxosmithkline |                |
|                                                                                                                                                         | Lexapro                     |                    |                    | S               | Unknown              |                                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2011                                                                                                                                             | 7778009                     | NON-EXPEDITED      | Y                  |                 | A0871968A            |                                         |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>      |                |
| Headache                                                                                                                                                | Wellbutrin                  |                    |                    | S               |                      |                                         |                 | Glaxosmithkline |                |
|                                                                                                                                                         | Lexapro                     |                    |                    | S               |                      |                                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2011                                                                                                                                             | 7809598                     | EXPEDITED (15-DAY) | Y                  | HO              | THQ2011A00194        |                                         | 36 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>      |                |
| Epistaxis; Gingival Bleeding; Haematoma; Haemoglobin Decreased; Haemoptysis; Immune Thrombocytopenic Purpura; Iron Deficiency; Oropharyngeal Blistering | Lansoprazole (Lansoprazole) |                    |                    | S               | Oral                 | 1 Df (1 Df, 1 In 1 D), Per Oral         | 1 MTH           | Not Reported    |                |
|                                                                                                                                                         | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 10 Mg 910 Mg, 1 In 1 D), Per Oral       | 2 MTH           | Not Reported    |                |
|                                                                                                                                                         | Amoxicillin Trihydrate      |                    |                    | S               | Oral                 | Per Oral                                |                 | Not Reported    |                |
|                                                                                                                                                         | Prednisolone                |                    |                    | S               | Oral                 | Per Oral                                |                 | Not Reported    |                |
|                                                                                                                                                         | Levothyroxine Sodium        |                    |                    | S               | Oral                 | 12.5 Mcg (12.5 Mcg, 1 In 1 D), Per Oral |                 | Not Reported    |                |
|                                                                                                                                                         | Amoxicillin Trihydrate      |                    |                    | C               |                      |                                         |                 | Not Reported    |                |
|                                                                                                                                                         | Prednisolone                |                    |                    | C               |                      |                                         |                 | Not Reported    |                |
|                                                                                                                                                         | Levothyroxine Sodium        |                    |                    | C               |                      |                                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 28-Jan-2011                                                                                                                                             | 7810940                     | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000018264           |                                         | 43 YR           | Male            | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Haemoglobin Decreased;<br>Haemorrhage; Pallor;<br>Pneumonia; Pulmonary<br>Haemorrhage | Escitalopram Oxalate                                                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                       | Warfarin (Warfarin) (Tablets)                                              |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Digoxin (Digoxin) (0.25<br>Milligram, Tablets) (Digoxin)                   |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Clopidogrel (Clopidogrel)<br>(Tablets) (Clopidogrel)                       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Ramipril (Ramipril) (Tablets)<br>(Ramipril)                                |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Carvedilol (Carvedilol) (Tablets)<br>(Carvedilol)                          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Furosemide (Furosemide)<br>(Tablets) (Furosemide)                          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Spironolactone (Spironolactone)<br>(Tablets) (Spironolactone)              |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                       | Rosuvastatin (Rosuvastatin<br>Calcium) (Tablets) (Rosuvastatin<br>Calcium) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7814664       | EXPEDITED (15-DAY) | Y                  | DE              | 2011VX000212         |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Diazepam                                    |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                 | Escitalopram Oxalate                        |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                 | Hydrocodone Bitartrate And<br>Acetaminophen |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                 | Morphine                                    |              |            | S           | Oral         | Po                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7817065       | EXPEDITED (15-DAY) | Y                  | CA              | 1000018277           |                      |            | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                         |         |   |                |                                                                                                                                                                                  |              |
|---------------------------------------------------------|---------|---|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Craniosynostosis;<br>Maternal Drugs Affecting<br>Foetus | Lexapro | S | Transplacental | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental , 10 Mg (10<br>Mg,1 In 1<br>D),Transmammary<br>10 Mg (10 Mg, 1 In 1 D),<br>Transplacental , 10 Mg (10<br>Mg,1 In 1<br>D),Transmammary | Not Reported |
|                                                         |         |   | Transplacental |                                                                                                                                                                                  |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7817120       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000018285           |                      | 65 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Confusional State;<br>Decreased Interest;<br>Disturbance In Attention;<br>Fall; Muscle Spasms;<br>Upper Limb Fracture | Lexapro                    |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                       | Trilipix (Fenofibric Acid) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                       | Norvasc                    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                       | Lisinopril (Lisinopril)    |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Jan-2011              | 7822964       | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00122_2011       |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Metoclopramide Hydrochloride |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Metoprolol                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Quetiapine                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Duloxetine                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Escitalopram Oxalate         |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                 | Clonazepam                   |              |            | S           | Oral         | Df Oral            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2011              | 7734967       | EXPEDITED (15-DAY) | N                  | OT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15453160 |                      | 78 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|----------------------|
| Cataract              | Aprovel                    |              |            | S           | Oral         |                                                              |                 | Bristol Myers Squibb |
|                       | Cortancyl                  |              |            | S           |              | Initial Dose 70 Mg/D Then<br>At Lower Dose From Jul-<br>2009 |                 | Not Reported         |
|                       | Femara                     |              |            | S           | Oral         |                                                              |                 | Not Reported         |
|                       | Plaquenil                  |              |            | S           | Oral         | Rechallenged On 3dec10<br>At 2 Tab Daily                     |                 | Sandoz               |
|                       | Methotrexate Sodium        |              |            | S           |              | Every Monday                                                 |                 | Bristol Myers Squibb |
|                       | Folic Acid                 |              |            | S           | Oral         | Every Day Except Monday                                      |                 | Not Reported         |
|                       | Inipomp                    |              |            | S           |              | From Prior To August<br>2009                                 |                 | Not Reported         |
|                       | Calcium Carbonate          |              |            | S           | Oral         | From Prior To August<br>2009                                 |                 | Not Reported         |
|                       | Fosamax                    |              |            | S           | Oral         | Every Friday From Prior<br>To August 2009                    |                 | Not Reported         |
|                       | Valacyclovir Hydrochloride |              |            | S           | Oral         |                                                              |                 | Not Reported         |
|                       | Escitalopram Oxalate       |              |            | S           | Oral         |                                                              |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2011              | 7811204       | DIRECT           | N                  | OT              |                      |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthma; Drug Ineffective;<br>Dyspnoea; Feeling<br>Abnormal; Head Banging;<br>Hyperhidrosis; Influenza<br>Like Illness | Lexapro        |              |            | S           |              | One A Day          |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2011              | 7813256       | DIRECT           | Y                  | HO              |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                               |                    |                    |                 |                      |                      |                 |              |                |
|---------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Generalised Tonic-Clonic Seizure            |                               | Lexapro            | S                  | Oral            | Lexapro 10mg Po Qd   |                      | 1 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2011                                 | 7821569                       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05315_2011       |                      | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Poisoning                                   | Oxymorphone Hydrochloride     |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                             | Cyclobenzaprine               |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                             | Zolpidem                      |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                             | Escitalopram Oxalate          |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                             | Desogestrel\Ethinyl Estradiol |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2011                                 | 7834619                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000018410           |                      | 32 YR           | Male         | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                       | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Cyclobenzaprine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Alprazolam (Alprazolam)       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Desogestrel\Ethinyl Estradiol |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                             | Zolpidem                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2011                                 | 7420521                       | EXPEDITED (15-DAY) | Y                  | LT              | 2010AL003263         |                      | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased;<br>Drug Interaction | Mirtazapine                   |                    |                    | S               | Oral                 | 15 Mg;Po             |                 | Not Reported |                |
|                                             | Escitalopram Oxalate          |                    |                    | S               |                      | 5 Mg;Qd              |                 | Not Reported |                |
|                                             | Bendroflumethiazide           |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                             | Seroquel                      |                    |                    | C               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 01-Feb-2011                                                                       | 7704273                                                       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000017208                 |                      | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;<br>Intentional Overdose;<br>Somnolence                    | Escitalopram Oxalate                                          |                    |                    | S               | Oral                       | 280 Mg, Once, Oral   |                 | Not Reported |                |
|                                                                                   | Loxen (Nicardipine Hydrochloride)                             |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                   | Cibadrex (Benazepril) (Tablets) (Benazepril)                  |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                   | Seloken (Metoprolol Tartrate) (Tablets) (Metoprolol Tartrate) |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2011                                                                       | 7749944                                                       | EXPEDITED (15-DAY) | Y                  | HO              | TW-RANBAXY-2010RR-40818    |                      | 58 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia; Tardive<br>Dyskinesia                                                   | Fluoxetine                                                    |                    |                    | S               |                            | 20-40 Mg/Day         |                 | Ranbaxy      |                |
|                                                                                   | Escitalopram Oxalate                                          |                    |                    | S               |                            | 10 Mg, Unk           |                 | Not Reported |                |
|                                                                                   | Mirtazapine                                                   |                    |                    | S               |                            | 15 Mg, Unk           |                 | Not Reported |                |
|                                                                                   | Paroxetine Hydrochloride                                      |                    |                    | S               |                            | 10-40 Mg/Day         |                 | Not Reported |                |
|                                                                                   | Trazodone Hydrochloride                                       |                    |                    | S               |                            | 50-125 Mg/Day        |                 | Not Reported |                |
|                                                                                   | Venlafaxine                                                   |                    |                    | S               |                            | 37.5-225 Mg/Day      |                 | Not Reported |                |
|                                                                                   | Duloxetine                                                    |                    |                    | S               |                            | 30-60 Mg/Day         |                 | Not Reported |                |
|                                                                                   | Trazodone Hydrochloride                                       |                    |                    | C               |                            | 100 Mg, Qd           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2011                                                                       | 7794822                                                       | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-2011SE04229 |                      | 21 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Prolactin Increased;<br>Breast Discomfort; Breast<br>Pain; Breast Swelling; | Seroquel Xr                                                   |                    |                    | S               | Oral                       | 350mg                |                 | Astrazeneca  |                |
|                                                                                   | Seroquel Xr                                                   |                    |                    | S               | Oral                       | 100mg                |                 | Astrazeneca  |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |           |   |      |        |              |
|-------------------------------------|-----------|---|------|--------|--------------|
| Breast Tenderness;<br>Galactorrhoea | Ciprallex | S | Oral | 20mg   | Not Reported |
|                                     | Ciprallex | S | Oral | 10mg   | Not Reported |
|                                     | Depakene  | C | Oral | 1500mg | Not Reported |
|                                     | Lorazepam | C | Oral | 1-10mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2011              | 7825473       | EXPEDITED (15-DAY) | Y                  | LT              | 1000018533           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Aggression; Drug<br>Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2011              | 7844450       | EXPEDITED (15-DAY) | Y                  | LT              | 2011SP004009         |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                       | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Drug Interaction | Mirtazapine                               |              |            | S           | Oral         | 15 Mg; Po          |                 | Not Reported |
|                                             | Bendroflumethiazide\Potassium<br>Chloride |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                             | Escitalopram Oxalate                      |              |            | S           |              | 5 Mg; Qd           |                 | Not Reported |
|                                             | Seroquel                                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2011              | 7801128       | EXPEDITED (15-DAY) | Y                  | LT, RI, OT      | 1000018064           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Alcohol Poisoning;<br>Intentional Overdose;<br>Seizure; Suicide Attempt;<br>Tachycardia | Escitalopram Oxalate      |              |            | S           | Oral         | 950 Mg, Once, Oral  |                 | Not Reported |
|                                                                                         | Cetirizine Hydrochloride  |              |            | S           | Oral         | 50 Mg, Once, Oral   |                 | Not Reported |
|                                                                                         | Lamotrigine               |              |            | S           | Oral         | 2500 Mg, Once, Oral |                 | Not Reported |
|                                                                                         | Promethazine Hydrobromide |              |            | S           | Oral         | 2000 Mg, Once, Oral |                 | Not Reported |
|                                                                                         | Metamizole Sodium         |              |            | S           | Oral         | 5000 Mg, Once, Oral |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                       |                                                                            |                    |                    |                       |                      |                                  |                 |                                                              |                |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------|--------------------|-----------------------|----------------------|----------------------------------|-----------------|--------------------------------------------------------------|----------------|
| Unspecified Ingredient<br>Alcohol (Ethanol)                                           |                                                                            |                    | S                  | S                     |                      | Oral                             | Oral            | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 02-Feb-2011                                                                           | 7816747                                                                    | DIRECT             | N                  | OT                    |                      |                                  | 58 YR           | Male                                                         | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Abnormal Behaviour;<br>Aggression; Memory<br>Impairment; Social<br>Avoidant Behaviour | Lexapro<br>Testim                                                          |                    |                    | S<br>S                |                      |                                  |                 | Not Reported<br>Not Reported                                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 02-Feb-2011                                                                           | 7818269                                                                    | DIRECT             | Y                  | LT, OT                |                      |                                  | 72 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Platelet Count Decreased                                                              | Lexapro                                                                    |                    |                    | S                     | Oral                 | 5 Mg Po Daily                    |                 | Not Reported                                                 |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 02-Feb-2011                                                                           | 7818307                                                                    | DIRECT             | Y                  | HO                    |                      |                                  | 83 YR           | Female                                                       | USA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Fluid Overload;<br>Hyponatraemia; Nausea                                              | Escitalopram Oxalate<br>Methimazole<br>Vitamin D Nos<br>Ibandronate Sodium |                    |                    | S<br>C<br>C<br>C      | Oral                 | 10 Mg Daily Po                   |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>                                                   | <u>Country</u> |
| 02-Feb-2011                                                                           | 7829051                                                                    | EXPEDITED (15-DAY) | Y                  | DS, HO, LT, RI,<br>OT | 1000018565           |                                  | 77 YR           | Female                                                       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>                                                   |                |
| Acute Kidney Injury;<br>Anterograde Amnesia;                                          | Escitalopram Oxalate                                                       |                    |                    | S                     | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported                                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                                                                         |   |                                       |                                                                                 |              |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|---|---------------------------------------|---------------------------------------------------------------------------------|--------------|
| Dialysis; Disturbance In Attention; Echolalia; Epilepsy; Metabolic Encephalopathy; Myoclonus | Ceftazidime                                                             | S | Intravenous (not otherwise specified) | 6 G (6 Gm, 1 In 1 D), Intravenous                                               | Not Reported |
|                                                                                              | Primperan                                                               | S | Oral                                  | 10 Gtt (10 Gtt, 1 In 1 D), Oral                                                 | Not Reported |
|                                                                                              | Primperan                                                               | S | Intravenous (not otherwise specified) | 3 Dosage Form (1 Dosage Forms, 3 In 1 D), Intravenous (Not Otherwise Specified) | Not Reported |
|                                                                                              | Dalacine (Clindamycin) (Solution) (Clindamycin)                         | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Rifampicine (Rifampicin) (Rifampicin)                                   | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Lyrica (Pregabalin) (Capsules) (Pregabalin)                             | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Inexium (Esomeprazole Magnesium) (Tablets) (Esomeprazole Magnesium)     | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Kardegic (Acetylsalicylate Lysine) (Powder) (Acetylsalicylate Lysine)   | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Innohep (Heparin-Fraction, Sodium Salt) (Heparin-Fraction, Sodium Salt) | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Doliprane (Paracetamol) (Paracetamol)                                   | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Lexomil (Bromazepam) (Tablets) (Bromazepam)                             | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate)                  | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Contramal (Tramadol Hydrochloride) (Tramadol Hydrochloride)             | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Ramipril                                                                | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Lasilix (Furosemide) (Tablets) (Furosemide)                             | C |                                       |                                                                                 | Not Reported |
|                                                                                              | Elisor (Pravastatin Sodium) (Tablets) (Pravastatin Sodium)              | C |                                       |                                                                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2011              | 7829064       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018589           |                      | 53 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------------------|-----------------|--------------|----------------|
| Small Intestinal Ulcer<br>Haemorrhage                                      | Escitalopram Oxalate                      |                    |                    | S               | Oral                          | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Feb-2011                                                                | 7831559                                   | EXPEDITED (15-DAY) | N                  | OT              | 2011SP003919                  |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema Peripheral;<br>Swelling Face                                        | Polyethylene Glycol 3350                  |                    |                    | S               | Oral                          | 17 Gm;Bid;Po                     |                 | Not Reported |                |
|                                                                            | Seroquel                                  |                    |                    | S               | Oral                          | 50 Mg;Bid;Po                     |                 | Not Reported |                |
|                                                                            | Topamax                                   |                    |                    | S               | Oral                          | 200 Mg; Qd; Po                   |                 | Not Reported |                |
|                                                                            | Escitalopram Oxalate                      |                    |                    | S               | Oral                          | 40 Mg, Qd, Po                    |                 | Not Reported |                |
|                                                                            | Neurontin                                 |                    |                    | S               | Oral                          | 600 Mg; Tid; Po                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2011                                                                | 7798586                                   | EXPEDITED (15-DAY) | Y                  | LT              | DK-MYLANLABS-<br>2011S1001547 |                                  | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Hyponatraemia                                         | Mirtazapine                               |                    |                    | S               | Oral                          |                                  |                 | Not Reported |                |
|                                                                            | Seroquel                                  |                    |                    | C               | Oral                          |                                  |                 | Not Reported |                |
|                                                                            | Bendroflumethiazide\Potassium<br>Chloride |                    |                    | S               | Oral                          |                                  | 1240 DAY        | Not Reported |                |
|                                                                            | Escitalopram Oxalate                      |                    |                    | S               |                               |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2011                                                                | 7820672                                   | DIRECT             | N                  |                 |                               |                                  | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Muscle<br>Spasms;<br>Temporomandibular Joint<br>Syndrome | Trileptal                                 |                    |                    | S               |                               |                                  |                 | Not Reported |                |
|                                                                            | Lexapro                                   |                    |                    | S               |                               |                                  |                 | Not Reported |                |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2011              | 7852748       | NON-EXPEDITED    | N                  | OT              | 017873               |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------|-----------------|--------------|
| Crying; Dry Mouth; Feeling Abnormal; Pain; Suicidal Ideation; Thirst; Weight Increased | Keppra<br>Lexapro         |              |            | S           |              |                                                                                  |                 | Not Reported |
|                                                                                        |                           |              |            | S           | Oral         | (10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral) |                 | Not Reported |
|                                                                                        |                           |              |            |             | Oral         | (10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral) |                 |              |
|                                                                                        |                           |              |            |             | Oral         | (10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral) |                 |              |
|                                                                                        | Synthroid<br>Baby Aspirin |              |            |             | Oral         | (10 Mg Qd Oral), (5 Mg Qd Oral), (2.5 Mg, Every Other Day Oral), (10 Mg Qd Oral) |                 |              |
|                                                                                        |                           |              |            | C           |              |                                                                                  |                 | Not Reported |
|                                                                                        |                           |              |            | C           |              |                                                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2011              | 7774636       | EXPEDITED (15-DAY) | Y                  | DS, RI, OT      | 1000017922           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------|-----------------|--------------|
| Cataract              | Escitalopram Oxalate<br>Prednisone Acetate |              |            | S           | Oral         | Oral                                |                 | Not Reported |
|                       |                                            |              |            | S           | Oral         | 70 Mg (70 Mg, 1 In 1 D), Oral; Oral |                 | Not Reported |
|                       |                                            |              |            |             | Oral         | 70 Mg (70 Mg, 1 In 1 D), Oral; Oral |                 |              |
|                       | Femara                                     |              |            | S           | Oral         | (2.5 Mg), Oral                      |                 | Not Reported |
|                       | Plaquenil                                  |              |            | S           | Oral         | 400 Mg (200 Mg, 2 In 1 D), Oral     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |   |      |                                                |              |
|-----------------------------------|---|------|------------------------------------------------|--------------|
| Plaquenil                         | S | Oral | Oral                                           | Not Reported |
| Methotrexate Sodium               | S |      | 1,4286 Mg (10 Mg, 1 In 1 Wk)                   | Not Reported |
| Speciafoldine (Folic Acid)        | S | Oral | Oral                                           | Not Reported |
| Inipomp                           | S | Oral | 40 Mg (40 Mg, 1 In 1 D), Oral                  | Not Reported |
| Calcium Carbonate\Cholecalciferol | S | Oral | 1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral | Not Reported |
| Fosamax                           | S | Oral | 10 Mg (70 Mg, 1 In 1 Wk), Oral                 | Not Reported |
| Valacyclovir Hydrochloride        | S | Oral | Oral                                           | Not Reported |
| Irbesartan                        | S | Oral | Oral                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 04-Feb-2011              | 7800453       | EXPEDITED (15-DAY) | Y                  | HO              | US-CEPHALON-2011000455 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arrhythmia; Cardiac Arrest; Coma; Confusional State; Hypotension; Hypoventilation; Hypoxia; Overdose; Respiratory Failure; Rhabdomyolysis; Seizure; Suicidal Ideation; Vomiting | Amrix            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                 | Tanezumab        |              |            | S           |              |                    | 167 DAY         | Not Reported |
|                                                                                                                                                                                 | Fioricet         |              |            | S           |              |                    | 167 DAY         | Not Reported |
|                                                                                                                                                                                 | Phenergan        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Lexapro          |              |            | S           |              |                    | 2 YR            | Not Reported |
|                                                                                                                                                                                 | Nortriptyline    |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Lotrel           |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                 | Theragesic Creme |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Feb-2011              | 7836546       | EXPEDITED (15-DAY) | Y                  | OT              | 2011SP003773         |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Paralysis      | Mirtazapine    |              |            | S           |              |                    |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         | Po                 |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| 04-Feb-2011                                                                                   | 7836727              | EXPEDITED (15-DAY) | Y                  | HO              | 1000018580           |                                     | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Adjustment Disorder;<br>Anxiety; Obsessive-<br>Compulsive Disorder;<br>Phobia; Sleep Disorder | Escitalopram Oxalate |                    |                    | S               |                      | 15 Mg (15 Mg,1 In 1 D)              |                 | Not Reported |                |
|                                                                                               | Escitalopram Oxalate |                    |                    | S               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2011                                                                                   | 7836800              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018575           |                                     | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition<br>Aggravated; Suicidal<br>Ideation                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2011                                                                                   | 7836803              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018570           |                                     | 31 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Condition<br>Aggravated; Obsessive-<br>Compulsive Disorder;<br>Overdose             | Escitalopram Oxalate |                    |                    | S               |                      | (1 In 1 D) ; 40 Mg (40 Mg,1 In 1 D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2011                                                                                   | 7838284              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018552           |                                     | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Drunk; Loss Of<br>Consciousness; Malaise;<br>Mydriasis                                | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                               | Prazepam             |                    |                    | C               |                      |                                     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------|-----------------|--------------|----------------|
| 04-Feb-2011                                                                                                                            | 7838289              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018560                 |                                     | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Sexual Arousal; Hypomania                                                                                               | Escitalopram Oxalate |                    |                    | S               |                            | 10 Mg (10 Mg, 1 In 1 D)             |                 | Not Reported |                |
|                                                                                                                                        | Lithium              |                    |                    | C               |                            |                                     |                 | Not Reported |                |
|                                                                                                                                        | Surmontil            |                    |                    | C               |                            |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Feb-2011                                                                                                                            | 7838294              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018554                 |                                     | 94 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cognitive Disorder; Hyponatraemia                                                                                            | Escitalopram Oxalate |                    |                    | S               | Oral                       | 5 Mg (5 Mg, 1 In 1 D), Oral         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2011                                                                                                                            | 7801541              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | DE-ASTRAZENECA-2011SE05761 |                                     | 33 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Long Qt Syndrome                                                                                                                       | Seroquel             |                    |                    | S               | Oral                       | 100/200 Mg; 200-900 Mg Daily Per Os | 185 DAY         | Zeneca       |                |
|                                                                                                                                        | Ciprallex            |                    |                    | S               | Oral                       | 10-40 Mg Daily Per Os               | 98 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Feb-2011                                                                                                                            | 7802733              | EXPEDITED (15-DAY) | Y                  | HO              | PHHO2011US01819            |                                     |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Arrhythmia; Cardiac Arrest; Coma; Confusional State; Hypotension; Hypoventilation; Hypoxia; Intentional Overdose; Respiratory Failure; | Lotrel               |                    |                    | S               | Oral                       | 10/40                               |                 | Novartis     |                |
|                                                                                                                                        | Fioricet             |                    |                    | S               |                            | Unk                                 | 169 DAY         | Not Reported |                |
|                                                                                                                                        | Phenergan            |                    |                    | S               |                            |                                     |                 | Not Reported |                |
|                                                                                                                                        | Lexapro              |                    |                    | S               |                            | 10 Mg, Qd                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                     |   |  |  |           |  |              |
|----------------------------|---------------------|---|--|--|-----------|--|--------------|
| Rhabdomyolysis; Seizure;   | Nortriptyline       | S |  |  |           |  | Not Reported |
| Suicidal Ideation; Suicide | Amrix               | S |  |  |           |  | Not Reported |
| Attempt; Vomiting          | Theragesic Creme    | C |  |  | Unk       |  | Not Reported |
|                            | Hydrochlorothiazide | C |  |  | Unk       |  | Not Reported |
|                            | Prozac              | C |  |  | 40 Mg, Qd |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2011              | 7824420       | DIRECT           | N                  | HO, LT          |                      |                      | 24 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Headache;<br>Hypersensitivity;<br>Paraesthesia; Refusal Of<br>Treatment By Patient | Lexapro        |              |            | S           |              | 20 Mg Once Daily   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2011              | 7838162       | EXPEDITED (15-DAY) | Y                  | CA              | 1000018566           |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-----------------------------------------------------------------------------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Caesarean Section;<br>Carbon Dioxide Increased;<br>Dyspnoea; Increased<br>Bronchial Secretion;<br>Maternal Drugs Affecting<br>Foetus; Maternal<br>Exposure During Breast<br>Feeding | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental; 10 Mg (10<br>Mg, 1 In 1 D),<br>Transmammary |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2011              | 7838833       | EXPEDITED (15-DAY) | Y                  | DE, HO          | KADN20110016         |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lethargy; Loss Of<br>Consciousness; | Morphine       |              |            | S           | Oral         | Per Oral           |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                     |                                           |   |      |          |              |
|---------------------------------------------------------------------|-------------------------------------------|---|------|----------|--------------|
| Myocardial Infarction;<br>Respiratory Depression;<br>Rhabdomyolysis | Escitalopram                              | S | Oral | Per Oral | Not Reported |
|                                                                     | Hydrocodone Bitartrate &<br>Acetaminophen | S | Oral | Per Oral | Not Reported |
|                                                                     | Diazepam                                  | S | Oral | Per Oral | Not Reported |

| <u>FDA Received Date</u>                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 07-Feb-2011                                                     | 7841151        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018608           |                                 | 42 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Restlessness;<br>Sleep Disorder; Suicidal<br>Behaviour | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------------------|------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 07-Feb-2011                                                                  | 7849247                  | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000018649                               |                                                                              | 87 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health<br>Deterioration; Organ<br>Failure; Thrombocytopenia | Escitalopram Oxalate     |                    |                    | S               | Oral                                     | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                             |                 | Not Reported |                |
|                                                                              | Calciparine              |                    |                    | S               | Subcutaneous                             | 10,000 Iu/L 0.4 MI,<br>Subcutaneous                                          |                 | Not Reported |                |
|                                                                              | Ceftriaxone Sodium       |                    |                    | S               | Intravenous (not<br>otherwise specified) | 1 Gram (1 Gm, 1 In 1 D),<br>Intravenous                                      |                 | Not Reported |                |
|                                                                              | Inexium (Esomeprazole)   |                    |                    | S               | Intravenous (not<br>otherwise specified) | 40 Mg (40 Mg, 1 In 1 D),<br>Intravenous                                      |                 | Not Reported |                |
|                                                                              | Alizapride Hydrochloride |                    |                    | S               | Intravenous (not<br>otherwise specified) | 2 Df (1 Dosage Forms, 2<br>In 1 D), Intravenous (Not<br>Otherwise Specified) |                 | Not Reported |                |
|                                                                              | Acupan                   |                    |                    | S               | Intravenous (not<br>otherwise specified) | 3 Df (1 Dosage Forms, 3<br>In 1 D), Intravenous (Not<br>Otherwise Specified) |                 | Not Reported |                |
|                                                                              | Solu-Medrol              |                    |                    | S               | Intravenous (not<br>otherwise specified) | 1 Gram (1 Gm, 1 In 1 D),<br>Intravenous (Not<br>Otherwise Specified)         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |              |              |              |
|--|----------------------|---|--------------|--------------|--------------|
|  | Arixtra              | S | Subcutaneous | Subcutaneous | Not Reported |
|  | Lasilix (Furosemide) | C |              |              | Not Reported |
|  | Bisoprolol Fumarate  | C |              |              | Not Reported |
|  | Casodex              | C |              |              | Not Reported |
|  | Forlax (Macrogol)    | C |              |              | Not Reported |
|  | Triatec (Ramipril)   | C |              |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2011              | 7738044       | EXPEDITED (15-DAY) | Y                  | OT              | FR-MERCK-1012FRA00127 |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract              | Fosamax                           |              |            | S           | Oral         |                    |                 | Merck        |
|                       | Prednisone                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Letrozole                         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydroxychloroquine Sulfate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Hydroxychloroquine Sulfate        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Methotrexate Sodium               |              |            | S           | Parenteral   |                    |                 | Not Reported |
|                       | Folic Acid                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Pantoprazole Sodium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Calcium Carbonate\Cholecalciferol |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Valacyclovir Hydrochloride        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate              |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Irbesartan                        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2011              | 7792630       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2011SE04819 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Thrombocytopenia      | Inexium        |              |            | S           | Intravenous (not otherwise specified) |                    | 34 DAY          | Astrazeneca  |
|                       | Calciparine    |              |            | S           | Subcutaneous                          |                    | 10 DAY          | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |                                       |        |              |
|--------------------------|---|---------------------------------------|--------|--------------|
| Ceftriaxone              | S | Intravenous (not otherwise specified) | 11 DAY | Not Reported |
| Escitalopram Oxalate     | S | Oral                                  | 15 DAY | Not Reported |
| Alizapride Hydrochloride | S | Intravenous (not otherwise specified) | 16 DAY | Not Reported |
| Acupan                   | S |                                       | 35 DAY | Not Reported |
| Solu-Medrol              | S | Intravenous (not otherwise specified) | 12 DAY | Not Reported |
| Arixtra                  | S | Subcutaneous                          |        | Not Reported |
| Casodex                  | C |                                       |        | Not Reported |
| Lasix                    | C |                                       |        | Not Reported |
| Bisoprolol Fumarate      | C |                                       |        | Not Reported |
| Forlax                   | C |                                       |        | Not Reported |
| Ramipril                 | C |                                       |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2011              | 7793447       | EXPEDITED (15-DAY) | HO                 |                 | FR-PFIZER INC-2011017087 |                      | 87 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|--------------|
| Thrombocytopenia      | Solu-Medrol        |              |            | S           | Intravenous (not otherwise specified) | 1 G, 1x/Day        |                 | Pfizer       |
|                       | Calciparin         |              |            | S           | Subcutaneous                          | 1 Df, 2x/Day       |                 | Not Reported |
|                       | Ceftriaxone Sodium |              |            | S           | Intravenous (not otherwise specified) | 1 G, 1x/Day        |                 | Not Reported |
|                       | Inexium            |              |            | S           | Intravenous (not otherwise specified) | 40 Mg, 1x/Day      |                 | Not Reported |
|                       | Seroplex           |              |            | S           | Oral                                  | 10 Mg, 1x/Day      |                 | Not Reported |
|                       | Plitican           |              |            | S           | Intravenous (not otherwise specified) | 1 Df, 2x/Day       |                 | Not Reported |
|                       | Acupan             |              |            | S           |                                       | 1 Df, 3x/Day       |                 | Not Reported |
|                       | Arixtra            |              |            | S           | Subcutaneous                          | Unk                |                 | Not Reported |
|                       | Lasilix            |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Cardensiel         |              |            | C           |                                       |                    |                 | Not Reported |
|                       | Casodex            |              |            | C           |                                       |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                      |                                             |                    |                    |                 |                              |                                       |                 |              |                |
|----------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------------------|-----------------|--------------|----------------|
| Forlax<br>Triatec (Ramipril)                                         |                                             |                    | C<br>C             |                 | Not Reported<br>Not Reported |                                       |                 |              |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2011                                                          | 7799148                                     | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-<br>2011023117 |                                       |                 | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Oedema Peripheral;<br>Swelling Face                                  | Neurontin                                   |                    |                    | S               | Oral                         | 600 Mg, 3x/Day                        |                 | Pfizer       |                |
|                                                                      | Miralax                                     |                    |                    | S               | Oral                         | 1 Capful At 1300, 1 Capful<br>At 1830 |                 | Not Reported |                |
|                                                                      | Seroquel                                    |                    |                    | S               | Oral                         | 50 Mg, 2x/Day                         |                 | Not Reported |                |
|                                                                      | Topamax                                     |                    |                    | S               | Oral                         | 200 Mg, 1x/Day                        |                 | Not Reported |                |
|                                                                      | Lexapro                                     |                    |                    | S               | Oral                         | 40 Mg, 1x/Day                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2011                                                          | 7803393                                     | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2011024094 |                                       |                 | Male         | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective                                                     | Sinequan                                    |                    |                    | S               |                              | Unk                                   |                 | Pfizer       |                |
|                                                                      | Lexapro                                     |                    |                    | S               |                              |                                       |                 | Not Reported |                |
|                                                                      | Tofranil                                    |                    |                    | S               |                              |                                       |                 | Not Reported |                |
|                                                                      | Wellbutrin                                  |                    |                    | S               |                              |                                       |                 | Not Reported |                |
|                                                                      | Prozac                                      |                    |                    | S               |                              | Unk                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2011                                                          | 7803794                                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-<br>2011023899 |                                       | 81 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Confusional State;<br>Hallucination, Visual | Lyrica                                      |                    |                    | S               | Oral                         | Unk                                   |                 | Pfizer       |                |
|                                                                      | Tramadol Hydrochloride And<br>Acetaminophen |                    |                    | S               | Oral                         | Unk                                   | 9 DAY           | Not Reported |                |
|                                                                      | Zolpidem                                    |                    |                    | S               | Oral                         | 10 Mg, 1x/Day                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                      |   |      |                     |              |
|--|----------------------|---|------|---------------------|--------------|
|  | Escitalopram Oxalate | S | Oral | 5 Mg, Alternate Day | Not Reported |
|  | Propranolol          | C |      |                     | Not Reported |
|  | Furosemide           | C |      |                     | Not Reported |
|  | Diffu K              | C |      |                     | Not Reported |
|  | Plavix               | C |      |                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2011              | 7794136       | EXPEDITED (15-DAY) | N                  | HO              | 2010P1003456         |                      | 81 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Atrial Fibrillation; Blood Potassium Decreased; Depression; Dizziness; Drug Ineffective; Fluid Retention; Ileus | Fentanyl Patch         |              |            | S           | Transdermal  | 50 Mcg/Hr; Q 72 Hr; Tder, 50 Mcg/Hr; Q 72 Hr; Tder |                 | Not Reported |
|                                                                                                                 | Fentanyl Patch         |              |            | S           | Transdermal  | 50 Mcg/Hr; Q 72 Hr; Tder, 50 Mcg/Hr; Q 72 Hr; Tder |                 | Not Reported |
|                                                                                                                 | Fentanyl Patch         |              |            | S           | Transdermal  | 75 Mcg/Jr; Q 72 Hr; Tder                           |                 | Not Reported |
|                                                                                                                 | Furosemide             |              |            | S           | Oral         | 40 Mg; Qd; Po                                      |                 | Not Reported |
|                                                                                                                 | Lexapro                |              |            | S           | Oral         | 20 Mg; Po                                          |                 | Not Reported |
|                                                                                                                 | Sertraline             |              |            | S           |              | 50 Mg; Qd                                          |                 | Not Reported |
|                                                                                                                 | Pantoprazole           |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Diazyde                |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Potassium Chloride     |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Detrol La              |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Re Dualvit Plus (Iron) |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Amlodipine             |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Milk Of Magnesia       |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Tylenol                |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Vitamin D Nos          |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                                                 | Prev Meds              |              |            | C           |              |                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2011              | 7839583       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018620           |                      | 82 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Fatigue; Gastric Ulcer; Haematochezia; Haemoglobin Decreased; | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                                                           |   |      |                                     |              |
|--------------|-----------------------------------------------------------|---|------|-------------------------------------|--------------|
| Haemorrhoids | Prednisolone                                              | S | Oral | 2.5 Mg (12.5 Mg, 1 In 1 D),<br>Oral | Not Reported |
|              | Vagifem (Estradiol) (Estradiol)                           | C |      |                                     | Not Reported |
|              | Heminevrin (Heminevrin)<br>(Heminevrin)                   | C |      |                                     | Not Reported |
|              | Kalcipos-D (Calcium, Vitamin D3)<br>(Calcium, Vitamin D3) | C |      |                                     | Not Reported |
|              | Omeprazole (Omeprazole)<br>(Omeprazole)                   | C |      |                                     | Not Reported |
|              | Metoprolol Succinate                                      | C |      |                                     | Not Reported |
|              | Folacin (Folic Acid) (Folic Acid)                         | C |      |                                     | Not Reported |
|              | Panodil (Paracetamol)<br>(Paracetamol)                    | C |      |                                     | Not Reported |
|              | Behepan (Cyanocobalamin)<br>(Cyanocobalamin)              | C |      |                                     | Not Reported |
|              | Nitromex (Glyceryl Trinitrate)<br>(Glyceryl Trinitrate)   | C |      |                                     | Not Reported |
|              | Duphalac (Lactulose)<br>(Lactulose)                       | C |      |                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Feb-2011              | 7839692       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018680           |                      | 80 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                            | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Affective Disorder;<br>Asthenia; Decreased<br>Appetite; Dementia;<br>Diarrhoea; Disorientation;<br>Drug Interaction; General<br>Physical Health<br>Deterioration; Logorrhoea;<br>Oedema Peripheral;<br>Pancreatic Cyst;<br>Psychomotor Retardation;<br>Renal Cyst; Vomiting;<br>Weight Loss Poor | Escitalopram Oxalate                            |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Digoxin                                         |              |            | S           | Oral         | 0.125 Mg (0.125 Mg, 1 In<br>1 D),Oral             |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Digoxin                                         |              |            | S           |              |                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Colchicine                                      |              |            | S           | Oral         | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Previscan (Fluindione)<br>(Fluindione)          |              |            | S           |              |                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Adenuric (Febuxostat) (Tablets)<br>(Febuxostat) |              |            | C           |              |                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Cordarone                                       |              |            | C           |              |                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Coversyl (Perindopril)<br>(Perindopril)         |              |            | C           |              |                                                   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                  | Levothyrox (Levothyroxine)                      |              |            | C           |              |                                                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                           |                    |                    |                 |                      |                      |                 |              |                |
|------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Carvedilol                                                                         |                           | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| Transipeg (Macrogol)                                                               |                           | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Feb-2011                                                                        | 7845559                   | EXPEDITED (15-DAY) | Y                  | DE              | 2011S1000082         |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                  | Morphine Sulfate          |                    |                    | S               | Oral                 | ;Po                  |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate      |                    |                    | S               | Oral                 | ;Po                  |                 | Not Reported |                |
|                                                                                    | Acetaminophen\Hydrocodone |                    |                    | S               | Oral                 | ;Po                  |                 | Not Reported |                |
|                                                                                    | Diazepam                  |                    |                    | S               | Oral                 | ;Po                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2011                                                                        | 7807168                   | EXPEDITED (15-DAY) | Y                  | DE              | CHPA2011US02089      |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                  | Diphenhydramine           |                    | Y                  | S               | Oral                 |                      |                 | Novartis     |                |
|                                                                                    | Venlafaxine               |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                    | Cocaine                   |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                    | Lisinopril                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate      |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                    | Unspecified Ingredient    |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Feb-2011                                                                        | 7831742                   | DIRECT             | Y                  | DS              |                      |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia;<br>Extrapyramidal Disorder;<br>Therapeutic Product Effect<br>Decreased | Lexapro                   |                    |                    | S               | Oral                 | 20 Mg Daily Po       | 4 MTH           | Forest       |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2011              | 7842339                | EXPEDITED (15-DAY) | Y                  | DE              | AE11-014-2           |                      | 56 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Unspecified Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Alcohol                |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Lorcet                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate   |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Feb-2011                                           | 7842345              | EXPEDITED (15-DAY) | Y                  | DE              | AE11-014-1           |                      | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Lorcet               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Morphine             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                       | Diazepam             |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------------------|--------------------------|-----------------|--------------|----------------|
| 10-Feb-2011                        | 7843580              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2011000494                            |                          | 64 YR           | Female       | FRA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroduodenal Ulcer; Oesophagitis | Tarceva              |                    |                    | S               | Oral                                  | (150 Mg,Qd), Oral        |                 | Not Reported |                |
|                                    | Solu-Medrol          |                    |                    | S               | Intravenous (not otherwise specified) | (120 Mg,Qd), Intravenous |                 | Not Reported |                |
|                                    | Escitalopram Oxalate |                    |                    | S               | Oral                                  | (10 Mg,Qd), Oral         |                 | Not Reported |                |

| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| 10-Feb-2011                        | 7855847              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000018686           |                          | 64 YR           | Female       | DNK            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroduodenal Ulcer; Oesophagitis | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |                |



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|                                                      |   |                                          |                                                                        |              |
|------------------------------------------------------|---|------------------------------------------|------------------------------------------------------------------------|--------------|
| Erlotinib                                            | S | Oral                                     | Oral<br>150 Mg (150 Mg, 1 In 1 D),<br>Oral                             | Not Reported |
| Solu-Medrol                                          | S | Intravenous (not<br>otherwise specified) | 120 Mg (120 Mg, 1 In 1 D),<br>Intravenous (Not<br>Otherwise Specified) | Not Reported |
| Mannitol                                             | C |                                          |                                                                        | Not Reported |
| Irbesartan                                           | C |                                          |                                                                        | Not Reported |
| Atarax                                               | C |                                          |                                                                        | Not Reported |
| Keppra                                               | C |                                          |                                                                        | Not Reported |
| Lasix (Furosemide)                                   | C |                                          |                                                                        | Not Reported |
| Zofran                                               | C |                                          |                                                                        | Not Reported |
| Spasfon (Phloroglucinol,<br>Trimethylphloroglucinol) | C |                                          |                                                                        | Not Reported |
| Hypnovel (Midazolam)                                 | C |                                          |                                                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2011              | 7679153       | EXPEDITED (15-DAY) | Y                  | HO              | PHHO2010US05532      |                      | 88 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                       | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|------------------------------------------|--------------------|-----------------|--------------|
| Aphasia; Cerebrovascular<br>Accident; Delirium;<br>Encephalopathy; Fall;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Urinary Tract Infection<br>Bacterial; White Blood Cell<br>Count Increased | Zoledronic Acid        |              |            | S           | Intravenous (not<br>otherwise specified) | Double Blind       | 1 DAY           | Not Reported |
|                                                                                                                                                                                                                             | Unspecified Ingredient |              |            | S           | Intravenous (not<br>otherwise specified) | Double Blind       | 1 DAY           | Not Reported |
|                                                                                                                                                                                                                             | Unspecified Ingredient |              |            | S           | Intravenous (not<br>otherwise specified) | Double Blind       | 1 DAY           | Not Reported |
|                                                                                                                                                                                                                             | Methylphenidate        |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Celexa                 |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Ditropan               |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Wellbutrin             |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Oxycodone              |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Lexapro                |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Zyrtec                 |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Clindamycin            |              |            | S           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Calcium                |              |            | C           |                                          |                    |                 | Not Reported |
|                                                                                                                                                                                                                             | Vitamin D3             |              |            | C           |                                          |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Feb-2011              | 7834561       | DIRECT           | Y                  | RI              |                      |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Amnesia; Aphasia      | Lexapro        |              |            | S           | Oral         | 20mg At Night Po   |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2011              | 7811071       | EXPEDITED (15-DAY) | Y                  | HO              | AT-ASTRAZENECA-2011SE06286 |                      | 28 YR      | Female     | AUT            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia;<br>Electrocardiogram Qt<br>Prolonged; Generalised<br>Tonic-Clonic Seizure;<br>Leukopenia | Seroquel       |              |            | S           | Oral         |                    | 3 DAY           | Zeneca       |
|                                                                                                       | Seroquel       |              |            | S           | Oral         |                    | 45 DAY          | Zeneca       |
|                                                                                                       | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                                                       | Haldol         |              |            | S           |              |                    | 15 DAY          | Not Reported |
|                                                                                                       | Amisulpride    |              |            | S           |              |                    | 22 DAY          | Not Reported |
|                                                                                                       | Cipralelex     |              |            | S           |              |                    | 19 DAY          | Not Reported |
|                                                                                                       | Cipralelex     |              |            | S           |              |                    | 15 DAY          | Not Reported |
|                                                                                                       | Cipralelex     |              |            | S           |              |                    | 52 DAY          | Not Reported |
|                                                                                                       | Topamax        |              |            | C           |              |                    | 2 DAY           | Not Reported |
|                                                                                                       | Topamax        |              |            | C           |              |                    | 35 DAY          | Not Reported |
|                                                                                                       | Lorazepam      |              |            | C           |              |                    | 8 DAY           | Not Reported |
|                                                                                                       | Lorazepam      |              |            | C           |              |                    | 11 DAY          | Not Reported |
|                                                                                                       | Lorazepam      |              |            | C           |              |                    | 10 DAY          | Not Reported |
|                                                                                                       | Lorazepam      |              |            | C           |              |                    | 57 DAY          | Not Reported |
|                                                                                                       | Lisinopril     |              |            | C           |              |                    | 86 DAY          | Not Reported |
|                                                                                                       | Amlodipine     |              |            | C           |              |                    | 86 DAY          | Not Reported |
|                                                                                                       | Abilify        |              |            | C           |              |                    | 11 DAY          | Not Reported |
|                                                                                                       | Abilify        |              |            | C           |              |                    | 52 DAY          | Not Reported |
|                                                                                                       | Kalium         |              |            | C           |              |                    | 86 DAY          | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|--------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Feb-2011                                      | 7624610                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010082389 |                      | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Fatigue; Somnolence; Weight Increased | Neurontin                |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                  | Pristiq Extended Release |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                  | Pristiq Extended Release |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                  | Effexor Xr               |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                  | Effexor Xr               |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                  | Lexapro                  |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                  | Lexapro                  |                  |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                 | <u>Case #</u>                                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 15-Feb-2011                                                                                                                                                                                                                              | 7759412                                                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000017706           |                                  | 36 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                    | <u>Product</u>                                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Body Temperature Fluctuation; Drug Ineffective; Drug Interaction; Epilepsy; Epistaxis; Excessive Eye Blinking; Intentional Product Misuse; Loss Of Consciousness; Muscle Rigidity; Overdose; Seizure; Toxicity To Various Agents; Tremor | Escitalopram Oxalate                                    |                    |                    | S               | Oral                 | 40 Mg (20 Mg,2 In 1 D), Oral     |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Flupentixol                                             |                    |                    | S               | Intramuscular        | (40 Mg, 1 In 4 C), Intramuscular |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Levetiracetam (Levetiracetam) (Tablets) (Levetiracetam) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Olanzapine                                              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Diazepam (Diazepam) (Tablets) (Diazepam)                |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Metformin (Metformin) (Tablets) (Metformin)             |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Atorvastatin (Atorvastatin) (Tablets) (Atorvastatin)    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                          |                                                         |                    |                    |                 |                      |                                  |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Feb-2011              | 7812298        | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-2011031442 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                          |   |      |                    |              |
|-----------------------------|--------------------------|---|------|--------------------|--------------|
| Mydriasis; Weight Increased | Pristiq Extended Release | S | Oral | 50 Mg, 1x/Day      | Pfizer       |
|                             | Lexapro                  | S |      | Unk                | Not Reported |
|                             | Xanax                    | C | Oral | 0.25 Mg, As Needed | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Feb-2011              | 7841812       | DIRECT           | Y                  | RI, OT          |                      |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Coordination Abnormal; Disorientation; Dizziness; Palpitations; Restlessness | Abilify        |              |            | S           |              | 10 Mg At Bedtime   |                 | Not Reported |
|                                                                                         | Lexapro        |              |            | S           |              | 20 Mg In Morning   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2011              | 7815709       | EXPEDITED (15-DAY) | Y                  | HO              | ES-JNJFOC-20110203842 |                      | 70 YR      | Female     | ESP            |

| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug Interaction; Parkinsonism | Risperdal                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Escitalopram Oxalate     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Imipramine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2011              | 7838311       | DIRECT           | Y                  | HO, LT          |                      |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angioedema; Anxiety; Autoimmune Disorder; Endocrine Disorder; Formication; Infection; Pruritus; Rash; Swollen Tongue; Thyroid Disorder; Urticaria | Lexapro        |              |            | S           | Oral         | 5mg Daily Po       |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| 16-Feb-2011                                                                                                                                                     | 7859431                  | EXPEDITED (15-DAY) | N                  | OT              | DSA_44928_2011               |                                  | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Crying;<br>Drug Ineffective; Suicidal<br>Ideation                                                                                             | Wellbutrin               |                    |                    | S               |                              | Df                               |                 | Not Reported |                |
|                                                                                                                                                                 | Lexapro                  |                    |                    | S               | Oral                         | 20 Mg, Qd, Oral                  |                 | Not Reported |                |
|                                                                                                                                                                 | Trazodone                |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                                                                                                                                 | Topamax                  |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2011                                                                                                                                                     | 7590370                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2010115950 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Drug<br>Ineffective; Headache;<br>Hypersensitivity; Nausea;<br>Therapeutic Response<br>Unexpected; Wrong<br>Technique In Product<br>Usage Process | Zoloft                   |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                                                                                                                 | Pristiq Extended Release |                    |                    | S               |                              | 50 Mg, Each Morning              |                 | Pfizer       |                |
|                                                                                                                                                                 | Pristiq Extended Release |                    |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                 | Lexapro                  |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                                                                                                                 | Vitamin C                |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2011                                                                                                                                                     | 7749160                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017604                   |                                  | 35 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Lip Oedema; Paraesthesia<br>Oral                                                                                                                                | Escitalopram Oxalate     |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                 | Imovane (Zopiclone)      |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2011                                                                                                                                                     | 7749932                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017607                   |                                  | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                             |   |      |                               |              |
|-------------------------------------------|-----------------------------|---|------|-------------------------------|--------------|
| Eye Oedema; Face Oedema; Hypersensitivity | Escitalopram Oxalate        | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral | Not Reported |
|                                           | Prazepam                    | C |      |                               | Not Reported |
|                                           | Amitriptyline Hydrochloride | C |      |                               | Not Reported |
|                                           | Imovane (Zopiclone)         | C |      |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7766776       | EXPEDITED (15-DAY) | Y                  | CA              | 1000017759           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                   | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Ankyloglossia Congenital; Apgar Score Low; Caesarean Section; Face Presentation; Maternal Drugs Affecting Foetus; Meconium In Amniotic Fluid; Selective Eating Disorder | Lexapro                                                |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |
|                                                                                                                                                                         | Prenatal Vitamin (Prenatal Vitamin) (Prenatal Vitamin) |              |            | C           |                |                                         |                 | Not Reported |
|                                                                                                                                                                         | Fish Oil (Fish Oil) (Fish Oil)                         |              |            | C           |                |                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7817328       | EXPEDITED (15-DAY) | N                  | OT              | A0913841A            |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Crying; Drug Ineffective; Product Quality Issue; Suicidal Ideation | Wellbutrin     |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                                    | Lexapro        |              |            | S           | Oral         | 20mg Per Day       |                 | Not Reported    |
|                                                                    | Trazodone      |              |            | C           |              | 150mg Per Day      |                 | Not Reported    |
|                                                                    | Topamax        |              |            | C           |              |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7829026       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018543           |                      | 36 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|-----------------------|--------------|------------|-------------|---------------|----------------------|-----------------|--------------|
| Body Temperature Fluctuation; Drug Ineffective; Drug | Lexapro               |              |            | S           | Oral          | 40 Mg, Once, Oral    |                 | Not Reported |
|                                                      | Flupentixol Decanoate |              |            | S           | Intramuscular | 40 Mg, Intramuscular |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                             |   |              |
|------------------------------|-----------------------------|---|--------------|
| Interaction; Epilepsy;       | Diazepam (Diazepam)         | C | Not Reported |
| Epistaxis; Loss Of           | Atorvastatin (Atorvastatin) | C | Not Reported |
| Consciousness;               | Levetiracetam               | C | Not Reported |
| Nephropathy Toxic;           | Metformin Hydrochloride     | C | Not Reported |
| Overdose; Parkinsonism;      | Olanzapine (Olanzapine)     | C | Not Reported |
| Product Administration Error |                             |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7852484       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018791           |                      | 81 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Confusional State;<br>Hallucination, Visual | Escitalopram Oxalate                        |              |            | S           | Oral         | 2.5 Mg (5 Mg, 1 In 2 D),<br>Oral |                 | Not Reported |
|                                                                      | Zolpidem                                    |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                      | Lyrica                                      |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                                                                      | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                                                                      | Tramadol Hydrochloride                      |              |            | S           |              | 150 Mg (50 Mg, 3 In 1 D)         |                 | Not Reported |
|                                                                      | Avlocardyl (Propranolol)                    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                      | Furosemide (Furosemide)                     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                      | Potassium Chloride                          |              |            | C           |              |                                  |                 | Not Reported |
|                                                                      | Plavix                                      |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7853407       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018790           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Dysphagia; Oedema<br>Peripheral; Pharyngeal<br>Oedema | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2011              | 7853487       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018822           |                      |            | Female     | DNK            |

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| <u>Preferred Term</u>                                                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| Lymphopenia; Nausea; Thrombocytopenia; Vomiting                                 | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral                               |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                 | Prazepam                                          |                    |                    | C               |                      |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2011                                                                     | 7853513                                           | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018821           |                                                            | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Diplopia; Fatigue; Female Orgasmic Disorder; Libido Decreased; Weight Increased | Escitalopram Oxalate                              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                              |                 | Not Reported |                |
|                                                                                 | Lamotrigine (Lamotrigine) (Tablets) (Lamotrigine) |                    |                    | C               |                      |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2011                                                                     | 7854524                                           | EXPEDITED (15-DAY) | Y                  | HO              | 2011SP000428         |                                                            | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Insomnia; Intentional Overdose; Suicide Attempt               | Lunesta                                           |                    |                    | S               | Oral                 | 2 Mg; Hs; Oral, 60 Mg; 1x, Oral                            |                 | Not Reported |                |
|                                                                                 |                                                   |                    |                    |                 | Oral                 | 2 Mg; Hs; Oral, 60 Mg; 1x, Oral                            |                 |              |                |
|                                                                                 | Ambien Cr                                         |                    |                    | S               |                      | 12.5 Mg; Hs;                                               |                 | Not Reported |                |
|                                                                                 | Xanax                                             |                    |                    | S               |                      |                                                            |                 | Not Reported |                |
|                                                                                 | Lexapro                                           |                    |                    | S               |                      |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2011                                                                     | 7819544                                           | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2008FR25786      |                                                            | 66 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                            |                               |   |      |             |              |
|--------------------------------------------|-------------------------------|---|------|-------------|--------------|
| Aphasia; Hyponatraemia;<br>Seizure; Tremor | Tegretol                      | S | Oral | 400 Mg, Tid | Novartis     |
|                                            | Inipomp                       | S | Oral | 20 Mg, Qd   | Not Reported |
|                                            | Hydrochlorothiazide/Valsartan | S | Oral | 1 Df, Qd    | Not Reported |
|                                            | Escitalopram Oxalate          | S | Oral | 20 Mg, Qd   | Not Reported |
|                                            | Actonel                       | C |      | 35 Mg, Qw   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2011              | 7827165       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018154           |                      | 33 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Coma; Hypotension;<br>Hypothermia; Intentional<br>Overdose; Poisoning<br>Deliberate | Escitalopram Oxalate |              |            | S           | Oral         | 10 Dosage Forms, Once,<br>Oral                    |                 | Not Reported |
|                                                                                     | Equanil              |              |            | S           | Oral         | 4000 Mg, Once, 800 Mg<br>(400 Mg, 2 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2011              | 7855836       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018727           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination, Visual;<br>Intentional Self-Injury;<br>Papilloedema; Visual Field<br>Defect | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Feb-2011              | 7860482       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018813           |                      | 54 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Clonus                | Escitalopram Oxalate                   |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                       | Tercian (Cyamemazine)<br>(Cyamemazine) |              |            | C           |              |                                                                    |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2011              | 7858905       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018876           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abdominal Pain; Feeling | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral   |                 | Not Reported |
| Abnormal; Muscle        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
| Tightness               |                      |              |            |             |              |                             |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2011              | 7637187       | EXPEDITED (15-DAY) | N                  | HO              | 1000016393           |                      | 89 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Arrhythmia; Hypersomnia; | Lexapro                        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Insomnia; Lethargy;      | Namenda                        |              |            | C           |              |                             |                 | Not Reported |
| Staphylococcus Test      | Aricept                        |              |            | C           |              |                             |                 | Not Reported |
| Positive; Urinary Tract  | Cozaar                         |              |            | C           |              |                             |                 | Not Reported |
| Infection                | Clonidine Transdermal System   |              |            | C           |              |                             |                 | Not Reported |
|                          | Methylphenidate                |              |            | C           |              |                             |                 | Not Reported |
|                          | (Methylphenidate)              |              |            |             |              |                             |                 |              |
|                          | (Methylphenidate)              |              |            |             |              |                             |                 |              |
|                          | Metoprolol Succinate           |              |            | C           |              |                             |                 | Not Reported |
|                          | Omeprazole                     |              |            | C           |              |                             |                 | Not Reported |
|                          | Oxytrol (Oxybutynin            |              |            | C           |              |                             |                 | Not Reported |
|                          | Transdermal)(Oxybutynin        |              |            |             |              |                             |                 |              |
|                          | Transdermal)                   |              |            |             |              |                             |                 |              |
|                          | Seroquel (Quetiapine Fumarate) |              |            | C           |              |                             |                 | Not Reported |
|                          | (Quetiapine Fumarate)          |              |            |             |              |                             |                 |              |
|                          | Stalevo(Carbidopa, Levodopa,   |              |            | C           |              |                             |                 | Not Reported |
|                          | Entacapone)(Carbidopa,         |              |            |             |              |                             |                 |              |
|                          | Levodopa, Entacapone)          |              |            |             |              |                             |                 |              |
|                          | Fludrocortisone Acetate        |              |            | C           |              |                             |                 | Not Reported |
|                          | (Fludrocortisone               |              |            |             |              |                             |                 |              |
|                          | Acetate)(Fludrocortisone       |              |            |             |              |                             |                 |              |
|                          | Acetate)                       |              |            |             |              |                             |                 |              |
|                          | Finasteride                    |              |            | C           |              |                             |                 | Not Reported |
|                          | (Finasteride)(Finasteride)     |              |            |             |              |                             |                 |              |

# FDA Adverse Event Reporting System

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### Detailed Report

| Tpn (Tpn) (Liquid) (Tpn)                                                               |                                                                 |                           | C                           |                          |                                                 |                                          | Not Reported             |                     |                         |
|----------------------------------------------------------------------------------------|-----------------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|------------------------------------------|--------------------------|---------------------|-------------------------|
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a>            | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Feb-2011                                                                            | 7670642                                                         | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | GB-ROCHE-741254                                 |                                          | 87 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>              | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cerebral Haemorrhage                                                                   | Naproxen                                                        |                           |                             | S                        | Oral                                            |                                          |                          | Roche               |                         |
|                                                                                        | Aspirin                                                         |                           |                             | S                        | Oral                                            |                                          |                          | Not Reported        |                         |
|                                                                                        | Cipralex                                                        |                           |                             | S                        | Oral                                            |                                          |                          | Not Reported        |                         |
|                                                                                        | Omeprazole                                                      |                           |                             | C                        | Oral                                            |                                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a>            | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Feb-2011                                                                            | 7704327                                                         | EXPEDITED (15-DAY)        | N                           | OT                       | DK-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15433980 |                                          | 36 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>              | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Agitation; Initial Insomnia;<br>Mania                                                  | Abilify                                                         |                           |                             | S                        |                                                 | 26jan09;2.5mg,Discontin<br>ed On 04nov09 |                          | Not Reported        |                         |
|                                                                                        | Escitalopram Oxalate                                            |                           |                             | S                        |                                                 |                                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a>            | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Feb-2011                                                                            | 7810742                                                         | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000018268                                      |                                          | 83 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a>                                         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>              | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Failure; General<br>Physical Health<br>Deterioration;<br>Pancytopenia; Purpura | Escitalopram Oxalate                                            |                           |                             | S                        | Oral                                            | 10 Mg (10 Mg,1 In 1<br>D),Oral           |                          | Not Reported        |                         |
|                                                                                        | Kardegic (Acetylsalicylate<br>Lysine) (Acetylsalicylate Lysine) |                           |                             | C                        |                                                 |                                          |                          | Not Reported        |                         |
|                                                                                        | Temerit (Nebivolol) (Nebivolol)                                 |                           |                             | C                        |                                                 |                                          |                          | Not Reported        |                         |
|                                                                                        | Atarax                                                          |                           |                             | C                        |                                                 |                                          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>                                          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a>            | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Feb-2011                                                                            | 7856114                                                         | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | 1000018877                                      |                                          | 76 YR                    | Female              | DNK                     |

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| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Drug Interaction; Gastric Ulcer; Haematocrit Decreased; International Normalised Ratio Decreased; Upper Gastrointestinal Haemorrhage                                 | Escitalopram Oxalate                                   |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                      | Sintrom                                                |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                                                                      | Ibuprofen (Ibuprofen)                                  |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2011                                                                                                                                                          | 7856142                                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000018879           |                               | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alexia; Aphasia; Blood Pressure Systolic Increased; Central Nervous System Vasculitis; Cerebral Haematoma; Cerebral Vasoconstriction; Meningorrhagia; Pupils Unequal | Escitalopram Oxalate                                   |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                                                                      | Cardensiel (Bisoprolol Fumarate) (Bisoprolol Fumarate) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Feb-2011                                                                                                                                                          | 7861663                                                | EXPEDITED (15-DAY) | Y                  | DE              | 1000018747           |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Oedema                                                                                                                                                     | Lexapro                                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2011                                                                                                                                                          | 7826247                                                | EXPEDITED (15-DAY) | Y                  | HO, LT          | ZA-TEVA-245995ISR    |                               | 83 YR           | Female       | ZAF            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Delusion; Dyskinesia;                                                                                                                                                | Azilect                                                |                    |                    | S               | Oral                 |                               |                 | Teva         |                |

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|                                                                                                                                                              |                                                                                                                                                                                             |                                                |                                                                                     |                        |                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hallucination, Visual;<br>Hyperhidrosis;<br>Hyperkalaemia;<br>Hypertension; Psychotic<br>Disorder; Pyrexia; Renal<br>Failure; Rhabdomyolysis;<br>Tachycardia | Tramadol Hydrochloride And<br>Acetaminophen<br>Fentanyl<br>Stalevo<br>Escitalopram Oxalate<br>Escitalopram Oxalate<br>Celecoxib<br>Zopiclone<br>Sinemet<br>Ergocalciferol<br>Ocuvite Lutein | S<br>S<br>S<br>S<br>S<br>C<br>C<br>C<br>C<br>C | Oral<br>Transdermal<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | 50/200 Mg Od For Years | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2011              | 7826563       | EXPEDITED (15-DAY) | N                  | HO              | US-WATSON-2011-01859 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>                                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                               | <u>Route</u>                                                                                        | <u>Dosage Text</u>                                                                                   | <u>Duration</u>                                      | <u>Mfr</u>                                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Arrhythmia; Cardiac<br>Arrest; Coma; Confusional<br>State; Hypotension;<br>Hypoventilation; Hypoxia;<br>Overdose; Respiratory<br>Failure; Rhabdomyolysis;<br>Seizure; Suicide Attempt;<br>Vomiting | Fioricet<br>Phenergan<br>Lexapro<br>Pamelor<br>Amrix<br>Lotrel<br>Unspecified Ingredient<br>Hydrochlorothiazide<br>Theragesic Creme |              |            | S<br>S<br>S<br>S<br>S<br>S<br>S<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Intravenous (not<br>otherwise specified)<br>Unknown | 25 Mg, Single<br>Unk<br>10 Mg 1x/Day<br>25 Mg, 1x/Day<br>Unk<br>10/40<br>Every 8 Weeks<br>Unk<br>Unk | 1 DAY<br>1 DAY<br>1 DAY<br>1 DAY<br>1 DAY<br>169 DAY | Watson<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2011              | 7873786       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 100017897            |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |                              |   |      |                                 |              |
|------------------------------------------|------------------------------|---|------|---------------------------------|--------------|
| Atrioventricular Block;<br>Hyponatraemia | Escitalopram Oxalate         | S | Oral | 20 Mg (20 Mg,1 In 1 D),<br>Oral | Not Reported |
|                                          | Remeron                      | C |      |                                 | Not Reported |
|                                          | Surmontil                    | C |      |                                 | Not Reported |
|                                          | Fosicomp (Elidiur) (Elidiur) | C |      |                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 25-Feb-2011              | 7774891       | EXPEDITED (15-DAY) | Y                  | HO              | CH-ABBOTT-11P-151-<br>0700235-00 |                      | 61 YR      | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombosis            | Valproic Acid  |              |            | S           | Oral         | 150-600 Mg A Day   |                 | Not Reported |
|                       | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Valproic Acid  |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Remeron        |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Pantozol       |              |            | S           |              |                    |                 | Not Reported |
|                       | Tamsulosin     |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Ciprofloxacin  |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Ciprofloxacin  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Feb-2011              | 7826175       | EXPEDITED (15-DAY) | N                  | HO              | A0914964A            |                      |            | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Blood Ph Decreased;<br>Depressed Level Of<br>Consciousness;<br>Endotracheal Intubation;<br>Hypotension; Hypoxia;<br>Overdose; Suicidal<br>Ideation | Propafenone             |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                                    | Metoprolol              |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                    | Clonazepam              |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                                    | Lorazepam               |              |            | S           |              |                    |                 | Not Reported    |
|                                                                                                                                                    | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                                    | Apixaban                |              |            | C           |              | 5mg Twice Per Day  |                 | Not Reported    |
|                                                                                                                                                    | Warfarin Sodium         |              |            | C           |              | 7mg Per Day        |                 | Glaxosmithkline |
|                                                                                                                                                    | Metformin Hydrochloride |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                                                                                                                    | Gliclazide              |              |            | C           |              |                    |                 | Not Reported    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                               |                      |                    |                    |                 |                                                 |                                                                                                                         |                 |            |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------|------------|----------------|
| Ezetrol                                                                                                                                       |                      |                    | C                  |                 |                                                 | Glaxosmithkline                                                                                                         |                 |            |                |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Feb-2011                                                                                                                                   | 7855990              | DIRECT             | N                  | DE              |                                                 |                                                                                                                         | 56 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                                      | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide                                                                                                                             | Lexapro              |                    |                    | S               |                                                 |                                                                                                                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Feb-2011                                                                                                                                   | 7763368              | EXPEDITED (15-DAY) | N                  | OT              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15479660 |                                                                                                                         | 20 YR           | Female     | FRA            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                                      | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour;<br>Disinhibition; Hypomania;<br>Initial Insomnia; Libido<br>Increased; Logorrhoea;<br>Sexually Inappropriate<br>Behaviour | Abilify              |                    |                    | S               | Oral                                            | Morning                                                                                                                 |                 |            | Not Reported   |
|                                                                                                                                               | Abilify              |                    |                    | S               | Oral                                            | Morning                                                                                                                 |                 |            | Not Reported   |
|                                                                                                                                               | Abilify              |                    |                    | S               | Oral                                            | Morning                                                                                                                 |                 |            | Not Reported   |
|                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                                            | Also 20mg/Day Reduced<br>To 10mg/Day From<br>07oct10                                                                    |                 |            | Not Reported   |
|                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                                            | Also 20mg/Day Reduced<br>To 10mg/Day From<br>07oct10                                                                    |                 |            | Not Reported   |
|                                                                                                                                               | Xanax                |                    |                    | C               | Oral                                            | Before Jun10 Also :5mg<br>Dosageg:1-3 Tabs                                                                              |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                                                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2011                                                                                                                                   | 7702698              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017209                                      |                                                                                                                         | 25 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                                                      | <u>Duration</u> | <u>Mfr</u> |                |
| Chest Discomfort;<br>Oropharyngeal Spasm;<br>Overdose; Tongue Spasm                                                                           | Escitalopram Oxalate |                    |                    | S               |                                                 | 10 Mg (10 Mg,1 In 1<br>D),Oral, 20 Mg (20 Mg, 1<br>In 1 D),Oral, 30 Mg (30<br>Mg, 1 In 1 D) Oral<br>10 Mg (10 Mg,1 In 1 |                 |            | Not Reported   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

D),Oral, 20 Mg (20 Mg, 1  
In 1 D),Oral, 30 Mg (30  
Mg, 1 In 1 D) Oral  
10 Mg (10 Mg,1 In 1  
D),Oral, 20 Mg (20 Mg, 1  
In 1 D),Oral, 30 Mg (30  
Mg, 1 In 1 D) Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2011              | 7832163       | NON-EXPEDITED    | N                  |                 | A0863154A            |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Pruritus              | Lamictal       |              |            | S           | Oral         |                    |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                       | Seroquel       |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2011              | 7833467       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-<br>2010042881 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache              | Geodon         |              |            | S           |              | 20 Mg, Unk         |                 | Pfizer       |
|                       | Mirtazapine    |              |            | S           |              | 15 Mg, Unk         |                 | Not Reported |
|                       | Clonazepam     |              |            | S           |              | 0.5 Mg, Unk        |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |
|                       | Bupropion      |              |            | S           |              | 300 Mg, Unk        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Feb-2011              | 7867342       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018918           |                      | 20 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Malaise; Oedema<br>Peripheral; Pain; Pain In<br>Extremity | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral<br>, 2.5 Mg (2.5 Mg, 1 In 1 D), |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oral  
5 Mg (5 Mg, 1 In 1 D), Oral  
, 2.5 Mg (2.5 Mg, 1 In 1 D),  
Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2011              | 7865643       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018920           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Overdose; Poisoning   | Escitalopram Oxalate      |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Deliberate;           | Lexomil (Bromazepam)      |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Rhabdomyolysis        | Tropatepine Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Amisulpride               |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2011              | 7793798       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000018075           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Alcohol Poisoning;        | Escitalopram Oxalate |              |            | S           | Oral         | (2500 Mg,Once),Oral |                 | Not Reported |
| Disturbance In Attention; | Chlorprothixene      |              |            | S           | Oral         | (1200 Mg,Once),Oral |                 | Not Reported |
| Electrocardiogram Qt      | Seroquel             |              |            | S           | Oral         | (4500 Mg,Once),Oral |                 | Not Reported |
| Prolonged; Intentional    | Alcohol (Ethanol)    |              |            | S           | Oral         | (Once),Oral         |                 | Not Reported |
| Overdose; Suicide         |                      |              |            |             |              |                     |                 |              |
| Attempt; Vomiting         |                      |              |            |             |              |                     |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Mar-2011              | 7869874       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019016           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Fall; Loss Of Consciousness | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 03-Mar-2011                              | 7775881                                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017897           |                                  | 66 YR           | Female       | DNK            |
| <u>Preferred Term</u>                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block;<br>Hyponatraemia | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                          | Remeron                                     |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                          | Surmontil                                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                          | Fosicomp (Elidiur)                          |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2011                              | 7839134                                     | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2011FR03795      |                                  | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Somnolence                   | Exelon Patch                                |                    |                    | S               | Transdermal          | 4.6 Mg, Qd                       | 1 DAY           | Novartis     |                |
|                                          | Exelon Patch                                |                    |                    | S               | Transdermal          | 4.6 Mg, Qd                       | 1 DAY           | Novartis     |                |
|                                          | Escitalopram Oxalate                        |                    |                    | S               |                      | 10 Mg Daily                      |                 | Not Reported |                |
|                                          | Tramadol Hydrochloride And<br>Acetaminophen |                    |                    | S               |                      | 37.5 Mg Daily                    | 3 DAY           | Not Reported |                |
|                                          | Levothyrox                                  |                    |                    | C               | Oral                 | 50 Ug Daily                      |                 | Not Reported |                |
|                                          | Coumadin                                    |                    |                    | C               | Oral                 | 4 Mg Daily                       |                 | Not Reported |                |
|                                          | Lasix                                       |                    |                    | C               | Oral                 | 40 Mg Daily                      |                 | Not Reported |                |
|                                          | Ramipril                                    |                    |                    | C               | Oral                 | 5 Mg Daily                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Mar-2011                              | 7865709                                     | DIRECT             | N                  | DS              |                      |                                  | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Fall; Nightmare                 | Lexapro                                     |                    |                    | S               | Oral                 | 30mg 1 At Night Oral             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Mar-2011                                                                                 | 7840664              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-42358        |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                           | Lisinopril           |                    |                    | S               | Oral                           | Unk                  |                 | Ranbaxy      |                |
|                                                                                             | Venlafaxine          |                    |                    | S               | Oral                           | Unk, Unk             |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Cocaine              |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
|                                                                                             | Diphenhydramine      |                    |                    | S               | Oral                           | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2011                                                                                 | 7841423              | EXPEDITED (15-DAY) | Y                  | OT              | AU-PFIZER INC-2011045974       |                      |                 | Male         | AUS            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased                   | Lipitor              |                    |                    | S               |                                | 80 Mg, Unk           |                 | Pfizer       |                |
|                                                                                             | Dipyridamole         |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
|                                                                                             | Lexapro              |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2011                                                                                 | 7841998              | EXPEDITED (15-DAY) | Y                  | DE              | CH-SANOFI-AVENTIS-2011SA011557 |                      | 1 DAY           | Male         | CHE            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Cavity Infection; Foetal Death; Maternal Exposure During Pregnancy; Premature Baby | Stilnox              |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Stilnox              |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Abilify              |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Abilify              |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |
|                                                                                             | Lorazepam            |                    |                    | S               | Transplacental                 |                      |                 | Not Reported |                |

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|                                                                                                                                     | Zyprexa                                     |                    | S                  | Transplacental  |                             |                                            |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|-----------------------------|--------------------------------------------|-----------------|--------------|----------------|
|                                                                                                                                     | Zyprexa                                     |                    | S                  | Transplacental  |                             |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2011                                                                                                                         | 7871221                                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019083                  |                                            | 32 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Amniotic Cavity Infection;<br>Maternal Exposure During<br>Pregnancy; Off Label Use;<br>Pregnancy; Premature<br>Rupture Of Membranes | Escitalopram Oxalate                        |                    |                    | S               |                             | 20 Mg (20 Mg,2 In 1 D)                     |                 | Not Reported |                |
|                                                                                                                                     | Abilify                                     |                    |                    | S               |                             | (15 Mg)                                    |                 | Not Reported |                |
|                                                                                                                                     | Zolpidem                                    |                    |                    | S               |                             | 12.5 Mg (23.5 Mg,1 In 1 D)                 |                 | Not Reported |                |
|                                                                                                                                     | Lorazepam                                   |                    |                    | S               |                             |                                            |                 | Not Reported |                |
|                                                                                                                                     | Zyprexa                                     |                    |                    | S               |                             | 7.5 Mg (7.5 Mg,1 In 1 D)                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Mar-2011                                                                                                                         | 7871479                                     | EXPEDITED (15-DAY) | Y                  | DE              | 1000019084                  |                                            |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion; Maternal Drugs<br>Affecting Foetus;<br>Premature Baby;<br>Premature Rupture Of<br>Membranes                               | Escitalopram Oxalate                        |                    |                    | S               | Transplacental              | 20 Mg (10 Mg,2 In 1 D),<br>Transplacental  |                 | Not Reported |                |
|                                                                                                                                     | Abilify                                     |                    |                    | S               | Transplacental              | (15 Mg), Transplacental                    |                 | Not Reported |                |
|                                                                                                                                     | Lorazepam                                   |                    |                    | S               | Transplacental              | Transplacental                             |                 | Not Reported |                |
|                                                                                                                                     | Zyprexa                                     |                    |                    | S               | Transplacental              | 7.5 Mg (7.5 Mg,1 In 1<br>D),Transplacental |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2011                                                                                                                         | 7842660                                     | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-<br>42564 |                                            | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                   | Hydrocodone Bitartrate And<br>Acetaminophen |                    |                    | S               | Oral                        | Unk, Unk                                   |                 | Ranbaxy      |                |
|                                                                                                                                     | Escitalopram Oxalate                        |                    |                    | S               | Oral                        |                                            |                 | Not Reported |                |

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| Alcohol                  |                                          |                    | S                  |                 | Oral                                  |                      |                 | Not Reported |                |
|--------------------------|------------------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2011              | 7842666                                  | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-42546               |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Hydrocodone Bitartrate And Acetaminophen |                    |                    | S               | Oral                                  | Unk, Unk             |                 | Ranbaxy      |                |
|                          | Diazepam                                 |                    |                    | S               | Oral                                  | Unk, Unk             |                 | Not Reported |                |
|                          | Escitalopram Oxalate                     |                    |                    | S               | Oral                                  | Unk, Unk             |                 | Not Reported |                |
|                          | Morphine                                 |                    |                    | S               | Oral                                  | Unk, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011              | 6893896                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-FR-WYE-G02939109        |                      | 41 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt          | Effexor Xr                               |                    |                    | S               | Oral                                  | 75 Mg, 1x/Day        |                 | Pfizer       |                |
|                          | Lyrica                                   |                    |                    | S               | Oral                                  | 600 Mg, 1x/Day       |                 | Pfizer       |                |
|                          | Tahor                                    |                    |                    | S               | Oral                                  | Unk                  |                 | Pfizer       |                |
|                          | Rivotril                                 |                    |                    | S               | Oral                                  | 2 Mg, 1x/Day         |                 | Not Reported |                |
|                          | Anafranil                                |                    |                    | S               | Oral                                  | 50 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Escitalopram Oxalate                     |                    |                    | S               | Oral                                  | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Levomepromazine                          |                    |                    | S               | Oral                                  | 25 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Lasix                                    |                    |                    | S               | Oral                                  | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Tranxene T-Tab                           |                    |                    | S               | Oral                                  | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                          | Tysabri                                  |                    |                    | S               | Intravenous (not otherwise specified) | 300 Mg, 1x/Cyc       |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011              | 7775891                                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017902                            |                      | 45 YR           | Male         | DNK            |

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| <u>Preferred Term</u>        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------|--------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|-------------------------------|-----------------|--------------|----------------|
| Aggression; Physical Assault | Escitalopram Oxalate                 |                    |                    | S               | Oral                                        | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011                  | 7842813                              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-42654                     |                               | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide            | Gabapentin                           |                    |                    | S               | Oral                                        | Unk                           |                 | Ranbaxy      |                |
|                              | Quetiapine                           |                    |                    | S               | Oral                                        | Unk, Unk                      |                 | Not Reported |                |
|                              | Escitalopram Oxalate                 |                    |                    | S               | Oral                                        | Unk                           |                 | Not Reported |                |
|                              | Clonazepam                           |                    |                    | S               | Oral                                        | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011                  | 7842826                              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-42722                     |                               | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose         | Cyclobenzaprine Hydrochloride        |                    |                    | S               | Oral                                        | Unk, Unk                      |                 | Ranbaxy      |                |
|                              | Escitalopram Oxalate                 |                    |                    | S               | Oral                                        | Unk                           |                 | Not Reported |                |
|                              | Zolpidem Tartrate                    |                    |                    | S               | Oral                                        | Unk                           |                 | Ranbaxy      |                |
|                              | Alprazolam                           |                    |                    | S               | Oral                                        | Unk                           |                 | Not Reported |                |
|                              | Desogestrel\Ethinyl Estradiol        |                    |                    | S               | Oral                                        | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>     | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011                  | 7843088                              | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO HEALTHCARE/MALLIN CKRODT-T201100434 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>        | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide            | Acetaminophen\Hydrocodone Bitartrate |                    |                    | S               | Oral                                        |                               |                 | Tyco         |                |
|                              | Morphine Sulfate                     |                    |                    | S               | Oral                                        |                               |                 | Tyco         |                |

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|                                                    | Escitalopram Oxalate                                |                    | S                  | Oral            |                              |                                  |                 | Not Reported |                |
|----------------------------------------------------|-----------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                    | Diazepam                                            |                    | S                  | Oral            |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011                                        | 7856140                                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000018889                   |                                  | 19 YR           | Female       | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                              | Escitalopram Oxalate                                |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                    | Contraceptives (Contraceptives)<br>(Contraceptives) |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2011                                        | 7877999                                             | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019076                   |                                  | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Metrorrhagia                                       | Escitalopram Oxalate                                |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                    | Xanax                                               |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                                    | Acetaminophen                                       |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2011                                        | 7846089                                             | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2011048172 |                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersomnia; Myalgia;<br>Nephrolithiasis; Overdose | Lipitor                                             |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                    | Lexapro                                             |                    |                    | S               | Oral                         | 10 Mg, Daily                     | 7 DAY           | Not Reported |                |
|                                                    | Lexapro                                             |                    |                    | S               | Oral                         | 20 Mg, 1x/Day                    |                 | Not Reported |                |
|                                                    | Lexapro                                             |                    |                    | S               | Oral                         | 40 Mg, 1x/Day                    |                 | Not Reported |                |
|                                                    | Lexapro                                             |                    |                    | S               | Oral                         | 20 Mg, 1x/Day                    |                 | Not Reported |                |
|                                                    | Lexapro                                             |                    |                    | S               | Oral                         | 30 Mg, 1x/Day                    |                 | Not Reported |                |
|                                                    | Nadolol                                             |                    |                    | C               |                              | Unk                              |                 | Not Reported |                |

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|             |   |     |              |
|-------------|---|-----|--------------|
| Dexidrine   | C | Unk | Not Reported |
| Dexidrine   | C | Unk | Not Reported |
| Adderall    | C | Unk | Not Reported |
| Pravastatin | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2011              | 7875978       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019093           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                           | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Agitation; Hyperventilation;<br>Suicide Attempt | Escitalopram Oxalate           |              |            | S           | Oral         | 15 Mg, Once, Oral             |                 | Not Reported |
|                                                 | Acetaminophen\Aspirin\Caffeine |              |            | S           | Oral         | 1 Dosage Forms, Once,<br>Oral |                 | Not Reported |
|                                                 | Clonazepam                     |              |            | S           | Oral         | Once, Oral                    |                 | Not Reported |
|                                                 | Opipramol Hydrochloride        |              |            | S           | Oral         | Once, Oral                    |                 | Not Reported |
|                                                 | Alcohol (Ethanol)              |              |            | S           | Oral         | Once, Oral                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2011              | 7882894       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019127           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Abdominal Pain Upper;<br>Choking Sensation;<br>Depression; Headache;<br>Hyperhidrosis; Insomnia;<br>Malaise; Skin Burning<br>Sensation; Tachycardia;<br>Tinnitus; Tremor; Vaginal<br>Haemorrhage | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                  | Alprazolam (Alprazolam) |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                  | (Tablets) (Alprazolam)  |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                  | Atenolol                |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                  | Amlodipine              |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                  | Hydrochlorothiazide     |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2011              | 7871240       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018755           |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                 |                     |   |      |                                 |              |
|-------------------------------------------------|---------------------|---|------|---------------------------------|--------------|
| Generalised Tonic-Clonic Seizure; Hyponatraemia | Lexapro             | S | Oral | 10 Mg (10 Mg, 1 In 1 D), Oral   | Not Reported |
|                                                 | Hydrochlorothiazide | S | Oral | 12.5 Mg (25 Mg, 1 In 1 D), Oral | Not Reported |

| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-Mar-2011                                  | 7871064              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000019043           |                      | 16 YR           | Male         | DNK            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Sopor; Suicide Attempt | Escitalopram Oxalate |                    |                    | S               | Oral                 | 100 Mg, Once, Oral   |                 | Not Reported |                |
|                                              | Codeine              |                    |                    | S               | Oral                 | 240 Mg, Once, Oral   |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|--------------|----------------|
| 11-Mar-2011              | 7852983                              | EXPEDITED (15-DAY) | Y                  | DE              | US-TYCO HEALTHCARE/MALLIN CKRODT-T201100437 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Acetaminophen\Hydrocodone Bitartrate |                    |                    | S               | Oral                                        |                      |                 | Tyco         |                |
|                          | Unspecified Ingredient               |                    |                    | S               | Oral                                        |                      |                 | Not Reported |                |
|                          | Alcohol                              |                    |                    | S               | Oral                                        |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate                 |                    |                    | S               | Oral                                        |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 15-Mar-2011                                            | 7824147              | EXPEDITED (15-DAY) | Y                  | HO              | AT-ABBOTT-11P-009-0706350-00 |                      | 29 YR           | Female       | AUT            |
| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Leukopenia; Overdose | Escitalopram Oxalate |                    |                    | S               |                              | 30 Mg Daily          |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate |                    |                    | S               |                              | 15 Mg Daily          |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate |                    |                    | S               |                              | 20 Mg Daily          |                 | Not Reported |                |
|                                                        | Amisulpride          |                    |                    | S               | Oral                         | 1200 Mg Daily        |                 | Not Reported |                |
|                                                        | Seroquel             |                    |                    | S               |                              | 900 Mg Daily         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |           |   |      |               |              |
|--|-----------|---|------|---------------|--------------|
|  | Seroquel  | S |      | 800 Mg Daily  | Not Reported |
|  | Seroquel  | S |      | 1000 Mg Daily | Not Reported |
|  | Haldol    | S |      | 10 Mg Daily   | Not Reported |
|  | Topamax   | C |      |               | Not Reported |
|  | Topamax   | C |      |               | Not Reported |
|  | Lorazepam | C | Oral |               | Not Reported |
|  | Lorazepam | C | Oral |               | Not Reported |
|  | Lorazepam | C | Oral |               | Not Reported |
|  | Lorazepam | C | Oral |               | Not Reported |
|  | Kalium    | C |      |               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Mar-2011              | 7878890       | DIRECT           | N                  | OT              |                      |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Gambling Disorder; Mania | Lexapro        |              |            | S           | Oral         | 1 Tablet Daily Po  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Mar-2011              | 7810079       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018273           |                      | 72 YR      | Female     | DNK            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Blood Osmolarity Decreased; | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D), |                 | Not Reported |
| Hypokalaemia;               | Lamictal             |              |            | S           |              |                          |                 | Not Reported |
| Hyponatraemia               | Bumetanide           |              |            | S           |              | 1 Mg (1 Mg, 1 In 1 D),   |                 | Not Reported |
|                             | Spironolactone       |              |            | S           |              | 25 Mg (25 Mg, 1 In 1 D); |                 | Not Reported |
|                             | Abilify              |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D); |                 | Not Reported |
|                             | Warfarin Sodium      |              |            | C           |              |                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2011              | 7857432       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010150860 |                      | 57 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>             | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Sedation;<br>Somnolence | Pristiq Extended Release |              |            | S           | Oral         | 50 Mg, 1x/Day      | 42 DAY          | Pfizer       |
|                                   | Lexapro                  |              |            | S           | Oral         | 5 Mg, 1x/Day       |                 | Not Reported |
|                                   | Wellbutrin               |              |            | S           | Oral         | 100 Mg, 1x/Day     |                 | Not Reported |
|                                   | Femara                   |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                   | Tamoxifen                |              |            | C           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2011              | 7702687       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017193           |                      | 62 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Abnormal Sleep-Related<br>Event; Agitation;<br>Nightmare; Violence-<br>Related Symptom | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                        | Atarax               |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2011              | 7860202       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ROCHE-764501      |                      | 22 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Poisoning; Somnolence | Rivotril             |              |            | S           | Oral         | Frequency: Once     |                 | Roche        |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Frequency: Once     |                 | Not Reported |
|                       | Valpromide           |              |            | S           | Oral         | Frequency: Once     |                 | Not Reported |
|                       | Zyprexa              |              |            | S           | Oral         | Frequency: At Once. |                 | Not Reported |
|                       | Theralene            |              |            | S           | Oral         |                     |                 | Not Reported |
|                       | Dafalgan             |              |            | C           | Oral         | Frequency-Once      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 17-Mar-2011              | 7860661       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-VIROPHARMA<br>INCORPORATED-<br>20110303CINRY1852 |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |          |   |              |
|----------------------------|----------|---|--------------|
| Depression; Hereditary     | Cinryze  | S | Viropharma   |
| Angioedema;                | Lexapro  | S | Not Reported |
| Inappropriate Schedule Of  | Diazepam | S | Not Reported |
| Product Administration;    | Atenolol | S | Not Reported |
| Infusion Related Reaction; |          |   |              |
| Lip Swelling; Rash;        |          |   |              |
| Thyroid Disorder           |          |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Mar-2011              | 7875126       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019019           |                      | 29 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Leukopenia; Overdose | Escitalopram Oxalate |              |            | S           | Oral         | 30, 15 Mg (30 Mg, 1 In 1 D), Oral          |                 | Not Reported |
|                                                        |                      |              |            |             | Oral         | 30, 15 Mg (30 Mg, 1 In 1 D), Oral          |                 |              |
|                                                        | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral              |                 | Not Reported |
|                                                        | Seroquel             |              |            | S           | Oral         | 900, 800, 1000 Mg (900 Mg, 1 In 1 D). Oral |                 | Not Reported |
|                                                        |                      |              |            |             | Oral         | 900, 800, 1000 Mg (900 Mg, 1 In 1 D). Oral |                 |              |
|                                                        | Amisulpride          |              |            | S           | Oral         | 1200 Mg (1200 Mg, 1 In 1 D), Oral          |                 | Not Reported |
|                                                        | Haldol               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral              |                 | Not Reported |
|                                                        | Topamax              |              |            | C           |              |                                            | Not Reported    |              |
|                                                        | Lorazepam            |              |            | C           |              |                                            | Not Reported    |              |
|                                                        | Kalium (Potassium)   |              |            | C           |              |                                            | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Mar-2011              | 7768399       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017778           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Alopecia; Anxiety; Bedridden; Cold Sweat; | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Disturbance In  
Attention; Dizziness; Heart  
Rate Increased; Increased  
Appetite; Paraesthesia;  
Presyncope; Sleep  
Disorder; Suicidal  
Ideation; Weight  
Decreased; Yawning

Oral

D),Oral  
5 Mg (5 Mg,1 In 1 D),Oral ;  
10 Mg (10 Mg,1 In 1  
D),Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-Mar-2011              | 7863081       | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-ASTRAZENECA-<br>2011SE13676 |                      | 21 YR      | Female     | CHE            |

| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Breast Pain;<br>Galactorrhoea | Seroquel Xr    |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                               | Seroquel Xr    |              |            | S           | Oral         |                    | 13 DAY          | Astrazeneca  |
|                               | Cipralext      |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Cipralext      |              |            | S           | Oral         |                    | 9 DAY           | Not Reported |
|                               | Depakene       |              |            | C           | Oral         |                    |                 | Not Reported |
|                               | Lorazepam      |              |            | C           | Oral         | 1-10 Mg Daily      | 13 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Mar-2011              | 7763879       | EXPEDITED (15-DAY) | N                  | HO              | B0694112A            |                      | 72 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Blood Osmolarity<br>Decreased;<br>Hypokalaemia;<br>Hyponatraemia | Lamictal       |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                                  | Abilify        |              |            | S           | Unknown      |                    |                 | Not Reported    |
|                                                                  | Bumetanide     |              |            | S           | Unknown      | 1mg Per Day        |                 | Not Reported    |
|                                                                  | Spirolactone   |              |            | S           | Unknown      | 25mg Per Day       |                 | Glaxosmithkline |
|                                                                  | Cipralext      |              |            | S           | Unknown      | 20mg Per Day       |                 | Not Reported    |
|                                                                  | Marevan        |              |            | C           |              |                    |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 21-Mar-2011                                                                                                                                     | 7860490                               | EXPEDITED (15-DAY) | Y                  | HO              | 1000018815           |                                  | 86 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Eosinophilia;<br>Hypersensitivity; Malaise;<br>Oedema Peripheral;<br>Pollakiuria; Pruritus;<br>Pseudomonas Infection;<br>Rash; Thrombocytopenia | Escitalopram Oxalate                  |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                 | Atorvastatin Calcium                  |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)          |                 | Not Reported |                |
|                                                                                                                                                 | Kardegic (Acetylsalicylate<br>Lysine) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                 | Modapar (Levodopa,<br>Benzerazide)    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                 | Seresta (Oxazepam)                    |                    |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                       | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Mar-2011                                                                                                    | 7864931                                                    | EXPEDITED (15-DAY) | N                  | OT              | GB-PFIZER INC-<br>2011058581 |                      |                 | Female       | GBR            |
| <u>Preferred Term</u>                                                                                          | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Back Pain; Burning<br>Sensation; Drug<br>Ineffective; Muscle<br>Spasms; Muscle<br>Twitching; Swollen<br>Tongue | Lyrica                                                     |                    |                    | S               |                              | 300 Mg, 3x/Day       |                 | Pfizer       |                |
|                                                                                                                | Lyrica                                                     |                    |                    | S               |                              |                      |                 | Pfizer       |                |
|                                                                                                                | Simvastatin                                                |                    |                    | S               |                              | 40 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                | Celebrex                                                   |                    |                    | S               |                              | 200 Mg, Unk          |                 | Pfizer       |                |
|                                                                                                                | Omeprazole                                                 |                    |                    | S               |                              | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                | Xenical                                                    |                    |                    | S               |                              | 120 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                | Dexamphetamine                                             |                    |                    | S               |                              | 5 Mg, Unk            |                 | Not Reported |                |
|                                                                                                                | Cipralext                                                  |                    |                    | S               |                              | 20 Mg, Unk           |                 | Not Reported |                |
|                                                                                                                | Tramadol                                                   |                    |                    | S               |                              | 100 Mg, Unk          |                 | Not Reported |                |
|                                                                                                                | Calcium Carbonate\Calcium<br>Glubionate\Sodium Bicarbonate |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                                                                                                                | Butrans                                                    |                    |                    | S               | Transdermal                  | 10 Ug/ Hr            |                 | Not Reported |                |
|                                                                                                                | Oxybutynin Chloride                                        |                    |                    | S               |                              | Unk                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------|-----------------|--------------|----------------|
| 23-Mar-2011                                                                                                             | 6792168                                                                        | EXPEDITED (15-DAY) | N                  | HO, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>13944517 |                                            | 63 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Arthritis; Back Pain; Diplopia; Dyskinesia; Fibromyalgia; Mania; Spinal Stenosis; Teeth Brittle; Tooth Loss | Abilify                                                                        |                    |                    | S               |                                                 | Started 7 Years Ago, Took 2 YR For 5 Years |                 | Not Reported |                |
|                                                                                                                         | Lexapro                                                                        |                    |                    | S               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Lasix                                                                          |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Oxybutynin                                                                     |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Metoprolol                                                                     |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Elavil                                                                         |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Flexeril                                                                       |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Atarax                                                                         |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Lipitor                                                                        |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Neurontin                                                                      |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Saphris                                                                        |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2011                                                                                                             | 7742876                                                                        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017504                                      |                                            | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Triglycerides Increased; Feeling Cold; Hyperhidrosis; Weight Increased                                            | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                                            | 20 Mg (20 Mg,1 In 1 D),Oral                |                 | Not Reported |                |
|                                                                                                                         | Cortisone                                                                      |                    |                    | S               | Oral                                            |                                            |                 | Not Reported |                |
|                                                                                                                         | Magnetran Extra (Magnesium Oxide) (Magnesium Oxide)                            |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Valette (Certostat)                                                            |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Rebif                                                                          |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Vigantoletten (Colecalciferol) (1000 Iu (International Unit)) (Colecalciferol) |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Ibuprofen (Ibuprofen) (400 Milligram) (Ibuprofen)                              |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         | Pantoprazol (Pantoprazole Sodium) (20 Milligram) (Pantoprazol Sodium)          |                    |                    | C               |                                                 |                                            |                 | Not Reported |                |
|                                                                                                                         |                                                                                |                    |                    |                 |                                                 |                                            |                 |              |                |
|                                                                                                                         |                                                                                |                    |                    |                 |                                                 |                                            |                 |              |                |

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| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------------------------|-----------------|--------------|----------------|
| 23-Mar-2011                                                                                                  | 7760194                  | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000017672               |                                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced; Limb Reduction Defect; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy | Escitalopram Oxalate     |                    |                    | S               | Transplacental           | Transplacental                              |                 | Not Reported |                |
|                                                                                                              | Diclestin                |                    |                    | S               |                          |                                             |                 | Not Reported |                |
|                                                                                                              | Tamiflu                  |                    |                    | S               | Transplacental           | Transplacental                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2011                                                                                                  | 7867607                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2011061038 |                                             |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia                                                                                                     | Pristiq Extended Release |                    |                    | S               |                          | Unk                                         |                 | Pfizer       |                |
|                                                                                                              | Lexapro                  |                    |                    | S               |                          | Unk                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2011                                                                                                  | 7867754                  | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-766685          |                                             | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                   | Diazepam                 |                    |                    | S               | Oral                     | Ongoing Status Unknown At The Time Of Death |                 | Roche        |                |
|                                                                                                              | Escitalopram Oxalate     |                    |                    | S               | Oral                     | Ongoing Status Unknown At The Time Of Death |                 | Not Reported |                |
|                                                                                                              | Acetaminophen            |                    |                    | S               | Oral                     | Ongoing Status Unknown At The Time Of Death |                 | Not Reported |                |
|                                                                                                              | Hydrocodone              |                    |                    | S               | Oral                     | Ongoing Status Unknown At The Time Of Death |                 | Not Reported |                |
|                                                                                                              | Morphine                 |                    |                    | S               | Oral                     | Ongoing Status Unknown At The Time Of Death |                 | Not Reported |                |



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| <a href="#">FDA Received Date</a>                                                                            | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------------------------|--------------------------|---------------------|-------------------------|
| 23-Mar-2011                                                                                                  | 7868173                                     | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | PHHY2011FR19942               |                                                 | 86 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                                               | <a href="#">Product</a>                     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dehydration; Disorientation; General Physical Health Deterioration; Hyponatraemia; Lower Limb Fracture; Pain | Hydrochlorothiazide/Valsartan               |                           |                             | S                        |                               | 160mg Valsartan And 25mg Hydrochlorothiazide Qd |                          | Novartis            |                         |
|                                                                                                              | Escitalopram Oxalate                        |                           |                             | S                        |                               | 10 Mg, Qd                                       |                          | Not Reported        |                         |
|                                                                                                              | Alprazolam                                  |                           |                             | C                        |                               | Unk                                             |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                            | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Mar-2011                                                                                                  | 7888821                                     | DIRECT                    | N                           |                          |                               |                                                 |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                                               | <a href="#">Product</a>                     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Headache; Tremor                                                                                             | Lexapro                                     |                           |                             | S                        |                               | Daily                                           | 5 WEEK                   | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                            | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Mar-2011                                                                                                  | 7898987                                     | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000019363                    |                                                 | 27 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>                                                                               | <a href="#">Product</a>                     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Overdose; Seizure                                                                                            | Escitalopram Oxalate                        |                           |                             | S                        | Oral                          | 40 Mg (40 Mg,1 In 1 D), Oral                    |                          | Not Reported        |                         |
|                                                                                                              | Trazodone (Trazodone) (Tablets) (Trazodone) |                           |                             | C                        |                               |                                                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                            | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Mar-2011                                                                                                  | 7899308                                     | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000019305                    |                                                 | 68 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                               | <a href="#">Product</a>                     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Ocular Hypertension                                                                                          | Escitalopram Oxalate                        |                           |                             | S                        | Oral                          | 10 Mg (10 Mg,1 In 1 D), Oral                    |                          | Not Reported        |                         |

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|                                                                                                     |                             | Alendronic Acid (Alendronic Acid) (Alendronic Acid)       |                    | C               |                      |                                                           |                 |              | Not Reported   |
|-----------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------|-----------------|--------------|----------------|
|                                                                                                     |                             | Antihypertensives (Antihypertensives) (Antihypertensives) |                    | C               |                      |                                                           |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>               | <u>Case Type</u>                                          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2011                                                                                         | 7899376                     | EXPEDITED (15-DAY)                                        | Y                  | RI, OT          | 1000019349           |                                                           | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>              | <u>Comp.</u>                                              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine Phosphokinase Increased; Off Label Use                                               | Escitalopram Oxalate        |                                                           |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D), Oral                                |                 | Not Reported |                |
|                                                                                                     | Escitalopram Oxalate        |                                                           |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D), Oral                              |                 | Not Reported |                |
|                                                                                                     | Doxepin (Doxepin) (Doxepin) |                                                           |                    | C               |                      |                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>               | <u>Case Type</u>                                          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                                                                                         | 7760148                     | EXPEDITED (15-DAY)                                        | Y                  | HO              | 1000017653           |                                                           |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>              | <u>Comp.</u>                                              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Heart Rate Increased; Overdose; Suicidal Ideation; Suicide Attempt; Urticaria | Escitalopram Oxalate        |                                                           |                    | S               |                      | 20 Mg; 30 Mg; 20 Mg                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>               | <u>Case Type</u>                                          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                                                                                         | 7760154                     | EXPEDITED (15-DAY)                                        | Y                  | RI, OT          | 1000017657           |                                                           | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>              | <u>Comp.</u>                                              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Pain In Jaw; Tooth Injury                                                                  | Escitalopram Oxalate        |                                                           |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                     |                             |                                                           |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D),Oral |                 |              |                |

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| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|--------------|----------------|
| 24-Mar-2011                               | 7760192              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017663               |                             | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Diarrhoea Haemorrhagic | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                               | 7856094              | EXPEDITED (15-DAY) | Y                  | HO              | US-PFIZER INC-2011055565 |                             | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Overdose;<br>Suicide Attempt    | Xanax                |                    |                    | S               |                          | Unk                         |                 | Pfizer       |                |
|                                           | Lunesta              |                    |                    | S               | Oral                     | 2 Mg, At Hs                 |                 | Not Reported |                |
|                                           | Lunesta              |                    |                    | S               | Oral                     | 60 Mg, Single               |                 | Not Reported |                |
|                                           | Ambien Cr            |                    |                    | S               |                          | 12.5 Mg, At Hs              |                 | Not Reported |                |
|                                           | Lexapro              |                    |                    | S               |                          | Unk                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                               | 7869443              | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-766630          |                             | 72 YR           | Male         | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                | Clonazepam           |                    |                    | S               | Oral                     |                             |                 | Roche        |                |
|                                           | Quetiapine           |                    |                    | S               | Oral                     |                             |                 | Not Reported |                |
|                                           | Escitalopram Oxalate |                    |                    | S               | Oral                     |                             |                 | Not Reported |                |
|                                           | Gabapentin           |                    |                    | S               | Oral                     |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                               | 7869567              | EXPEDITED (15-DAY) | Y                  | DE              | US-ROCHE-766936          |                             | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |

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|                            |                      |   |      |                                                                     |              |
|----------------------------|----------------------|---|------|---------------------------------------------------------------------|--------------|
| Toxicity To Various Agents | Clonazepam           | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Roche        |
|                            | Metoprolol           | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Not Reported |
|                            | Quetiapine           | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Not Reported |
|                            | Duloxetine           | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Not Reported |
|                            | Escitalopram Oxalate | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Not Reported |
|                            | Metoclopramide       | S | Oral | Route: Ingestion, Ongoing<br>Status Unknown At The<br>Time Of Death | Not Reported |

| <u>FDA Received Date</u>                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|----------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 24-Mar-2011                                        | 7869771                 | EXPEDITED (15-DAY) | Y                  | OT              | D0070542A            |                      |                 | Female          | DEU            |
| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Diabetes Insipidus;<br>Polydipsia                  | Bupropion Hydrochloride |                    |                    | S               | Oral                 | 300mg Per Day        |                 | Glaxosmithkline |                |
|                                                    | Lamotrigine             |                    |                    | S               | Unknown              | 200mg Per Day        |                 | Unknown         |                |
|                                                    | Quetiapine              |                    |                    | S               | Unknown              | 400mg Per Day        |                 | Glaxosmithkline |                |
|                                                    | Escitalopram Oxalate    |                    |                    | S               | Unknown              | 20mg Per Day         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 24-Mar-2011                                        | 7871193                 | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000019025           |                      | 88 YR           | Female          | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anaemia; Breast Cancer;<br>Erythema; Haemorrhoids; | Lexapro                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |                                                     |   |                                       |                                                                                                    |              |
|------------------------------------------------|-----------------------------------------------------|---|---------------------------------------|----------------------------------------------------------------------------------------------------|--------------|
| Rectal Haemorrhage; Skin Exfoliation; Tinnitus | Soliris                                             | S | Intravenous (not otherwise specified) | 600 Mg (600 Mg,1 In 1 1 Wk), Intravenous (Not Otherwise Specified); 900 Mg (1 In 2 Wk),Intravenous | Not Reported |
|                                                |                                                     |   | Intravenous (not otherwise specified) | 600 Mg (600 Mg,1 In 1 1 Wk), Intravenous (Not Otherwise Specified); 900 Mg (1 In 2 Wk),Intravenous |              |
|                                                | Tranlorazepate Potassium) (Clorazepate Dipotassium) | C |                                       |                                                                                                    | Not Reported |
|                                                | Folic Acid                                          | C |                                       |                                                                                                    | Not Reported |
|                                                | Centrum (Multivitamin) (Multivitamin)               | C |                                       |                                                                                                    | Not Reported |
|                                                | Lipitor                                             | C |                                       |                                                                                                    | Not Reported |
|                                                | Arimidex (Anastrozole) (Anastrozole)                | C |                                       |                                                                                                    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Mar-2011              | 7890639        | DIRECT           | N                  | DE              |                      |                      | 49 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Completed Suicide        | Ambien         |                  |                    | S               |                      |                      |                 |            | Not Reported   |
|                          | Lexapro        |                  |                    | S               |                      |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 24-Mar-2011                                                                       | 7894380        | DIRECT           | N                  | OT              |                      |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Distension; Abdominal Pain; Diarrhoea; Frequent Bowel Movements; Nausea | Lexapro        |                  |                    | S               | Oral                 | 10mg 1x Daily Oral   |                 |            | Forest         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| 24-Mar-2011                                                                                             | 7898902                                          | EXPEDITED (15-DAY) | Y                  | OT              | 1000019269           |                                                                    | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperprolactinaemia;<br>Pituitary Tumour Benign                                                         | Lexapro                                          |                    |                    | S               | Oral                 | 20 Mg (20 Mg,1 In 1 D),<br>Oral                                    |                 | Not Reported |                |
|                                                                                                         | Vyvanse (Lisdexamfetamine)<br>(Lisdexamfetamine) |                    |                    | C               |                      |                                                                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                                                                                             | 7901588                                          | EXPEDITED (15-DAY) | Y                  | CA              | 1000019384           |                                                                    | < 1 DAY         | Female       | DNK            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Duodenal Atresia;<br>Maternal Drugs Affecting<br>Foetus                        | Escitalopram Oxalate                             |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Mar-2011                                                                                             | 7901867                                          | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000019301           |                                                                    | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                   | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Bipolar Disorder;<br>Bruxism; Dyskinesia;<br>Dystonia; Grimacing; Initial<br>Insomnia; Mania | Lexapro                                          |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral   |                 | Not Reported |                |
|                                                                                                         |                                                  |                    |                    |                 | Oral                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral   |                 |              |                |
|                                                                                                         | Lexapro                                          |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                         |                                                  |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D),<br>Oral; 10 Mg (10 Mg, 1 In 1<br>D), Oral |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                               |   |      |                                |              |
|---------------------------------------------------------------|---|------|--------------------------------|--------------|
| Seroquel                                                      | S | Oral | 25 Mg Qam, 50 Mg Qpm,<br>Oral  | Not Reported |
| Seroquel                                                      | S | Oral | 50 Mg Qam, 100 Mg Qpm,<br>Oral | Not Reported |
| Clonidine (Clonidine) (0.1<br>Milligram, Tablets) (Clonidine) | C |      |                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Mar-2011              | 7906534       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019387           |                      | 29 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Bradycardia; Confusional<br>State; Hypotension; Loss<br>Of Consciousness;<br>Poisoning Deliberate | Escitalopram Oxalate                  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                   | Subutex                               |              |            | S           | Oral         | (2 Mg),Oral        |                 | Not Reported |
|                                                                                                   | Zyprexa                               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                   | Aceprometazine<br>Maleate\Meprobamate |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2011              | 7766516       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017534           |                      | 33 YR      | Male       | DNK            |

| <u>Preferred Term</u>                     | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Infertility Male;<br>Spermatozoa Abnormal | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral                                 |                 | Not Reported |
|                                           | Tranxene T-Tab         |              |            | S           | Oral         | 30 Mg (10 Mg,3 In 1<br>D,Oral) ; 10 Mg (5 Mg,2 In<br>1 D),Oral |                 | Not Reported |
|                                           |                        |              |            |             | Oral         | 30 Mg (10 Mg,3 In 1<br>D,Oral) ; 10 Mg (5 Mg,2 In<br>1 D),Oral |                 |              |
|                                           | Aceprometazine Maleate |              |            | S           | Oral         | 1 Dosage Form (1 Dosage<br>Forms,1 In 1 D),Oral                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Mar-2011              | 7872077       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2011FR21561      |                      | 76 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Asthenia; Blood Osmolarity Decreased; Cerebrovascular Accident; Dizziness; Fall; Feeling Abnormal; Gastroenteritis; Hemiparesis; Hyponatraemia | Aliskiren\Hydrochlorothiazide |                    |                    | S               | Oral                       | 1 Df, Qd                                                                      | 64 DAY          | Novartis     |                |
|                                                                                                                                                | Aldactazine                   |                    |                    | S               |                            | 1 Df, Qd                                                                      | 370 DAY         | Not Reported |                |
|                                                                                                                                                | Escitalopram Oxalate          |                    |                    | S               |                            | 1 Df, Qd                                                                      | 370 DAY         | Not Reported |                |
|                                                                                                                                                | Bisoprolol Fumarate           |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Levothyrox                    |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Plaquenil                     |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Piracetam                     |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Alprazolam                    |                    |                    | C               |                            | Unk                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Mar-2011                                                                                                                                    | 7872929                       | EXPEDITED (15-DAY) | Y                  | HO              | IT-ASTRAZENECA-2011SE15926 |                                                                               | 38 YR           | Male         | ITA            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Sinus Tachycardia; Sopor                                                                                                 | Nexium                        |                    |                    | S               | Oral                       |                                                                               | 1 DAY           | Astrazeneca  |                |
|                                                                                                                                                | Ciprallex                     |                    |                    | S               | Oral                       |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Depakene                      |                    |                    | S               | Oral                       |                                                                               | 1 DAY           | Not Reported |                |
|                                                                                                                                                | Promazine Hydrochloride       |                    |                    | S               | Oral                       | 4g/100 MI Oral Drops, Solution Flacon 30 MI, 20 MI Once/Single Administration | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2011                                                                                                                                    | 7360520                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000012910                 |                                                                               | 66 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Bipolar I Disorder; Confusional State                                                                                      | Escitalopram Oxalate          |                    |                    | S               |                            | (1 In 1 D)                                                                    |                 | Not Reported |                |
|                                                                                                                                                | Unspecified Ingredient        |                    |                    | S               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Clorazepate Dipotassium       |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Insulin (Insulin) (Insulin)   |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Enalapril Maleate             |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Enalapril Maleate             |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |
|                                                                                                                                                | Adiro (Acetylsalicylic        |                    |                    | C               |                            |                                                                               |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Acid)(Acetylsalicylic Acid)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2011              | 7905228       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019381           |                      | 22 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Poisoning Deliberate;<br>Somnolence; Suicide<br>Attempt; Toxicity To<br>Various Agents | Escitalopram Oxalate                    |              |            | S           | Oral         | (200 Mg,Once), Oral |                 | Not Reported |
|                                                                                        | Valpromide                              |              |            | S           | Oral         | (6 Gm, Once),Oral   |                 | Not Reported |
|                                                                                        | Zyprexa                                 |              |            | S           | Oral         | (110 Mg,Once), Oral |                 | Not Reported |
|                                                                                        | Trimeprazine Tartrate                   |              |            | S           | Oral         | (Once),Oral         |                 | Not Reported |
|                                                                                        | Rivotril (Clonazepam)                   |              |            | C           | Oral         | (14 Mg,Once), Oral  |                 | Not Reported |
|                                                                                        | Dafalgan (Paracetamol)<br>(Faracetamol) |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Mar-2011              | 7905269       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019382           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Cholestasis           | Escitalopram Oxalate                                                                     |              |            | S           | Oral         | 10 Mg (10 Mg, 1 N 1 D),<br>Oral                                    |                 | Not Reported |
|                       | Pantoprazole                                                                             |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral, 20 Mg (40 Mg, 1 In 2<br>D), Oral |                 | Not Reported |
|                       | Valoron (Tilidine Hydrochloride,<br>Naloxone)(Tilidine<br>Hydrochloride, Naloxone)       |              |            | C           |              |                                                                    |                 | Not Reported |
|                       | Lopresor (Metoprolol Tartrate)<br>(Metoprolol Tartrate)                                  |              |            | C           |              |                                                                    |                 | Not Reported |
|                       | Tavor (Lorazepam)                                                                        |              |            | C           |              |                                                                    |                 | Not Reported |
|                       | Dipiperon (Pipamperone<br>Hydrochloride) (40<br>Milligram)(Pipamperone<br>Hydrochloride) |              |            | C           |              |                                                                    |                 | Not Reported |
|                       | Paracetamol (Paracetamol)<br>(Paracetamol)                                               |              |            | C           |              |                                                                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 28-Mar-2011                                                                                  | 7905281                                                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019408           |                                 | 74 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Jaundice; Vomiting | Escitalopram Oxalate                                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                              | Athymil (Mianserin Hydrochloride)(Mianserin Hydrochloride) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2011                                                                                  | 7905315                                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000019413           |                                 | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Eosinophilia Myalgia Syndrome; Pyrexia                                     | Escitalopram Oxalate                                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                              | Tryptophan, DI-                                            |                    |                    | S               | Oral                 | 500 Mg (500 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2011                                                                                  | 7908349                                                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019372           |                                 | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypochromic Anaemia                                                                          | Escitalopram Oxalate                                       |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D)         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                     | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2011                                                                                  | 7908903                                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000019518           |                                 | 79 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Gastrointestinal Disorder; General Physical Health Deterioration;                  | Escitalopram Oxalate                                       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |         |   |      |                                                       |              |
|---------------------------------------------------|---------|---|------|-------------------------------------------------------|--------------|
| Hyperkalaemia;<br>Hyponatraemia; Renal<br>Failure | Bactrim | S | Oral | 6 Dosage Forms (6<br>Dosage Forms, 1 In 1 D),<br>Oral | Not Reported |
|---------------------------------------------------|---------|---|------|-------------------------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2011              | 7878217       | EXPEDITED (15-DAY) | N                  | HO              | B0708135A            |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Akathisia; Confusional<br>State; Decreased<br>Appetite; Dehydration;<br>Hepatitis; Hypernatraemia;<br>Thrombocytopenia | Augmentin            |              |            | S           | Oral         | 2g Per Day         | 5 DAY           | Glaxosmithkline |
|                                                                                                                        | Allopurinol          |              |            | S           | Oral         |                    |                 | Unknown         |
|                                                                                                                        | Simvastatin          |              |            | S           | Oral         |                    |                 | Unknown         |
|                                                                                                                        | Escitalopram Oxalate |              |            | S           | Oral         | 15mg Per Day       |                 | Unknown         |
|                                                                                                                        | Omeprazole           |              |            | S           | Oral         |                    |                 | Unknown         |
|                                                                                                                        | Memantine            |              |            | S           | Oral         | 20mg Per Day       |                 | Unknown         |
|                                                                                                                        | Exelon               |              |            | S           | Transdermal  | 4.6mg Per Day      |                 | Unknown         |
|                                                                                                                        | Isosorbide Dinitrate |              |            | C           | Unknown      | 1unit Per Day      |                 | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Mar-2011              | 7878772       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2011067304 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Heart Rate Increased;<br>Mental Impairment;<br>Tremor | Xanax          |              |            | S           | Oral         | 0.5 Mg, As Needed  |                 | Pfizer       |
|                                                       | Lexapro        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2011              | 7888922       | EXPEDITED (15-DAY) | Y                  | HO              | 2011SA007836         |                      | 56 YR      | Female     | DEU            |

| <u>Preferred Term</u>                       | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Pleural Effusion;<br>Pneumonia; Sarcoidosis | Escitalopram Oxalate                 |              |            | S           | Oral         | 10 Milligram (S);Daily; Po |                 | Not Reported |
|                                             | Ivy Dry (Isopropanol/Tannic<br>Acid) |              |            | C           |              |                            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                          | Enzyme Preparations (Enzyme Preparations) |                    | C                  |                 |                                |                      |                 |              | Not Reported   |
|--------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                          | Fusafungine (Fusafungine)                 |                    | C                  |                 |                                |                      |                 |              | Not Reported   |
|                                                                          | Ibuprofen (Ibuprofen)                     |                    | C                  |                 |                                |                      |                 |              | Not Reported   |
|                                                                          | Ofloxacin                                 |                    | C                  |                 |                                |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2011                                                              | 7879487                                   | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2011069659       |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Drug Ineffective; Dry Mouth; Loss Of Libido; Malaise | Zoloft                                    |                    |                    | S               |                                | Unk                  |                 | Pfizer       |                |
|                                                                          | Lexapro                                   |                    |                    | S               |                                | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Mar-2011                                                              | 7880616                                   | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011066571       |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pancreatitis Acute                                                       | Xanax                                     |                    |                    | S               | Oral                           | 0.5 Mg, 2x/Day       |                 | Pfizer       |                |
|                                                                          | Escitalopram Oxalate                      |                    |                    | S               | Oral                           | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                          | Levothyrox                                |                    |                    | S               | Oral                           | 125 Ug, 1x/Day       |                 | Not Reported |                |
|                                                                          | Lormetazepam                              |                    |                    | S               | Oral                           | 1 Df, 1x/Day         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                 | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Apr-2011                                                              | 7645673                                   | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-US-WYE-H14299410 |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Drug Ineffective; Tremor                                         | Effexor                                   |                    |                    | S               | Oral                           | 150.0 Mg, 2x/Day     |                 | Pfizer       |                |
|                                                                          | Zoloft                                    |                    |                    | S               | Oral                           | 100.0 Mg, 1x/Day     |                 | Pfizer       |                |
|                                                                          | Zoloft                                    |                    |                    | S               | Unknown                        | 50.0 Mg, 1x/Day      |                 | Pfizer       |                |
|                                                                          | Lexapro                                   |                    |                    | S               | Unknown                        | 100.0 Mg, 1x/Day     |                 | Not Reported |                |
|                                                                          | Acetylsalicylic Acid                      |                    |                    | C               | Unknown                        | 81 Mg, 1x/Day        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |         |                |              |
|------------------------|---|---------|----------------|--------------|
| Lipitor                | C | Unknown | 30 Mg, 1x/Day  | Not Reported |
| Fish Oil, Hydrogenated | C | Unknown | Unk            | Not Reported |
| Gemfibrozil            | C | Oral    | 600 Mg, 2x/Day | Not Reported |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 01-Apr-2011                   | 7835700        | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-2011038703 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Suicidal Ideation | Prozac         |                  |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                               | Prozac         |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                               | Cymbalta       |                  |                    | S               |                          | 1 Df, Single         |                 | Not Reported |                |
|                               | Cymbalta       |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                               | Lexapro        |                  |                    | S               |                          | Unknown              |                 | Not Reported |                |
|                               | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
|--------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|-------------------|----------------|
| 01-Apr-2011                                            | 7879117                    | EXPEDITED (15-DAY) | Y                  | HO              | US-RB-024118-11      |                              | 29 YR           | Male              | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>        |                |
| Bradycardia; Confusional State; Hypotension; Poisoning | Subutex                    |                    |                    | S               | Nasal                | Other Dosing Details Unknown |                 | Reckitt Benckiser |                |
|                                                        | Escitalopram Oxalate       |                    |                    | S               | Nasal                | Dosing Details Unknown       |                 | Not Reported      |                |
|                                                        | Zyprexa                    |                    |                    | S               | Nasal                | Dosing Details Unknown       |                 | Not Reported      |                |
|                                                        | Aceprometazine\Meprobamate |                    |                    | S               | Nasal                | Dosing Details Unknown       |                 | Not Reported      |                |

| <u>FDA Received Date</u>        | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 01-Apr-2011                     | 7880385                | EXPEDITED (15-DAY) | Y                  | DS, HO          | FR-ASTRAZENECA-2011SE16980 |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>           | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia | Paracetamol            |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                 | Tramadol Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |      |  |  |        |  |              |
|--|----------------------|---|------|--|--|--------|--|--------------|
|  | Cortancyl            | S | Oral |  |  |        |  | Not Reported |
|  | Omeprazole           | S | Oral |  |  | 11 MTH |  | Not Reported |
|  | Escitalopram Oxalate | S | Oral |  |  |        |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2011              | 7910735       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019655           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|----------------------------------------|-----------------|--------------|
| Irritability; Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome; Neonatal Seizure | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1d), Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2011              | 7911271       | EXPEDITED (15-DAY) | Y                  | OT              | 1000019390           |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Glaucoma              | Lexapro                               |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Navelbine (Vinorelbine) (Vinorelbine) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Apr-2011              | 7913406       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019456           |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|---------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Infusion Related Reaction; Lip Swelling; Rash | Lexapro             |              |            | S           |              |                                 |                 | Not Reported |
|                                               | Cinryze             |              |            | S           |              | 500 Unit (500 Units, 1 In 1 Wk) |                 | Not Reported |
|                                               | Diazepam            |              |            | S           |              |                                 |                 | Not Reported |
|                                               | Atenolol (Atenolol) |              |            | S           |              |                                 |                 | Not Reported |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 04-Apr-2011                 | 7325793              | EXPEDITED (15-DAY) | N                  | DE, OT          | AU-PFIZER INC-2010031875 |                      | 29 YR           | Female       | AUS            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;         | Zoloft               |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Completed Suicide;          | Effexor              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| Confusional State;          | Lexapro              |                    |                    | S               |                          | 5 Mg, 1x/Day         |                 | Not Reported |                |
| Depression; Feeling         | Lexapro              |                    |                    | S               |                          | 10 Mg, 1x/Day        |                 | Not Reported |                |
| Abnormal; Mood Altered;     | Fish Oil             |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| Nervousness;                |                      |                    |                    |                 |                          |                      |                 |              |                |
| Restlessness                |                      |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2011                 | 7882958              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2010035994 |                      | 38 YR           | Male         | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chills; Drug Ineffective;   | Zoloft               |                    |                    | S               | Oral                     | 100 Mg, 1x/Day       |                 | Pfizer       |                |
| Tremor                      | Effexor              |                    |                    | S               | Oral                     | 150 Mg, 2x/Day       |                 | Pfizer       |                |
|                             | Lexapro              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                             | Lipitor              |                    |                    | C               | Oral                     | 30 Mg, 1x/Day        |                 | Not Reported |                |
|                             | Gemfibrozil          |                    |                    | C               | Oral                     | 600 Mg, 2x/Day       |                 | Not Reported |                |
|                             | Acetylsalicylic Acid |                    |                    | C               | Oral                     | 81 Mg, 1x/Day        |                 | Not Reported |                |
|                             | Fish Oil             |                    |                    | C               |                          | Unk, Once A Day      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2011                 | 7883106              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2003037020 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Exostosis; Pain; | Zoloft               |                    |                    | S               | Oral                     | 50 Mg, 1x/Day        |                 | Pfizer       |                |
| Panic Attack;               | Zoloft               |                    |                    | S               |                          |                      |                 | Pfizer       |                |
| Paraesthesia; Plantar       | Zoloft               |                    |                    | S               |                          |                      |                 | Pfizer       |                |
| Fasciitis; Swelling;        | Alprazolam           |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
| Tinnitus                    |                      |                    |                    |                 |                          |                      |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                       |                                                  |                    |                    |                 |                          |                                |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                                                                                                  |                                                  |                    | S                  | Oral            |                          | Not Reported                   |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2011                                                                                                                                           | 7883156                                          | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2009284276 |                                | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity; Eye Pruritus; Food Allergy; Hypersensitivity; Ocular Hyperaemia; Reaction To Preservatives; Scleral Disorder; Thyroid Disorder | Zoloft                                           |                    |                    | S               | Oral                     | 12.5 Mg, Unk                   |                 | Pfizer       |                |
|                                                                                                                                                       | Zoloft                                           |                    |                    | S               | Oral                     | 12.5 Mg, Unk                   |                 | Pfizer       |                |
|                                                                                                                                                       | Lexapro                                          |                    |                    | S               |                          | Unk                            |                 | Not Reported |                |
|                                                                                                                                                       | Multivitamins                                    |                    |                    | C               |                          | Unk                            |                 | Not Reported |                |
|                                                                                                                                                       | Folic Acid                                       |                    |                    | C               |                          | Unk                            |                 | Not Reported |                |
|                                                                                                                                                       | Vitamin B12                                      |                    |                    | C               |                          | Unk                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2011                                                                                                                                           | 7915285                                          | EXPEDITED (15-DAY) | Y                  | HO              | 1000019702               |                                | 47 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                                             | Escitalopram Oxalate                             |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                                                                                       | Tramadol Hydrochloride                           |                    |                    | S               | Oral                     | 100 Mg (50 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                       | Seresta (Oxazepam) (Tablet)                      |                    |                    | C               |                          |                                |                 | Not Reported |                |
|                                                                                                                                                       | Nicobion (Nicotinamide) (Tablets) (Nicotinamide) |                    |                    | C               |                          |                                |                 | Not Reported |                |
|                                                                                                                                                       | Imovane (Zopiclone) (Tablets) (Zopiclone)        |                    |                    | C               |                          |                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2011                                                                                                                                           | 7871053                                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019047               |                                | 30 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |



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|                                   |                           |   |                         |              |
|-----------------------------------|---------------------------|---|-------------------------|--------------|
| Diabetes Insipidus;<br>Polydipsia | Escitalopram Oxalate      | S | Up To 20 Mg (1 In 1 D)  | Not Reported |
|                                   | Quetiapine Fumarate       | S | Up To 400 Mg (1 In 1 D) | Not Reported |
|                                   | Bupropion                 | S | Up To 300 Mg (1 In 1 D) | Not Reported |
|                                   | Lamotrigine (Lamotrigine) | S | Up To 200 Mg (1 In 1 D) | Not Reported |

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 05-Apr-2011                          | 7886079        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2010074098 |                               | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Insomnia;<br>Tachycardia | Xanax Xr       |                    |                    | S               |                          | Unk, As Needed Before Bedtime |                 | Pfizer       |                |
|                                      | Effexor Xr     |                    |                    | S               |                          | Unk, Once Daily               |                 | Pfizer       |                |
|                                      | Lexapro        |                    |                    | S               |                          | Unk                           |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 05-Apr-2011              | 7886169              | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011069374 |                      | 56 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Vasospasm      | Xalatan              |                    |                    | S               | Ophthalmic               | 1 Gtt, 1x/Day        |                 | Pfizer       |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 05-Apr-2011                                                           | 7908921              | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000019453           |                               | 17 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Erectile Dysfunction; Genital Hypoaesthesia; Sensory Loss | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

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### Detailed Report

| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 05-Apr-2011                                                                                                                        | 7914393                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000018797           |                               | 20 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hallucination, Auditory; Hallucination, Synaesthetic;                                                                     | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D, Oral    |                 | Not Reported |                |
| Hallucination, Visual; Suicidal Behaviour; Suicidal Ideation                                                                       | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                    | Atarax                              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                    | Atarax                              |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2011                                                                                                                        | 7914938                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000019637           |                               | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Epilepsy; Epistaxis; Fall; Goitre; Haematoma; Loss Of Consciousness; Rib Fracture; Tooth Fracture; Urinary Incontinence | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                    | Escitalopram Oxalate                |                    |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                                                                                    | Zolpidem (Zolpidem) (Zolpidem)      |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                    | Tercian (Cyamemazine) (Cyamemazine) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2011                                                                                                                        | 7915000                             | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019638           |                               | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                          | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2011                                                                                                                        | 7916168                             | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019641           |                               | 38 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                      |                                    |   |      |      |  |  |  |  |              |
|--------------------------------------|------------------------------------|---|------|------|--|--|--|--|--------------|
| Compulsions; Intentional Self-Injury | Escitalopram Oxalate               | S | Oral | Oral |  |  |  |  | Not Reported |
|                                      | Seroquel (Quetiapine) (Quetiapine) | C |      |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2011              | 7916171       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019635           |                      | 38 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                              | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Dry Mouth; Formication; Malaise; Nausea; Sinus Tachycardia; Skin Burning Sensation | Escitalopram Oxalate                    |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                    | Eutirox (Levothyroxine) (Levothyroxine) |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Apr-2011              | 7730283       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-2010176653 |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Cataract              | Inipomp                    |              |            | S           | Oral         | 40 Mg, 1x/Day              | 365 DAY         | Pfizer       |
|                       | Cortancyl                  |              |            | S           | Oral         | 70 Mg, (Then Dose Reduced) |                 | Not Reported |
|                       | Femara                     |              |            | S           | Oral         | Unk                        |                 | Not Reported |
|                       | Plaquenil                  |              |            | S           | Oral         | 200 Mg, 2x/Day             |                 | Not Reported |
|                       | Methotrexate               |              |            | S           |              | 10 Mg, Every Monday        |                 | Not Reported |
|                       | Folic Acid                 |              |            | S           | Oral         | Everyday Except Mondays    |                 | Not Reported |
|                       | Calcium Carbonate          |              |            | S           | Oral         | 1 Dosage Forms             |                 | Not Reported |
|                       | Fosamax                    |              |            | S           | Oral         | 1 Df, Weekly               |                 | Not Reported |
|                       | Valacyclovir Hydrochloride |              |            | S           | Oral         | Unk                        |                 | Not Reported |
|                       | Aprovel                    |              |            | S           | Oral         | Unk                        |                 | Not Reported |
|                       | Escitalopram Oxalate       |              |            | S           | Oral         | Unk                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Apr-2011              | 7808071       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011025477 |                      | 86 YR      | Male       | FRA            |

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| <u>Preferred Term</u>                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Eosinophilia; Pollakiuria;<br>Pruritus; Rash;<br>Thrombocytopenia                        | Tahor                             |                    |                    | S               | Oral                       | 10 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                                          | Escitalopram Oxalate              |                    |                    | S               | Oral                       | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                          | Kardegic                          |                    |                    | C               | Oral                       | 160 Mg, 1x/Day       |                 | Not Reported |                |
|                                                                                          | Modopar                           |                    |                    | C               | Oral                       | 1 Df, 6x/Day         |                 | Not Reported |                |
|                                                                                          | Oxazepam                          |                    |                    | C               | Oral                       | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2011                                                                              | 7887305                           | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2011SE18589 |                      | 82 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                                                  | Inexium                           |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                          | Loxen (Nicardipine Hydrochloride) |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                          | Captopril                         |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                          | Furosemide                        |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                          | Framycetin Sulfate                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                                                                                          | Tahor                             |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                          | Tropatepine Hydrochloride         |                    |                    | C               | Oral                       |                      | 9 DAY           | Not Reported |                |
|                                                                                          | Previscan (Fluindione)            |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                          | Escitalopram Oxalate              |                    |                    | S               | Oral                       |                      | 45 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2011                                                                              | 7908338                           | DIRECT             | N                  | OT              |                            |                      | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased;<br>Dysuria; Gastrointestinal Disorder; Malaise; Pain; Tinnitus | Cymbalta                          |                    |                    | S               |                            | 30 Mg. 1 A Day       |                 | Not Reported |                |
|                                                                                          | Lexapro                           |                    |                    | S               |                            | Lexapro 1 A Day      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------------------------------------|-----------------|--------------|----------------|
| 06-Apr-2011                                                                                                                                                                                                                                                                        | 7917846                                                               | EXPEDITED (15-DAY) | Y                  | HO              | 1000019629                               |                                                             | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Hepatic Steatosis;<br>Hepatitis; Hepatitis B Core<br>Antibody; Hepatocellular<br>Injury; Hepatomegaly; Hiv<br>Infection; Hyponatraemia;<br>Oropharyngeal<br>Candidiasis; Parvovirus<br>B19 Test Positive;<br>Pneumocystis Jirovecii<br>Pneumonia; Pyrexia | Escitalopram Oxalate                                                  |                    |                    | S               | Oral                                     | 10 Mg (10 Mg,1 In 1<br>D),Oral                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Bactrim Forte                                                         |                    |                    | S               | Oral                                     | 4800 Mg/ 960 Mg (2<br>Dosage Forms,3 In 1<br>D),Oral        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Bactrim                                                               |                    |                    | S               | Intravenous (not<br>otherwise specified) | 2000 Mg/ 400<br>Mg,Intravenous (Not<br>Otherwise Specified) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Lederfoline (Calcium Folate)<br>(Calcium Folate)                      |                    |                    | C               |                                          |                                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Levothyroxine Sodium<br>(Levothyroxine Sodium)                        |                    |                    | C               |                                          |                                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Gyno-Pevaryl (Econazole<br>Nitrate) (Capsules) (Econazole<br>Nitrate) |                    |                    | C               |                                          |                                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Fungizone (Amphotericin B)<br>(Amphotericin B)                        |                    |                    | C               |                                          |                                                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                    | Lovenox                                                               |                    |                    | C               |                                          |                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                           | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Apr-2011                                                                                                                                                                                                                                                                        | 6805354                                                               | EXPEDITED (15-DAY) | N                  | DE, OT          | AU-PFIZER INC-AU-<br>WYE-G02474308       |                                                             | 17 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                              | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anhedonia;<br>Anxiety; Bipolar Disorder;<br>Bipolar II Disorder;<br>Cognitive Disorder;<br>Completed Suicide;<br>Condition Aggravated;<br>Confusional State; Crying;<br>Depression; Distractibility;                                                                    | Effexor                                                               |                    |                    | S               |                                          | 75.0 Mg, 1x/Day                                             |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                    | Effexor                                                               |                    |                    | S               |                                          | 75 Mg, Unk                                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                    | Effexor                                                               |                    |                    | S               |                                          | 112.5mg Daily                                               |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                    | Effexor                                                               |                    |                    | S               |                                          | 150 Mg, 1x/Day                                              |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                    | Effexor                                                               |                    |                    | S               |                                          | 75 Mg, 1x/Day                                               |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                    | Zoloft                                                                |                    |                    | S               |                                          | Unk                                                         |                 | Pfizer       |                |

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|                             |              |   |                     |       |              |
|-----------------------------|--------------|---|---------------------|-------|--------------|
| Disturbance In Attention;   | Lexapro      | S | 5 Mg, 1x/Day        | 3 DAY | Not Reported |
| Drug Ineffective; Drug      | Lexapro      | S | 10 Mg, 1x/Day       |       | Not Reported |
| Withdrawal Syndrome;        | Erythromycin | C | 20mg/G 2% Gel Daily |       | Not Reported |
| Feeling Abnormal; Feeling   | Fish Oil     | C | Unk                 |       | Not Reported |
| Guilty; Feeling Of Despair; |              |   |                     |       |              |
| Frustration Tolerance       |              |   |                     |       |              |
| Decreased; Impaired         |              |   |                     |       |              |
| Driving Ability; Impulsive  |              |   |                     |       |              |
| Behaviour; Insomnia;        |              |   |                     |       |              |
| Intentional Product         |              |   |                     |       |              |
| Misuse; Intentional Self-   |              |   |                     |       |              |
| Injury; Malaise; Memory     |              |   |                     |       |              |
| Impairment; Mental Status   |              |   |                     |       |              |
| Changes; Mood Altered;      |              |   |                     |       |              |
| Multiple Injuries;          |              |   |                     |       |              |
| Nervousness; Nonspecific    |              |   |                     |       |              |
| Reaction; Obsessive         |              |   |                     |       |              |
| Thoughts; Panic Attack;     |              |   |                     |       |              |
| Psychomotor                 |              |   |                     |       |              |
| Hyperactivity;              |              |   |                     |       |              |
| Restlessness; Road          |              |   |                     |       |              |
| Traffic Accident; Self      |              |   |                     |       |              |
| Esteem Decreased;           |              |   |                     |       |              |
| Sexual Dysfunction;         |              |   |                     |       |              |
| Speech Disorder; Suicidal   |              |   |                     |       |              |
| Ideation; Therapeutic       |              |   |                     |       |              |
| Product Effect Decreased;   |              |   |                     |       |              |
| Thinking Abnormal;          |              |   |                     |       |              |
| Unevaluable Event           |              |   |                     |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2011              | 7777681       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017936           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Cardiac Disorder;<br>Electrocardiogram Qt<br>Prolonged; Tachycardia | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral ; 10 Mg (10 Mg,1<br>In 1 D),Oral |                 | Not Reported |
|                                                                     |                      |              |            |             | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral ; 10 Mg (10 Mg,1<br>In 1 D),Oral |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |   |              |
|--------------------------------------|---|--------------|
| Metoprolol Succinate                 | C | Not Reported |
| Trazodone (Trazodone)<br>(Trazodone) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 07-Apr-2011              | 7843548       | EXPEDITED (15-DAY) | Y                  | DE, HO          | US-CELGENEUS-163-<br>21880-11022573 |                      | 84 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder;<br>Encephalopathy;<br>Musculoskeletal Pain;<br>Nausea; Plasma Cell<br>Myeloma | Revlimid       |              |            | S           | Oral         | 25 Milligram       |                 | Celgene      |
|                                                                                                   | Revlimid       |              |            | S           | Oral         | 25 Milligram       |                 | Celgene      |
|                                                                                                   | Revlimid       |              |            | S           | Oral         | 25 Milligram       |                 | Not Reported |
|                                                                                                   | Dexamethasone  |              |            | S           | Oral         | 40 Milligram       |                 | Not Reported |
|                                                                                                   | Dexamethasone  |              |            | S           | Oral         | 40 Milligram       |                 | Not Reported |
|                                                                                                   | Hydrocodone    |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Flexeril       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Dilaudid       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Dilaudid       |              |            | S           | Parenteral   | .4 Milligram       |                 | Not Reported |
|                                                                                                   | Xanax          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Protonix       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Rivastigmine   |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                                                   | Aspirin        |              |            | C           | Oral         | 325 Milligram      |                 | Not Reported |
|                                                                                                   | Antiviral      |              |            | C           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Apr-2011              | 7905273       | EXPEDITED (15-DAY) | Y                  | HO              | 029609               |                      | 70 YR      | Male       | ITA            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Syncope               | Keppra                  |              |            | S           | Oral         | (2000 Mg, 20 Tablets Oral) |                 | Not Reported |
|                       | Carvedilol (Carvedilol) |              |            | S           | Oral         | (12.5 Mg Oral)             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |      |                                        |              |
|---------------------|---|------|----------------------------------------|--------------|
| Ramipril            | S | Oral | (10 Mg, 5 Mg Tablets; 14 Tablets Oral) | Not Reported |
| Norvasc             | S |      |                                        | Not Reported |
| Cipralex            | S |      |                                        | Not Reported |
| Ticlopidine         | C |      |                                        | Not Reported |
| Metformin           | C |      |                                        | Not Reported |
| Allopurinol         | C |      |                                        | Not Reported |
| Actoplus Met        | C |      |                                        | Not Reported |
| Crestor             | C |      |                                        | Not Reported |
| Plavix              | C |      |                                        | Not Reported |
| Peptazol /01263202/ | C |      |                                        | Not Reported |
| Xanax               | C |      |                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Apr-2011              | 7184808       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2009296613 |                      |            | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ageusia; Constipation;     | Zoloft                   |              |            | S           |              | Unk                |                 | Pfizer       |
| Decreased Appetite;        | Trazodone Hydrochloride  |              |            | S           |              | Unk                |                 | Unknown      |
| Diarrhoea; Diverticulitis; | Doxepin Hydrochloride    |              |            | S           |              | Unk                |                 | Pfizer       |
| Drug Ineffective; Dry      | Pristiq Extended Release |              |            | S           | Oral         | 50 Mg, 1x/Day      |                 | Pfizer       |
| Mouth; Dyskinesia; Muscle  | Effexor Xr               |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Pfizer       |
| Twitching; Nightmare;      | Mirtazapine              |              |            | S           |              | Unk                |                 | Not Reported |
| Suicide Attempt;           | Wellbutrin               |              |            | S           |              | Unk                |                 | Not Reported |
| Therapeutic Product Effect | Zyprexa                  |              |            | S           |              | Unk                |                 | Not Reported |
| Decreased; Tremor          | Seroquel                 |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Lexapro                  |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Paroxetine               |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Cymbalta                 |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Paxil                    |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Prozac                   |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Depakote                 |              |            | S           |              | Unk                |                 | Not Reported |
|                            | Vitamins                 |              |            | C           |              | Unk                |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                          |                    |                    |                 |                                  |                                      |                 |              |                |
|---------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------------|--------------------------------------|-----------------|--------------|----------------|
| Fish Oil                                          |                          |                    | C                  |                 |                                  | Unk                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2011                                       | 7676784                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016972                       |                                      | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event                                  | Escitalopram Oxalate     |                    |                    | S               | Oral                             | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2011                                       | 7878017                  | EXPEDITED (15-DAY) | Y                  | HO              | IT-ABBOTT-11P-083-<br>0714762-00 |                                      | 38 YR           | Male         | ITA            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Sinus Tachycardia; Sopor | Valproic Acid            |                    |                    | S               | Oral                             | Once                                 |                 | Not Reported |                |
|                                                   | Cipralext                |                    |                    | S               | Oral                             | Once                                 |                 | Not Reported |                |
|                                                   | Promazine                |                    |                    | S               | Oral                             | 20ml Of 40mg/MI Solution             |                 | Not Reported |                |
|                                                   | Esomeprazole             |                    |                    | S               | Oral                             |                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2011                                       | 7891138                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2011073854     |                                      |                 | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Somnolence                               | Pristiq Extended Release |                    |                    | S               |                                  | Unk                                  |                 | Pfizer       |                |
|                                                   | Lexapro                  |                    |                    | S               |                                  | Unk                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Apr-2011                                       | 7901865                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000019288                       |                                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose;<br>Asthma; Bronchospasm;     | Lexapro                  |                    |                    | S               | Oral                             | Oral; 30 (30 Mg, 1 In 1 D),<br>Oral; |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                                 |   |              |
|---------------------------------------|---------------------------------|---|--------------|
| Pneumonia; Toxicity To Various Agents | Nafazodone                      | C | Not Reported |
|                                       | Trileptal                       | C | Not Reported |
|                                       | Lamictal                        | C | Not Reported |
|                                       | Xanax                           | C | Not Reported |
|                                       | Campral                         | C | Not Reported |
|                                       | Zyrtec (Cetirizine)             | C | Not Reported |
|                                       | Flonase                         | C | Not Reported |
|                                       | Robitussin Dm                   | C | Not Reported |
|                                       | (Dextromethorphan, Guaifenesin) |   |              |
|                                       | Flovent Hfa                     | C | Not Reported |
|                                       | Albuterol Hfa (Salbutamol)      | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Apr-2011              | 7906872       | DIRECT           |                    | OT              |                      |                      | 45 YR      | Female     | USA            |

  

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cheilitis; Gingival Disorder; Rash | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                    | Synthroid      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 11-Apr-2011              | 7549719       | EXPEDITED (15-DAY) | Y                  | HO, LT          | ZA-JNJFOC-20100806521 |                      | 83 YR      | Female     | ZAF            |

  

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Drug Dependence; Dyskinesia; Hyperhidrosis; Hyperkalaemia; Hypertension; Psychotic Disorder; Pyrexia; Renal Failure; Rhabdomyolysis; Tachycardia | Duragesic                            |              |            | S           | Transdermal  |                         |                 | Not Reported |
|                                                                                                                                                  | Acetaminophen\Tramadol Hydrochloride |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Stalevo                              |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Ciprallex                            |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Ciprallex                            |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Azilect                              |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Celebrex                             |              |            | S           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Zopiclone                            |              |            | C           | Oral         |                         |                 | Not Reported |
|                                                                                                                                                  | Sinemet Cr                           |              |            | C           | Oral         | 50/200 Mg               |                 | Not Reported |
|                                                                                                                                                  | Ergocalciferol                       |              |            | C           | Oral         | 50000 Iu Mg Mon/Wed/Fri |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Ocuville Lutein                                                                          |                          | C                  |                    | Unknown         |                            | Days                    |                 | Not Reported |                |
|------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2011                                                                              | 7893198                  | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | CH-PFIZER INC-2011075727   |                         | 33 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspartate                                                                                | Sortis                   |                    |                    | S               | Oral                       | 8 G, Single             | 1 DAY           | Pfizer       |                |
| Aminotransferase Increased; C-Reactive Protein Increased;                                | Sortis                   |                    |                    | S               | Oral                       | Unk                     |                 | Pfizer       |                |
| Diabetic Complication; Hyperkalaemia;                                                    | Lorazepam                |                    |                    | S               | Oral                       | 50 Mg, Single           | 1 DAY           | Pfizer       |                |
| Hyperthermia;                                                                            | Lorazepam                |                    |                    | S               | Oral                       | 2.5 Mg, 3x/Day          |                 | Pfizer       |                |
| Hypotension; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Mydriasis; | Lisinopril               |                    |                    | S               | Oral                       | 350 Mg, Single          | 1 DAY           | Not Reported |                |
| Rhabdomyolysis; Tachycardia; Vomiting                                                    | Lisinopril               |                    |                    | S               | Oral                       |                         |                 | Not Reported |                |
|                                                                                          | Seroquel                 |                    |                    | S               | Oral                       | 52 G, Single            | 1 DAY           | Not Reported |                |
|                                                                                          | Seroquel                 |                    |                    | S               | Oral                       | 1400 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                          | Cipralelex               |                    |                    | S               | Oral                       | 1.4 G, Single           | 1 DAY           | Not Reported |                |
|                                                                                          | Cipralelex               |                    |                    | S               | Oral                       | 40 Mg, 1x/Day           |                 | Not Reported |                |
|                                                                                          | Flurazepam Hydrochloride |                    |                    | S               | Oral                       | 750 Mg, Single          | 1 DAY           | Not Reported |                |
|                                                                                          | Flurazepam Hydrochloride |                    |                    | S               | Oral                       | 30 Mg, 1x/Day           |                 | Not Reported |                |
|                                                                                          | Potassium Chloride       |                    |                    | S               | Oral                       | 470 Mmol, Single        | 1 DAY           | Not Reported |                |
|                                                                                          | Potassium Chloride       |                    |                    | S               | Oral                       | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2011                                                                              | 7893670                  | EXPEDITED (15-DAY) | N                  | OT              | US-ASTRAZENECA-2011SE18638 |                         | 14 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Dystonia; Insomnia                                                     | Seroquel                 |                    |                    | S               | Oral                       | 25 Mg Qam And 50 Mg Qpm | 0 YR            | Zeneca       |                |
|                                                                                          | Seroquel                 |                    |                    | S               | Oral                       | 25 Mg Qam And 50 Mg Qpm | 0 YR            | Zeneca       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |                          |       |              |
|-----------|---|------|--------------------------|-------|--------------|
| Seroquel  | S | Oral | 50 Mg Qam And 100 Mg Qpm | 0 YR  | Zeneca       |
| Seroquel  | S | Oral | 50 Mg Qam And 100 Mg Qpm | 0 YR  | Zeneca       |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Lexapro   | S | Oral |                          | 4 MTH | Not Reported |
| Lexapro   | S | Oral |                          | 4 MTH | Not Reported |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Lexapro   | S | Oral |                          |       | Not Reported |
| Clonidine | C | Oral |                          |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 11-Apr-2011              | 7893864       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-ASTRAZENECA-2011SE19337 |                      | 33 YR      | Female     | CHE            |

| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Diabetic Complication;   | Lisinopril               |              |            | S           | Oral         | 350 Mgs Total      | 1 DAY           | Zeneca       |
| Hyperkalaemia;           | Ciprallex                |              |            | S           | Oral         |                    |                 | Not Reported |
| Hyperthermia;            | Ciprallex                |              |            | S           | Oral         | 1.4 Gms Total      | 1 DAY           | Not Reported |
| Hypotension; Intentional | Potassium                |              |            | S           | Oral         | 470 Mmol           | 1 DAY           | Not Reported |
| Overdose; Loss Of        | Seroquel                 |              |            | S           | Oral         |                    |                 | Not Reported |
| Consciousness; Metabolic | Seroquel                 |              |            | S           | Oral         | 52 Gms Total       | 1 DAY           | Not Reported |
| Acidosis; Mydriasis;     | Flurazepam Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
| Rhabdomyolysis;          | Flurazepam Hydrochloride |              |            | S           | Oral         | 750 Mgs Total      | 1 DAY           | Not Reported |
| Tachycardia; Vomiting    | Sortis                   |              |            | S           | Oral         | 8 Gms Total        | 1 DAY           | Not Reported |
|                          | Lorazepam                |              |            | S           | Oral         |                    |                 | Not Reported |
|                          | Lorazepam                |              |            | S           | Oral         | 50 Mgs Total       | 1 DAY           | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 11-Apr-2011                                                                       | 7928288                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000019726           |                                 | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Chest Discomfort; Dyspnoea; Hypoxia; Serotonin Syndrome | Lexapro                        |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral       |                 | Not Reported |                |
|                                                                                   | Lorazepam                      |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2011                                                                       | 7931231                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000019859           |                                 | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Cholestasis; Condition Aggravated; Hepatitis; Psychomotor Retardation; Somnolence | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                   | Trileptal                      |                    |                    | S               | Oral                 | 600 Mg (300 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                                   | Piracetam                      |                    |                    | S               | Oral                 | 800 Mg (800 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                   | Calcit (Calcium Carbonate)     |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                   | Ferrous Sulfate                |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                   | Levothyroxine Sodium           |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                   | Inipomp                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2011                                                                       | 7674425                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000016938           |                                 | 74 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastrointestinal Haemorrhage; Melaena; Peptic Ulcer                               | Lexapro                        |                    |                    | S               | Oral                 | 15 Mg (15 Mg,1 In 1 D), Oral    |                 | Not Reported |                |
|                                                                                   | Amlodipine                     |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                   | Aspirin                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                   | Zoton (Lansoprazole) (Tablets) |                    |                    | C               |                      |                                 |                 | Not Reported |                |

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(Lansoprazole)  
Vit B12 (Cyanocobalamin)  
(Tablets) (Cyanocobalamin)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7810436       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018242           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Decreased Appetite;<br>Hepatic Haematoma;<br>Hepatitis Cholestatic;<br>Incorrect Dose<br>Administered; Vomiting;<br>Weight Decreased | Escitalopram Oxalate                                            |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),<br>Oral             |                 | Not Reported |
|                                                                                                                                      | Acetaminophen\Caffeine\Propox<br>yphene                         |              |            | S           | Oral         | 6 Df (2 Dosage Forms,3 In<br>1 D), Oral     |                 | Not Reported |
|                                                                                                                                      | Acetaminophen                                                   |              |            | S           | Oral         | Up To 6 Gm Daily (1<br>Gm,On Request), Oral |                 | Not Reported |
|                                                                                                                                      | Loxen (Niacardipine<br>Hydrochloride)                           |              |            | C           |              |                                             |                 | Not Reported |
|                                                                                                                                      | Kardegic (Acetylsalicylate<br>Lysine) (Acetylsalicylate Lysine) |              |            | C           |              |                                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7840624       | EXPEDITED (15-DAY) | Y                  | CA              | GRT 2011-10388       |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>                                                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Induced; Arnold-<br>Chiari Malformation;<br>Maternal Drugs Affecting<br>Foetus; Spina Bifida;<br>Talipes | Lidoderm                                                                                                   |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Atarax                                                                                                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Escitalopram Oxalate                                                                                       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                   | Folic Acid                                                                                                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Tetrazepam                                                                                                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Lyrica                                                                                                     |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                   | Propofan (Caffeine, Carbasalate<br>Calcium, Chlorphenamine<br>Maleate, Dextropropoxyphene,<br>Paracetamol) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7895425       | EXPEDITED (15-DAY) | N                  | LT              | B0712146A            |                      | 67 YR      | Female     | ITA            |

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| <u>Preferred Term</u>                              | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Coma; Inappropriate Antidiuretic Hormone Secretion | Lamictal                        |              |            | S           | Oral         | 150mg Per Day      | 420 DAY         | Glaxosmithkline |
|                                                    | Escitalopram Oxalate            |              |            | S           |              | 10mg/ml Per Day    | 421 DAY         | Glaxosmithkline |
|                                                    | Tavor (Lorazepam)               |              |            | S           | Oral         | 7.5mg Per Day      | 8 DAY           | Not Reported    |
|                                                    | Seretide                        |              |            | S           |              |                    |                 | Glaxosmithkline |
|                                                    | Anafranil                       |              |            | C           |              |                    |                 | Not Reported    |
|                                                    | Bromazepam                      |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                    | Pentetrazol                     |              |            | C           |              |                    |                 | Not Reported    |
|                                                    | Dihydrocodeine                  |              |            | C           |              |                    |                 | Not Reported    |
|                                                    | Lasix                           |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                    | Tenormin                        |              |            | C           |              |                    |                 | Not Reported    |
|                                                    | Hydrochlorothiazide\Telmisartan |              |            | C           |              |                    |                 | Glaxosmithkline |
|                                                    | Prednisone                      |              |            | C           |              |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7905366       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000019459           |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                 | <u>Product</u>                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Anxiety; Arthralgia; Asthenia; Butterfly Rash; Cervicobrachial Syndrome; Depression; Disturbance In Attention; Dyskinesia; Fall; Feeling Abnormal; Gait Disturbance; Headache; Hypersomnia; Insomnia; Nail Disorder; Neck Pain; Pain In Extremity; Paraesthesia; Posture Abnormal; Product Dose Omission; Psoriasis; Restless Legs Syndrome; Tinnitus; Tourette'S Disorder; Tremor; Visual Impairment | Lexapro                                                                |              |            | S           | Oral         | 1.25 Mg (1.25 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                       | Hyzaar (Hydrochlorothiazide, Losartan) (Hydrochlorothiazide, Losartan) |              |            | C           |              |                                 |                 | Not Reported |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7920164       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000019697           |                      | 82 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Overdose; Seizure     | Escitalopram Oxalate                                                           |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Aricept                                                                        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 U), Oral   |                 | Not Reported |
|                       | Alvedon (Paracetamol) (500 Milligram, Tablets) (Paracetamol)                   |              |            | C           |              |                               |                 | Not Reported |
|                       | Simvastatin (Simvastatin) (40 Milligram, Tablets) (Simvastatin)                |              |            | C           |              |                               |                 | Not Reported |
|                       | Doxazosin (Doxazosin) (4 Milligram, Tablets) (Doxazosin)                       |              |            | C           |              |                               |                 | Not Reported |
|                       | Furix (Furosemide) (40 Milligram, Tablets) (Furosemide)                        |              |            | C           |              |                               |                 | Not Reported |
|                       | Nitromex (Glyceryl Trinitrate) (0.25 Milligram, Tablets) (Glyceryl Trinitrate) |              |            | C           |              |                               |                 | Not Reported |
|                       | Allopurinol (Allopurinol) (100 Milligram, Tablets) (Allopurinol)               |              |            | C           |              |                               |                 | Not Reported |
|                       | Trombyl (Acetylsalicylic Acid) (160 Milligram, Tablets) (Acetylsalicylic Acid) |              |            | C           |              |                               |                 | Not Reported |
|                       |                                                                                |              |            |             |              |                               |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7929088       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019862           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                   | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Amnestic Disorder; Dysgeusia; Dysphagia | Escitalopram Oxalate                           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                         | Plavix (Clopidogrel) (Tablets) (Clopidogrel)   |              |            | C           |              |                               |                 | Not Reported |
|                                         | Coversyl (Perindopril) (Tablets) (Perindopril) |              |            | C           |              |                               |                 | Not Reported |
|                                         | Kardegic (Acetylsalicylate)                    |              |            | C           |              |                               |                 | Not Reported |



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|                                                                                                                   |   |              |
|-------------------------------------------------------------------------------------------------------------------|---|--------------|
| Lysine) (Powder)<br>(Acetylsalicylate Lysine)<br>Tahor (Atorvastatin Calcium)<br>(Tablets) (Atorvastatin Calcium) | C | Not Reported |
| Procoralan (Ivabradine<br>Hydrochloride) (Tablets)<br>(Ivabradine Hydrochloride)                                  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7929559       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019866           |                      | 82 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                     | <u>Product</u>                                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Drug Interaction;<br>Hallucination; Serotonin<br>Syndrome | Escitalopram Oxalate                                                                                   |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),<br>Oral |                 | Not Reported |
|                                                           | Nexium                                                                                                 |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),<br>Oral |                 | Not Reported |
|                                                           | Loxen (Nifedipine<br>Hydrochloride)                                                                    |              |            | C           |              |                                 |                 | Not Reported |
|                                                           | Captopril (Captopril) (Captopril)                                                                      |              |            | C           |              |                                 |                 | Not Reported |
|                                                           | Furosemide                                                                                             |              |            | C           |              |                                 |                 | Not Reported |
|                                                           | Rhinotrophyl (Ethanamine<br>Tenate, Framycetin Sulfate)<br>(Ethanamine Tenoate,<br>Framycetin Sulfate) |              |            | C           |              |                                 |                 | Not Reported |
|                                                           | Tahor (Atorvastatin Calcium)<br>(Tablets) (Atorvastatin Calcium)                                       |              |            | C           |              |                                 |                 | Not Reported |
|                                                           | Previscan (Fluindione)                                                                                 |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2011              | 7930514       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019951           |                      | 38 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Blood Pressure<br>Decreased; Intentional<br>Overdose; Sinus<br>Tachycardia; Sopor | Escitalopram Oxalate |              |            | S           | Oral         | (40 Mg,Once), Oral   |                 | Not Reported |
|                                                                                                                                 | Valproic Acid        |              |            | S           | Oral         | (2500 Mg,Once), Oral |                 | Not Reported |
|                                                                                                                                 | Promazine            |              |            | S           | Oral         | (20 Ml,Once),Oral    |                 | Not Reported |
|                                                                                                                                 | Esomeprazole         |              |            | S           | Oral         | (80 Mg,Once), Oral   |                 | Not Reported |

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|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 12-Apr-2011              | 7931493              | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2011-01128         |                      | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Disorder         | Metoprolol Tartrate  |                    |                    | S               |                            | 50mg-                |                 | Not Reported |                |
|                          | Lipitor              |                    |                    | S               |                            | 20mg-                |                 | Not Reported |                |
|                          | Cardizem La          |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Lexapro              |                    |                    | S               |                            | 10mg-                |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2011              | 7897499              | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR27356            |                      | 90 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus; Purpura        | Leponex              |                    |                    | S               |                            | Unk                  |                 | Novartis     |                |
|                          | Plavix               |                    |                    | S               |                            | 75 Mg, Unk           |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                       | 20 Mg, Unk           |                 | Not Reported |                |
|                          | Modopar              |                    |                    | C               |                            | 100/25 Mg            |                 | Not Reported |                |
|                          | Xanax                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Lasix                |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Potassium            |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Debridat             |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Symbicort            |                    |                    | C               |                            |                      |                 | Not Reported |                |
|                          | Esomeprazole         |                    |                    | C               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2011              | 7898020              | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2010SE46008 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Migraine                 | Atenolol             |                    |                    | S               |                            |                      |                 | Zeneca       |                |
|                          | Lexapro              |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                          | Topamax              |                    |                    | S               |                            |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 14-Apr-2011                                | 7759841        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017769           |                        | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Feeling Abnormal; Myalgia; Tremor | Lexapro        |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |                |
|                                            | Lexapro        |                    |                    | S               |                      | 5 Mg (5 Mg, 1 In 1 D)  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 15-Apr-2011              | 7603967              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016114           |                               | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                          | Lorazepam            |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                          | Lexomil (Bromazepam) |                    |                    | C               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 15-Apr-2011                                                                                                                                                                        | 7869374              | EXPEDITED (15-DAY) | N                  | LT, OT          | PHHY2011US22074      |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Cold Sweat; Dizziness; Drug Dependence; Head Injury; Hot Flush; Hyperhidrosis; Insomnia; Precancerous Cells Present; Scar; Suicidal Behaviour; Visual Impairment | Vivelle Dot          |                    |                    | S               | Transdermal          | 0.0375, Twice Per Week |                 | Novartis     |                |
|                                                                                                                                                                                    | Flexeril             |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                                    | Escitalopram Oxalate |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                                    | Vicodin              |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                                                                                                    | Lexapro              |                    |                    | C               |                      |                        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 15-Apr-2011              | 7900571       | EXPEDITED (15-DAY) | Y                  | OT              | US-SANOI-AVENTIS-2011SA021233 |                      | 46 YR      | Male       | USA            |

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| <u>Preferred Term</u>                                                                           | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Flight Of Ideas;<br>Hypomania; Inappropriate<br>Affect; Overdose; Painful<br>Erection; Priapism | Zolpidem                |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      | Reduced Dosage          |                 | Not Reported |
|                                                                                                 | Quetiapine Fumarate     |              |            | S           | Unknown      | Reduced Dosage          |                 | Not Reported |
|                                                                                                 | Zolpidem                |              |            | S           | Unknown      | Dose: 40-60 Mg Overdose |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate    |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate    |              |            | S           | Unknown      | Returned To Baseline.   |                 | Not Reported |
|                                                                                                 | Marijuana               |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Marijuana               |              |            | S           | Unknown      | Taken Intermittently    |                 | Not Reported |
|                                                                                                 | Cocaine                 |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Unspecified Ingredient  |              |            | S           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Lamivudine & Zidovudine |              |            | C           | Unknown      |                         |                 | Not Reported |
|                                                                                                 | Nevirapine              |              |            | C           | Unknown      |                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Apr-2011              | 7934544       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020067           |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                         | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Communication Disorder;<br>Hyponatraemia; Seizure;<br>Unresponsive To Stimuli | Lexapro                                      |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                               | Xanax (Alprazolam) (Tablets)<br>(Alprazolam) |              |            | C           |              |                                |                 | Not Reported |
|                                                                               | Nortem (Temazepam) (Tablets)<br>(Temazepam)  |              |            | C           |              |                                |                 | Not Reported |
|                                                                               |                                              |              |            |             |              |                                |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------|-----------------|--------------|----------------|
| 18-Apr-2011                                                                                                                                    | 7354086                                                                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000012683           |                                           | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Spermatogenesis Abnormal                                                                                                                       | Lexapro                                                                    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral             |                 | Not Reported |                |
|                                                                                                                                                | Lexapro                                                                    |                    |                    | S               | Oral                 | Oral                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                       | <u>Case #</u>                                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2011                                                                                                                                    | 7379193                                                                    | EXPEDITED (15-DAY) | Y                  | CA, OT          | 1000013413           |                                           | < 1 DAY         | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                          | <u>Product</u>                                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Floppy Infant; Hypertonia Neonatal; Hypotonia Neonatal; Maternal Drugs Affecting Foetus; Nervous System Disorder; Poor Sucking Reflex; Talipes | Lexapro                                                                    |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D), Transplacental)  |                 | Not Reported |                |
|                                                                                                                                                | Seroquel                                                                   |                    |                    | S               | Transplacental       | 200 Mg (100 Mg, 2 In 1 D), Transplacental |                 | Not Reported |                |
|                                                                                                                                                | Affex (Fluoxetine) (Capsules)                                              |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Ranitidine                                                                 |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Amoxicillin                                                                |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Augmentin                                                                  |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Cytamen (Cyanocobalamin) (Injection) (Cyanocobalamin)                      |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Galfer (Ferrous Fumarate) (Ferrous Fumarate)                               |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Solpadol (Paracetamol, Codeine Phosphate) (Paracetamol, Codeine Phosphate) |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Difene (Diclofenac Sodium) (Diclofenac Sodium)                             |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Zimovane (Zopiclone) (Tablets) (Zopiclone)                                 |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Buscopan (Hyoscine Butylbromide) (Tablets) (Hyoscine Butylbromide)         |                    |                    | C               |                      |                                           |                 | Not Reported |                |
|                                                                                                                                                | Fastum (Ketoprofen) (Gel)                                                  |                    |                    | C               |                      |                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

(Ketoprofen)  
Gertac (Ranitidine) (Ranitidine)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Apr-2011              | 7903521       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011082157 |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Drug Ineffective;<br>Drug Intolerance; Erectile<br>Dysfunction; Headache | Pristiq Extended Release |              |            | S           |              | Unk, 1 X/Day       | 2 DAY           | Pfizer       |
|                                                                                     | Zoloft                   |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                     | Lexapro                  |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                     | Celexa                   |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                     | Abilify                  |              |            | C           |              | 2 Mg, Unk          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2011              | 7924737       | DIRECT           | Y                  |                 |                      |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Hyperreflexia;<br>Serotonin Syndrome;<br>Suicidal Ideation;<br>Tachycardia | Escitalopram Oxalate       |              |            | S           | Oral         | 1 Tab Qday Po > 3 Months |                 | Not Reported |
|                                                                                                               | Clomipramine Hydrochloride |              |            | S           | Oral         | 1 Tab Qday Po > 3 Months |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2011              | 7932654       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019988           |                      | 90 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Pruritus; Purpura     | Escitalopram Oxalate                             |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Plavix                                           |              |            | S           | Oral         | (75 Mg), Oral                    |                 | Not Reported |
|                       | Clozapine                                        |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                       | Modopar (Benserazide<br>Hydrochloride, Levodopa) |              |            | C           |              |                                  |                 | Not Reported |

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### Detailed Report

|                                                |   |              |
|------------------------------------------------|---|--------------|
| (Benserazide Hydrochloride,<br>Levodopa)       |   |              |
| Xanax                                          | C | Not Reported |
| Lasilix (Furosemide)                           | C | Not Reported |
| (Furosemide)                                   |   |              |
| Diffu K (Potassium Chloride)                   | C | Not Reported |
| (Potassium Chloride)                           |   |              |
| Transipeg (Macrogol)                           | C | Not Reported |
| Debridat (Trimebutine)                         | C | Not Reported |
| (Trimebutine)                                  |   |              |
| Symbicort (Budesonide,<br>Formoterol Fumarate) | C | Not Reported |
| (Budesonide, Formoterol<br>Fumarate)           |   |              |
| Inexium (Esomeprazole<br>Magnesium)            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2011              | 7932658       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019992           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety;      | Escitalopram Oxalate           |              |            | S           | Oral         | (5 Mg, Once), Oral |                 | Not Reported |
| Asthenia; Diarrhoea;     | Alendronic Acid (Alendronic    |              |            | C           |              |                    |                 | Not Reported |
| Feeling Cold; Heart Rate | Acid) (Alendronic Acid)        |              |            |             |              |                    |                 |              |
| Irregular; Hypertension; | Aspirin                        |              |            | C           |              |                    |                 | Not Reported |
| Hypoaesthesia; Insomnia; | Azathioprine                   |              |            | C           |              |                    |                 | Not Reported |
| Malaise; Nausea;         | Bisoprolol Fumarate            |              |            | C           |              |                    |                 | Not Reported |
| Paraesthesia             | Butran (Buprenorphine)         |              |            | C           |              |                    |                 | Not Reported |
|                          | (Buprenorphine)                |              |            |             |              |                    |                 |              |
|                          | Lekovit Ca (Colecalciferol,    |              |            | C           |              |                    |                 | Not Reported |
|                          | Calcium Carbonate)             |              |            |             |              |                    |                 |              |
|                          | (Colecalciferol, Calcium       |              |            |             |              |                    |                 |              |
|                          | Carboante)                     |              |            |             |              |                    |                 |              |
|                          | Ciprofibrate (Ciprofibrate)    |              |            | C           |              |                    |                 | Not Reported |
|                          | (Ciprofibrate)                 |              |            |             |              |                    |                 |              |
|                          | Diazepam                       |              |            | C           |              |                    |                 | Not Reported |
|                          | Lacri-Lube (Paraffin Liquid,   |              |            | C           |              |                    |                 | Not Reported |
|                          | Paraffin Soft White) (Paraffin |              |            |             |              |                    |                 |              |
|                          | Liquid, Paraffin Soft White)   |              |            |             |              |                    |                 |              |
|                          | Metoclopramide                 |              |            | C           |              |                    |                 | Not Reported |

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|                                                                      |   |              |
|----------------------------------------------------------------------|---|--------------|
| (Metoclopramide) (10 Milligram)                                      |   |              |
| (Metoclopramide)                                                     |   |              |
| Nitrolingual (Glyceryl Trinitrate)                                   | C | Not Reported |
| (Glyceryl Trinitrate)                                                |   |              |
| Omeprazole                                                           | C | Not Reported |
| Paracetamol (Paracetamol) (500 Milligram) (Paracetamol)              | C | Not Reported |
| Prednisolone                                                         | C | Not Reported |
| Ramipril                                                             | C | Not Reported |
| Tamsulosin Hydrochloride)                                            | C | Not Reported |
| (Tamsulosin Hydrochloride)                                           |   |              |
| (Tamsulosin Hydrochloride)                                           |   |              |
| Tears Naturale (Dextran 70, Hypromellose) (Dextran 70, Hypromellose) | C | Not Reported |
| Temazepam                                                            | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2011              | 7933110       | EXPEDITED (15-DAY) | Y                  | LT              | 1000020120           |                      | 67 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Inappropriate Antidiuretic Hormone Secretion | Escitalopram Oxalate                                                             |              |            | S           | Oral         | 5 Gtt (5 Gtt,1 In 1 D),Oral   |                 | Not Reported |
|                                              | Tavor (Lorazepam)                                                                |              |            | S           | Oral         | 7.5 Mg (7.5 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                              | Lamictal                                                                         |              |            | S           | Oral         | 150 Mg (150 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                              | Cardiazol-Paracodina (Dihydrocodeine, Pentetrazol) (Dihydrocodeine, Pentetrazol) |              |            | C           |              |                               |                 | Not Reported |
|                                              | Lasix                                                                            |              |            | C           |              |                               |                 | Not Reported |
|                                              | Tenormin                                                                         |              |            | C           |              |                               |                 | Not Reported |
|                                              | Pritorplus (Hydrochlorothiazide) (Hydrochlorothiazide)                           |              |            | C           |              |                               |                 | Not Reported |
|                                              | Seretide                                                                         |              |            | C           |              |                               |                 | Not Reported |
|                                              | Deltacortene (Prednisone) (Prednisone)                                           |              |            | C           |              |                               |                 | Not Reported |
|                                              |                                                                                  |              |            |             |              |                               |                 |              |



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| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 18-Apr-2011                                                                                                      | 7933652                                       | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000020103               |                               | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cervical Vertebral Fracture; Drug Interaction; Fall; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion | Escitalopram Oxalate                          |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                  | Mopral (Omeprazole)                           |                    |                    | S               | Oral                     | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                  | Contramal (Tramadol Hydrochloride) (Capsules) |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                                                                  | Acetaminophen                                 |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                                                                  | Cortancyl (Prednisone) (Tablets) (Prednisone) |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2011                                                                                                      | 7933656                                       | EXPEDITED (15-DAY) | Y                  | HO              | IPC201104-000561         |                               | 46 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Fall; Hypotension                                                                              | Hydrochlorothiazide                           |                    |                    | S               |                          | 12.5 Mg/D                     |                 | Not Reported |                |
|                                                                                                                  | Irbesartan                                    |                    |                    | S               |                          | 300 Mg/D                      |                 | Not Reported |                |
|                                                                                                                  | Quetiapine                                    |                    |                    | S               |                          | 50 Mg Bid                     |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate                          |                    |                    | S               |                          | 10 Mg In The Morning          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Apr-2011                                                                                                      | 7904565                                       | EXPEDITED (15-DAY) | Y                  | OT              | PL-PFIZER INC-2011082284 |                               | 36 YR           | Female       | POL            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Personal Independence In Daily Activities; Malaise; Somnolence                                           | Venlafaxine Hydrochloride                     |                    |                    | S               |                          | 150 Mg, 1x/Day                |                 | Pfizer       |                |
|                                                                                                                  | Bupropion                                     |                    |                    | S               |                          | 300 Mg, 1x/Day                |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate                          |                    |                    | S               |                          | 30 Mg, 1x/Day                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 20-Apr-2011                | 7907077              | EXPEDITED (15-DAY) | N                  | OT              | BR-PFIZER INC-2011083191 |                      | 55 YR           | Female       | BRA            |
| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Vomiting; Weight Decreased | Champix              |                    |                    | S               | Oral                     | 0.5 Mg, 1x/Day       |                 | Pfizer       |                |
|                            | Depakote             |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                            | Escitalopram Oxalate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 20-Apr-2011                                                                                 | 7907299              | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-JNJFOC-20110406972 |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Cognitive Disorder; Drug Ineffective; Hallucination, Auditory; Suicidal Ideation | Haloperidol          |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                             | Haloperidol          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Rufinamide           |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Rufinamide           |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Escitalopram Oxalate |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Ziprasidone          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Ziprasidone          |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                             | Zolpidem             |                    |                    | S               |                       | As Needed            |                 | Not Reported |                |
|                                                                                             | Zolpidem             |                    |                    | S               |                       | As Needed            |                 | Not Reported |                |

| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 21-Apr-2011                                           | 7760445              | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2010TW87821      |                      | 58 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Discomfort; Depressed Mood; Dystonia; Insomnia; | Fluoxetine           |                    |                    | S               |                      | 20 To 40 Mg/Day      |                 | Novartis     |                |
|                                                       | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg, Qd            |                 | Not Reported |                |

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|                                |                           |   |                    |              |
|--------------------------------|---------------------------|---|--------------------|--------------|
| Tardive Dyskinesia;<br>Trismus | Mirtazapine               | S | 15 Mg, Qd          | Not Reported |
|                                | Paroxetine Hydrochloride  | S | 10 To 40 Mg/Day    | Not Reported |
|                                | Trazodone Hydrochloride   | S | 15 To 125 Mg/Day   | Not Reported |
|                                | Venlafaxine Hydrochloride | S | 37.5 To 225 Mg/Day | Not Reported |
|                                | Duloxetine                | S | 30 To 60 Mg/Day    | Not Reported |

| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 21-Apr-2011                            | 7775880              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017896           |                           | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Vision Blurred; Visual<br>Field Defect | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5m (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Apr-2011                            | 7909495        | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-<br>2010SE10297 |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Oedema<br>Peripheral | Toprol XL      |                  |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                        | Synthroid      |                  |                    | C               |                                |                      |                 | Not Reported |                |
|                                        | Prevacid       |                  |                    | C               |                                |                      |                 | Not Reported |                |
|                                        | Aldactone      |                  |                    | C               |                                |                      |                 | Not Reported |                |
|                                        | Demadex        |                  |                    | C               |                                |                      |                 | Not Reported |                |
|                                        | Lexapro        |                  |                    | S               | Oral                           |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------|-----------------|--------------|----------------|
| 21-Apr-2011              | 7941597        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020146           |                                                   | 44 YR           | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Polyneuropathy           | Lexapro        |                    |                    | S               | Oral                 | (10 Mg),Oral, Temporarily<br>Dose Reduction, Oral |                 | Not Reported |                |
|                          |                |                    |                    |                 | Oral                 | (10 Mg),Oral, Temporarily<br>Dose Reduction, Oral |                 |              |                |
|                          | Lexapro        |                    |                    | S               | Oral                 | Oral                                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                             |   |              |
|-----------------------------------------------------------------------------|---|--------------|
| Fluticasone Propionate                                                      | C | Not Reported |
| Montelukast                                                                 | C | Not Reported |
| Pantozol (Pantoprazole Sodium)                                              | C | Not Reported |
| Aerius (Desloratadine) (Tablets)                                            | C | Not Reported |
| (Desloratadine)                                                             |   |              |
| Spiriva                                                                     | C | Not Reported |
| Symbicort(Budesonide, Formoterol Fumarate)(Budesonide, Formoterol Fumarate) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2011              | 7941688       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020108           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Aspiration; Blood Glucose Increased; Diabetic Complication;                              | Escitalopram Oxalate     |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1d), Oral; 1.4 Gm, Once, Oral       |                 | Not Reported |
| Haemodynamic Instability; Hyperkalaemia; Hyperthermia;                                   | Seroquel                 |              |            | S           | Oral         | 1400 Mg (1400 Mg, 1 In 1 D), Oral; (52 Gm, Once), Oral |                 | Not Reported |
| Hypotension; Intentional Overdose; Loss Of Consciousness; Metabolic Acidosis; Mydriasis; | Lorazepam                |              |            | S           | Oral         | 7.5 Mg (2.5 Mg, 3 In 1 D), Oral; 50 Mg, Once, Oral     |                 | Not Reported |
| Rhabdomyolysis; Tachycardia; Vomiting                                                    | Flurazepam Hydrochloride |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral; 750 Mg, Once, Oral      |                 | Not Reported |
|                                                                                          | Atorvastatin Calcium     |              |            | S           | Oral         | Oral; 8 Gm, Once, Oral                                 |                 | Not Reported |
|                                                                                          | Lisinopril               |              |            | S           | Oral         | Oral; 350 Mg, Once, Oral                               |                 | Not Reported |
|                                                                                          | Potassium Chloride       |              |            | S           | Oral         | Oral; 470 Milligram, Once, Oral                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Apr-2011              | 7941782       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020143           |                      | 76 YR      | Female     | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Burning Sensation; Feeling Abnormal; | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                        |                                                                                   |                         |                    |                 |                      |                                  |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Pneumonia; Syncope                                                                                                                                                                                     |                                                                                   | Quetiapine (Quetiapine) |                    | C               |                      | Not Reported                     |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>                                                                     | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2011                                                                                                                                                                                            | 7941804                                                                           | EXPEDITED (15-DAY)      | Y                  | RI, OT          | 1000020144           |                                  | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>                                                                    | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Serotonin Syndrome                                                                                                                                                                | Escitalopram Oxalate                                                              |                         |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                        | Naratriptan Hydrochloride                                                         |                         |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>                                                                     | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Apr-2011                                                                                                                                                                                            | 7944593                                                                           | EXPEDITED (15-DAY)      | N                  | CA              | 1000020152           |                                  | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>                                                                    | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary<br>Artery Anomaly; Maternal<br>Drugs Affecting Foetus                                                                                                                             | Lexapro                                                                           |                         |                    | S               | Transplacental       | Transplacental                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                               | <u>Case #</u>                                                                     | <u>Case Type</u>        | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Apr-2011                                                                                                                                                                                            | 7816534                                                                           | EXPEDITED (15-DAY)      | Y                  | HO, RI, OT      | 1000018510           |                                  | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>                                                                    | <u>Comp.</u>            | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Anaemia;<br>Asthenia; Chronic Kidney<br>Disease; Confusional<br>State; Fall; Gastric<br>Haemorrhage;<br>Inappropriate Antidiuretic<br>Hormone Secretion;<br>Nausea; Pneumonia;<br>Vomiting | Lexapro                                                                           |                         |                    | S               | Oral                 | Tablets (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                        | Lisinopril                                                                        |                         |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Zetia                                                                             |                         |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Thyroid Meta Max (Thyroid Meta<br>Max) (Thyroid Meta Max)                         |                         |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Coreg Cr (Carvedilol)<br>(Carvedilol)                                             |                         |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Avalide (Irbesartan,<br>Hydrochlorothiazide) (Irbesartan,<br>Hydrochlorothiazide) |                         |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                                        | Protonix                                                                          |                         |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                                                              |   |              |
|--|--------------------------------------------------------------|---|--------------|
|  | Requip (Ropinirole Hydrochloride) (Ropinirole Hydrochloride) | C | Not Reported |
|  | Rozerem (Ramelteon) (Ramelteon)                              | C | Not Reported |
|  | Wellbutrin XL                                                | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Apr-2011              | 7943623       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020249           |                      | 83 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>                                                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Drug Reaction With Eosinophilia And Systemic Symptoms | Escitalopram Oxalate                                                                         |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D), Oral |                 | Not Reported |
|                                                       | Seroquel (Quetiapine Fumarate) (Tablets-) (Quetiapine Fumarate)                              |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Cal-D-Vita (Colecalciferol, Calcium Carbonate) (Tablets) (Colecalciferol, Calcium Carbonate) |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Dominal Forte (Prothipendyl Hydrochloride)                                                   |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Dulcolax (Bisacodyl)                                                                         |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Lantus                                                                                       |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Lasix (Furosemide) (Tablets) (Furosemide)                                                    |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Lisinopril                                                                                   |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Lisinopril Hct (Lisinopril Dihydrate, Hydrochlorothiazide)                                   |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Mexalen (Paracetamol) (Tablets) (Paracetamol)                                                |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Novolog                                                                                      |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Oleovit D3 (Colecalciferol) (Tablets) (Colecalciferol)                                       |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Aerius (Ebastine) (Ebastine)                                                                 |              |            | C           |              |                              |                 | Not Reported |
|                                                       | Aricept (Donepezil) (Tablets) (Donepezil)                                                    |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Apr-2011              | 7340599       | EXPEDITED (15-DAY) | Y                  | DE              | 1000012466           |                      | 58 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Arteriosclerosis;<br>Arteriosclerosis Coronary<br>Artery; Body Fat Disorder;<br>Cardiomyopathy;<br>Cholelithiasis; Pleural<br>Fibrosis; Pulmonary<br>Congestion; Pulmonary<br>Oedema; Uterine Mass | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral                                                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2011                                                                                                                                                                                        | 7947758              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020281           |                                                                                                                                                                         |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematochezia                                                                                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral                                                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2011                                                                                                                                                                                        | 7951647              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 030896               |                                                                                                                                                                         | 76 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Blood<br>Cholesterol Increased;                                                                                                                                                  | Keppra               |                    |                    | S               | Oral                 | (1000 Mg Oral)                                                                                                                                                          |                 | Not Reported |                |
| Blood Glucose Increased;<br>Blood Potassium<br>Decreased; Blood<br>Triglycerides Increased;<br>Cerebral Haemorrhage;<br>Cognitive Disorder;                                                        | Ciprallex            |                    |                    | S               | Oral                 | (5 Mg Oral), (10 Mg Oral),<br>(20 Mg Oral) Depression<br>(5 Mg Oral), (10 Mg Oral),<br>(20 Mg Oral) Depression<br>(5 Mg Oral), (10 Mg Oral),<br>(20 Mg Oral) Depression |                 | Not Reported |                |
| Dementia; Depressed<br>Level Of Consciousness;<br>Dizziness; Fall;                                                                                                                                 | Torsemide            |                    |                    | S               | Oral                 | Specified) (10 Mg Oral)                                                                                                                                                 |                 | Not Reported |                |
| Hypotension; Hypotonia;<br>Skin Laceration; Urinary<br>Tract Infection; Vertigo                                                                                                                    | Bisoprolol Fumarate  |                    |                    | S               | Oral                 | (5 Mg Oral)                                                                                                                                                             | 6 DAY           | Not Reported |                |
|                                                                                                                                                                                                    | Pantozol             |                    |                    | C               |                      |                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                    | Aspirin              |                    |                    | C               |                      |                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                    | Mcp /00041901/       |                    |                    | C               |                      |                                                                                                                                                                         |                 | Not Reported |                |
|                                                                                                                                                                                                    | Ferro-Sanol B        |                    |                    | C               |                      |                                                                                                                                                                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 27-Apr-2011                                                                                                                                                                   | 7916525              | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR32095                               |                      | 23 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anticonvulsant Drug Level Above Therapeutic; Bradycardia; Clonus; Diplopia; Dizziness; Dysstasia; Fall; Headache; Motor Dysfunction; Mydriasis; Nausea; Periorbital Haematoma | Tegretol             |                    |                    | S               |                                               | 100 Mg, Qd           |                 | Novartis     |                |
|                                                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               | Oral                                          | 10 Mg, Qd            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2011                                                                                                                                                                   | 7917287              | EXPEDITED (15-DAY) | Y                  | OT              | US-ROXANE LABORATORIES, INC.- 2011-RO-00546RO |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure; Thrombocytopenia                                                                                                                                                     | Levetiracetam        |                    |                    | S               |                                               | 1000 Mg              |                 | Roxane       |                |
|                                                                                                                                                                               | Levetiracetam        |                    |                    | S               |                                               | 2000 Mg              |                 | Roxane       |                |
|                                                                                                                                                                               | Levetiracetam        |                    |                    | S               |                                               | 2250 Mg              |                 | Roxane       |                |
|                                                                                                                                                                               | Dexamethasone        |                    |                    | S               |                                               | 8 Mg                 |                 | Roxane       |                |
|                                                                                                                                                                               | Escitalopram Oxalate |                    |                    | S               |                                               |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Advair Diskus        |                    |                    | S               |                                               |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Ranitidine           |                    |                    | S               |                                               |                      |                 | Not Reported |                |
|                                                                                                                                                                               | Phenytoin            |                    |                    | S               |                                               | 300 Mg               |                 | Not Reported |                |
|                                                                                                                                                                               | Multivitamins        |                    |                    | C               |                                               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Apr-2011                                                                                                                                                                   | 7586957              | EXPEDITED (15-DAY) | Y                  | OT              | FI-TEVA-247872ISR                             |                      | 64 YR           | Male         | FIN            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Muscle Rupture; Myositis;                                                                                                                                   | Azilect              |                    |                    | S               | Oral                                          | 1 Milligram;         |                 | Teva         |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |                             |   |         |                 |              |
|------------|-----------------------------|---|---------|-----------------|--------------|
| Tendonitis | Levodopa W/Carbidopa        | C | Oral    | 100/200mg Daily | Not Reported |
|            | Ropinirole Hydrochloride    | C | Oral    |                 | Not Reported |
|            | Cabergoline                 | C | Oral    |                 | Not Reported |
|            | Neupro                      | C | Topical |                 | Not Reported |
|            | Pramipexole Dihydrochloride | C | Oral    |                 | Not Reported |
|            | Escitalopram Oxalate        | S | Oral    | 5-10 Mg         | Not Reported |
|            | Atorvastatin Calcium        | S | Oral    | 10 Milligram;   | Not Reported |

| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------|-----------------|----------------------|----------------|
| 28-Apr-2011                                                                                                                                                                                | 7892806                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15640170 |                         | 46 YR           | Male                 | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>           |                |
| Adjustment Disorder With<br>Depressed Mood; Drug<br>Interaction; Fall;<br>Hypotension; Liver<br>Function Test Abnormal;<br>Overdose; Renal Function<br>Test Abnormal; Suicidal<br>Ideation | Paracetamol              |                    |                    | S               |                                                 |                         |                 | Cadence              |                |
|                                                                                                                                                                                            | Codeine Phosphate        |                    |                    | S               |                                                 |                         |                 | Not Reported         |                |
|                                                                                                                                                                                            | Paroxetine Hydrochloride |                    |                    | S               |                                                 |                         |                 | Not Reported         |                |
|                                                                                                                                                                                            | Irbesartan + Hctz        |                    |                    | S               | Unknown                                         | 1df=300/12.5mg(312.5mg) |                 | Bristol Myers Squibb |                |
|                                                                                                                                                                                            | Quetiapine Fumarate      |                    |                    | S               | Unknown                                         |                         |                 | Not Reported         |                |
|                                                                                                                                                                                            | Escitalopram Oxalate     |                    |                    | S               |                                                 |                         |                 | Not Reported         |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 29-Apr-2011                                        | 7840783             | EXPEDITED (15-DAY) | Y                  | OT              | US-ENDO<br>PHARMACEUTICALS<br>INC.-HCTZ20110002 |                      | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic<br>Seizure; Hyponatraemia | Hydrochlorothiazide |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                    | Lexapro             |                    |                    | S               | Oral                                            |                      |                 | Not Reported |                |
|                                                    | Lexapro             |                    |                    | S               |                                                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 29-Apr-2011              | 7920178       | EXPEDITED (15-DAY) | Y                  | HO              | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15695604 |                      | 79 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------|-----------------|----------------------|
| Gastrointestinal<br>Haemorrhage;<br>Generalised Tonic-Clonic<br>Seizure; Hypocalcaemia;<br>International Normalised<br>Ratio Increased; Urinary<br>Tract Infection | Pravastatin Sodium     |              |            | S           | Oral         | 1 Df:1 Scored Tab/Day                                                   |                 | Bristol Myers Squibb |
|                                                                                                                                                                    | Escitalopram Oxalate   |              |            | S           | Oral         | 1 Df:1 Film Coated Score<br>Tab Formulation:Seroplex<br>10mg            |                 | Not Reported         |
|                                                                                                                                                                    | Noroxin                |              |            | S           | Oral         | 1 Df:2 Coated Tabs/Day<br>Formulation:400mg                             |                 | Not Reported         |
|                                                                                                                                                                    | Previscan (Fluindione) |              |            | S           | Oral         | 1 Df:3/4 Then 1/4 Scored<br>Tablet Formulation:20 Mg                    |                 | Not Reported         |
|                                                                                                                                                                    | Aspirin                |              |            | S           | Oral         | 1 Df:1 Oral Powder For<br>Oral Soln<br>Formulation:Kardegic 75<br>Mg    |                 | Not Reported         |
|                                                                                                                                                                    | Bisoprolol Fumarate    |              |            | S           | Oral         | 1 Df:1 Film-Coated Scored<br>Tablet<br>Formulation:Cardensiel<br>2.5 Mg |                 | Not Reported         |
|                                                                                                                                                                    | Levothyrox             |              |            | S           | Oral         | 1 Df:1 Scored Tablet<br>Formulation:Levothyrox<br>100 Mcg               |                 | Not Reported         |
|                                                                                                                                                                    | Inexium                |              |            | C           | Oral         | 1 Df:1 Enteric-Coated<br>Tablet<br>Formulation:Inexium 40<br>Mg         |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2011              | 7938570       | DIRECT           | N                  |                 |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Colitis Ulcerative;<br>Treatment Failure | Lexapro        |              |            | S           | Oral         | 20mg 1x Per Day Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Apr-2011              | 7952906       | EXPEDITED (15-DAY) | Y                  | HO              | 1000018276           |                      | 21 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------|-------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------------|-----------------------------------|-----------------|--------------|----------------|
| Breast Pain;<br>Galactorrhoea                        | Escitalopram Oxalate                                  |                    |                    | S               | Oral                             | 20 Mg (20 Mg) , Oral              |                 | Not Reported |                |
|                                                      | Seroquel                                              |                    |                    | S               | Oral                             | 350 Mg (350 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                      | Depakine (Valproic Acid)<br>(Tablets) (Valproic Acid) |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Temesta (Lorazepam) (Tablets)<br>(Lorazepam)          |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Marvelon (Marvelon0 (Marvelon)                        |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Apr-2011                                          | 7996286                                               | NON-EXPEDITED      | Y                  | HO              | US-JNJFOC-<br>20101005437        |                                   | 54 YR           | Male         | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose                                 | Tylenol                                               |                    | Y                  | S               | Oral                             | Oral                              |                 | Not Reported |                |
|                                                      | Lexapro                                               |                    |                    | S               |                                  | 20 Mg, 1 In 1 Day                 |                 | Not Reported |                |
|                                                      | Study Medication<br>(Investigational Drug)            |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Prednisone                                            |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Acyclovir                                             |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Lisinopril (Lisinopril)                               |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Nexium (Esomeprazole<br>Magnesium)                    |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Ativan                                                |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Atenolol (Atenolol)                                   |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
|                                                      | Lipitor                                               |                    |                    | C               |                                  |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2011                                          | 7923742                                               | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-11P-056-<br>0722455-00 |                                   | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                     | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| International Normalised<br>Ratio Increased; Melaena | Levothyroxine                                         |                    |                    | S               | Oral                             |                                   |                 | Not Reported |                |
|                                                      | Levothyroxine                                         |                    |                    | S               |                                  |                                   |                 | Not Reported |                |
|                                                      | Escitalopram Oxalate                                  |                    |                    | S               | Oral                             |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |      |              |
|---------------------|---|------|--------------|
| Noroxin             | S | Oral | Not Reported |
| Fluindione          | S |      | Not Reported |
| Aspirin             | S | Oral | Not Reported |
| Bisoprolol Fumarate | S | Oral | Not Reported |
| Pravastatin Sodium  | S | Oral | Not Reported |
| Inexium             | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2011              | 7078920       | EXPEDITED (15-DAY) | Y                  | DE              | 1000007846           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Blood Glucose Increased;<br>Blood Pressure Increased;<br>Blood Sodium Decreased;<br>Cardiac Failure; Chest<br>Pain; Fall; Glycosylated<br>Haemoglobin Increased;<br>Headache | Escitalopram Oxalate                                                  |              |            | S           |              | 5 Mg (15 Mg,1 In 1 D)              |                 | Not Reported |
|                                                                                                                                                                              | Flupentixol                                                           |              |            | S           | Oral         | 0.5 Mg (0.5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                              | Mianserin                                                             |              |            | S           |              | 10 Mg (10 Mg,1 In 1 D)             |                 | Not Reported |
|                                                                                                                                                                              | Nuvaring                                                              |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                              | Metformin Hydrochloride                                               |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                              | Novorapid Flexpen (Insulin<br>Aspart) (Solution ) (Insulin<br>Aspart) |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2011              | 7856201       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000018805           |                      | 17 YR      | Unknown    | DNK            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Amenorrhoea; Off Label<br>Use | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-May-2011              | 7892721       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019336           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                                                   |   |      |                                                                                                                  |              |
|---------------------------------------------|---------------------------------------------------|---|------|------------------------------------------------------------------------------------------------------------------|--------------|
| Breast Pain; Breast Swelling; Galactorrhoea | Escitalopram Oxalate                              | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                                                 | Not Reported |
|                                             | Escitalopram Oxalate                              | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                                                 | Not Reported |
|                                             | Seroquel Xr                                       | S |      | 350 Mg (350 Mg, 1 In 1 D),<br>100 Mg (100 Mg,1 In 1 D)<br>350 Mg (350 Mg, 1 In 1 D),<br>100 Mg (100 Mg,1 In 1 D) | Not Reported |
|                                             | Depakine (Valproic Acid)(Tablets) (Valproic Acid) | C |      |                                                                                                                  | Not Reported |
|                                             | Temesta (Lorazepam) (Tablets) (Lorazepam)         | C |      |                                                                                                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 02-May-2011              | 7900443       | EXPEDITED (15-DAY) | N                  | HO, LT, OT      | ZA-JNJFOC-20110404989 |                      | 17 YR      | Female     | ZAF            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Diplegia; Dizziness; Drug Interaction; Fall; Gait Inability; Gait Spastic; Loss Of Consciousness; Paralysis; Syncope; Visual Impairment | Acetaminophen\Tramadol Hydrochloride |              |            | S           | Unknown      | Prn                |                 | Not Reported |
|                                                                                                                                                         | Escitalopram Oxalate                 |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 02-May-2011              | 7924289       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011090956 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction; Insomnia; Therapeutic Response Unexpected | Xanax          |              |            | S           | Oral         | 0.5 Mg Daily As Needed |                 | Pfizer       |
|                                                                               | Lexapro        |              |            | S           | Oral         | 10 Mg, 1x/Day          |                 | Not Reported |
|                                                                               | Lexapro        |              |            | S           |              |                        |                 | Not Reported |
|                                                                               | Synthroid      |              |            | C           |              | Unk                    |                 | Not Reported |
|                                                                               | Imitrex        |              |            | C           |              | As Required            |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                           | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 02-May-2011                                        | 7951382                                                   | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020380                               |                                                                                               | 66 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cataract; Glaucoma                                 | Lexapro                                                   |                    |                    | S               | Oral                                     | 10 Mg (10 Mg,L In 1 D),Oral                                                                   |                 | Not Reported |                |
|                                                    | Aspirin (Acetylsalicylic Acid) (81 Milligram, Tablets)    |                    |                    | C               |                                          |                                                                                               |                 | Not Reported |                |
|                                                    | Coq10 (Ubidecarenone) (Ubide,Carenone)                    |                    |                    | C               |                                          |                                                                                               |                 | Not Reported |                |
|                                                    | Folic Acid (Folic Acid)(1 Milligram, Tablets)(Folic Acid) |                    |                    | C               |                                          |                                                                                               |                 | Not Reported |                |
|                                                    | Fish Oil (Fish Oil)(Fish Oil)                             |                    |                    | C               |                                          |                                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2011                                        | 7952280                                                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020465                               |                                                                                               | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypokinesia; Intentional Overdose; Suicide Attempt | Escitalopram Oxalate                                      |                    |                    | S               | Oral                                     | (1 Dosage Forms,Once), Oral                                                                   |                 | Not Reported |                |
|                                                    | Zopiclone                                                 |                    |                    | S               | Oral                                     | (150 Mg,Once),Oral                                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2011                                        | 7905044                                                   | EXPEDITED (15-DAY) | Y                  | HO              | CH-BRISTOL-MYERS SQUIBB COMPANY-15672900 |                                                                                               | 38 YR           | Female       | CHE            |
| <u>Preferred Term</u>                              | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Restlessness; Withdrawal Syndrome       | Abilify                                                   |                    |                    | S               | Oral                                     | Thereafter Dose Reduction To 5 Mg Daily (28sep10-30sep10) And 2.5 Mg Daily (01oct10-08oct10). |                 | Not Reported |                |
|                                                    | Cipralext                                                 |                    |                    | S               | Oral                                     | 22sep-14oct10 20mg                                                                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |                                                                   |              |
|-----------|---|------|-------------------------------------------------------------------|--------------|
| Seroquel  | S | Oral | 15oct10-Ong 25mg                                                  | Not Reported |
| Heroin    | S |      | 1df= 25-200 Mg Daily                                              | Not Reported |
|           |   |      | Heroin 1 G On Two Occasions In A Period From 13sep10-20sep10      |              |
| Cocaine   | S |      |                                                                   | Not Reported |
| Methadone | S | Oral | 22-23sep10 35mg 24-27sep10 50mg 28sep-6oct10 40mg 7oct10-Ong 35mg | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2011              | 7944446       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020240           |                      | 40 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|-------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Aggression; Personality Change; Thinking Abnormal; Weight Increased | Lexapro                                                           |              |            | S           |              | 10 Mg (10 Mg,1 In 1 D)                               |                 | Not Reported |
|                                                                     | Escitalopram Oxalate                                              |              |            | S           |              |                                                      |                 | Not Reported |
|                                                                     | Lexapro                                                           |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D) ; 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                     |                                                                   |              |            |             | Oral         | 10 Mg (10 Mg,1 In 1 D) ; 20 Mg (20 Mg,1 In 1 D),Oral |                 |              |
|                                                                     | Simvastatin (Simvastatin, Simvastatin) (Simvastatin, Simvastatin) |              |            | C           |              |                                                      |                 | Not Reported |
|                                                                     | Cassia (Cinnamomum Verum) (Cinnamomum Verum)                      |              |            | C           |              |                                                      |                 | Not Reported |
|                                                                     | Panadol (Paracetaol) (Paracetamol)                                |              |            | C           |              |                                                      |                 | Not Reported |
|                                                                     | Persaic (Persaic) (Persaic)                                       |              |            | C           |              |                                                      |                 | Not Reported |
|                                                                     | Norvasc                                                           |              |            | C           |              |                                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2011              | 7956981       | EXPEDITED (15-DAY) | Y                  | DS              | 1000020618           |                      | 44 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                           | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|------------------------------------------|-----------------------------|-----------------|--------------|----------------|
| Birth Mark; Drug Interaction; Eye Pain; Hot Flush; Hypertension | Escitalopram Oxalate<br>Tysabri |                    |                    | S               |                                          |                             |                 | Not Reported |                |
|                                                                 |                                 |                    |                    | S               |                                          | (300 Mg,Every 4-6 Weeks)    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2011                                                     | 7957041                         | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020528                               |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Insomnia; Muscle Tightness                            | Escitalopram Oxalate            |                    |                    | S               |                                          |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2011                                                     | 7371518                         | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000013252                               |                             | 79 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                           | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Depressed Level Of Consciousness; Hyponatraemia        | Escitalopram Oxalate            |                    |                    | S               | Oral                                     | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2011                                                     | 7931955                         | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011093619                 |                             | 48 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                 | Xanax                           |                    |                    | S               | Oral                                     | Unk                         |                 | Pfizer       |                |
|                                                                 | Escitalopram Oxalate            |                    |                    | S               | Oral                                     | Unk                         |                 | Not Reported |                |
|                                                                 | Zopiclone                       |                    |                    | S               | Oral                                     | Unk                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                        | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-May-2011                                                     | 7932007                         | EXPEDITED (15-DAY) | N                  | LT              | FR-BRISTOL-MYERS SQUIBB COMPANY-15712201 |                             | 43 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                           | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                               |                                                     |   |      |                                                            |              |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------|---|------|------------------------------------------------------------|--------------|
| Coma; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Status Epilepticus | Abilify                                             | S | Oral | Long Term-20mar11                                          | Not Reported |
|                                                                                               | Escitalopram Oxalate                                | S | Oral | 20mg 1 Df =2 Scored Film-Coated Tabs,Long Term To 20mar11  | Not Reported |
|                                                                                               | Oxazepam                                            | C | Oral | 0.5-0.5-1 From Long Term To 20mar11                        | Not Reported |
|                                                                                               | Valpromide                                          | C | Oral | (1-0-2) From Long Term To 20mar11                          | Not Reported |
|                                                                                               | Phenobarbital                                       | C | Oral | 1 Tab/D,100mg,Unk-28feb11,Then 50mg/D From 01mar11-18mar11 | Not Reported |
|                                                                                               | Keppra                                              | C |      | Film-Coated Tabs Bid From Long Term-20mar11                | Not Reported |
|                                                                                               | Omix                                                | C |      | Omix Lp Sr Caps                                            | Not Reported |
|                                                                                               | Acepromazine\Aceprometazine\Clorazepate Dipotassium | C | Oral | Scored Tab From Long Term To 20-Mar-2011                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-May-2011              | 7947295       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020276           |                      | 19 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|---------------|--------------------------------------------------------------------------------------------|-----------------|--------------|
| Drug Interaction; Overdose; Weight Increased | Escitalopram Oxalate |              |            | S           |               | 30 Mg (10 Mg,3 In 1 D) ;<br>15 Mg (1 N 1 D)<br>30 Mg (10 Mg,3 In 1 D) ;<br>15 Mg (1 N 1 D) |                 | Not Reported |
|                                              | Depo-Provera         |              |            | S           | Intramuscular | 1.6667 Mg (150 Mg,1 In 3 M),Intramuscular                                                  |                 | Not Reported |
|                                              | Risperidone          |              |            | S           | Oral          | 0.5 Mg (0.5 Mg,1 In 1 D),Oral                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 06-May-2011              | 7932530       | EXPEDITED (15-DAY) | Y                  | HO, OT          | TR-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR002933 |                      | 61 YR      | Female     | TUR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                    |                          |   |         |                  |         |              |
|--------------------|--------------------------|---|---------|------------------|---------|--------------|
| Tardive Dyskinesia | Alprazolam               | S | Unknown | 1 Mg, Unknown    | 365 DAY | Par          |
|                    | Risperidone              | S | Unknown | 2 Mg, Qd         |         | Par          |
|                    | Escitalopram Oxalate     | S | Unknown | 20 Mg, Per Day   |         | Not Reported |
|                    | Venlafaxine              | S | Unknown | 300 Mg/D         |         | Not Reported |
|                    | Olanzapine               | S | Unknown | 20 Mg/D          |         | Not Reported |
|                    | Paroxetine Hydrochloride | S | Unknown | Unk, Unknown     |         | Not Reported |
|                    | Mirtazapine              | S | Unknown | 15 G, Unknown    |         | Not Reported |
|                    | Reboxetine               | S | Unknown | 8 Mg, Unknown    |         | Not Reported |
|                    | Lamotrigine              | S | Unknown | 500 Mg, Unknown  |         | Not Reported |
|                    | Tianeptine               | S | Unknown | 12.5 Mg, Unknown |         | Not Reported |
|                    | Sulpiride                | S | Unknown | 200 Mg, Unknown  |         | Not Reported |
|                    | Clozapine                | S | Unknown | 100 Mg, Qd       |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2011              | 7949849       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020287           |                      | 70 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Condition Aggravated;<br>Deafness; Dysgeusia;<br>Insomnia; Night Blindness;<br>Tinnitus; Weight<br>Decreased | Escitalopram Oxalate                     |              |            | S           | Oral         | 5 Mg, Oral         |                 | Not Reported |
|                                                                                                              | Ultrapreventivo X (Multivitamin)         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Mirtazepina Ratiopharma<br>(Mirtazapine) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2011              | 7959256       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020574           |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-May-2011              | 7959695       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020611           |                      | 79 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Erosive Duodenitis;<br>Gastrointestinal<br>Haemorrhage;<br>Generalised Tonic-Clonic<br>Seizure; Haemoglobin<br>Decreased;<br>Hypocalcaemia;<br>Hypoparathyroidism<br>Secondary; International<br>Normalised Ratio<br>Increased; Red Blood Cell<br>Count Decreased; Urinary<br>Tract Infection | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Norfloxacin                         |                    |                    | S               | Oral                 | 800 Mg (400 Mg, 2 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Previscan (Fluindione)              |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D),            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Aspirin                             |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Bisoprolol Fumarate                 |                    |                    | S               | Oral                 | 2.5 Mg (2.5 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Pravastatin Sodium                  |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Levothyroxine Sodium                |                    |                    | S               | Oral                 | 100 Ug (100 Mcg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                               | Inexium (Esomeprazole<br>Magnesium) |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-May-2011                                                                                                                                                                                                                                                                                   | 8348729                             | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000020139           |                                     | 20 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypertension; Intentional<br>Overdose; Pallor; Suicide<br>Attempt                                                                                                                                                                                                                             | Escitalopram Oxalate                |                    |                    | S               | Oral                 | Once, Oral                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                      | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2011                                                                                                                                                                                                                                                                                   | 7696469                             | EXPEDITED (15-DAY) | Y                  | HO              | 1000017086           |                                     | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                         | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration;<br>Hyponatraemia; Malaise                                                                                                                                                                                                                                                        | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2011              | 7904963       | EXPEDITED (15-DAY) | N                  | HO, RI, OT      | S06-USA-01121-01     |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Asthma; Chronic Sinusitis;<br>Drug Intolerance; Dry Eye;<br>Fatigue; Feeling Abnormal;<br>Hypometabolism;<br>Insomnia; Lethargy; Lung<br>Carcinoma Cell Type<br>Unspecified Stage IV;<br>Malaise; Pneumonia;<br>Restlessness;<br>Somnolence; Tension<br>Headache; Tinnitus | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                            | Valium         |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 09-May-2011              | 7936184       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-ASTRAZENECA-<br>2011SE26195 |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>                               | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Screen Positive;<br>Toxicity To Various Agents | Seroquel               |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                     | Cocaine                |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Oxycodone              |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Xanax                  |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Morphine               |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Tch-CooH               |              |            | S           |              |                    |                 | Not Reported |
|                                                     | (Tetrahydrocannabinol) |              |            |             |              |                    |                 |              |
|                                                     | Hydroxyzine            |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Escitalopram Oxalate   |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Ibuprofen              |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Benzodiazepine         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 09-May-2011              | 7936915       | EXPEDITED (15-DAY) | Y                  | HO              | US-ALEXION-<br>A201100045 |                      | 88 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|---------------------------------------|-----------------------------------|-----------------|--------------|----------------|
| Anaemia; Asthenia; Haemorrhoids; Rectal Haemorrhage; Tinnitus                                                           | Soliris                         |                    |                    | S               | Intravenous (not otherwise specified) | 600 Mg, Qwx4                      |                 | Alexion      |                |
|                                                                                                                         | Soliris                         |                    |                    | S               | Intravenous (not otherwise specified) | 900 Mg, Q2w                       |                 | Alexion      |                |
|                                                                                                                         | Lexapro                         |                    |                    | S               | Oral                                  | Unk                               |                 | Not Reported |                |
|                                                                                                                         | Tranxene T-Tab                  |                    |                    | C               | Oral                                  | 7.5 Mg, Tid Prn                   |                 | Not Reported |                |
|                                                                                                                         | Folic Acid                      |                    |                    | C               | Oral                                  | 1 Mg, Qd                          |                 | Not Reported |                |
|                                                                                                                         | Centrum /00554501/              |                    |                    | C               | Oral                                  | Unk                               |                 | Not Reported |                |
|                                                                                                                         | Lipitor                         |                    |                    | C               | Oral                                  | 40 Mg, Qd                         |                 | Not Reported |                |
|                                                                                                                         | Arimidex                        |                    |                    | C               | Oral                                  | 1 Mg, Qd                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2011                                                                                                             | 7951869                         | DIRECT             | N                  | OT              |                                       |                                   | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Brain Injury; Disturbance In Attention; Euphoric Mood; Fatigue; Muscle Twitching; Serum Serotonin Increased; Tremor     | Lexapro                         |                    |                    | S               | Oral                                  | One Per Day Po 2 Or 3 Weeks Twice |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-May-2011                                                                                                             | 7952387                         | EXPEDITED (15-DAY) | Y                  | HO              | 1000020533                            |                                   | 39 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Anxiety; Bladder Dilatation; Depression; Drug Interaction; Social Avoidant Behaviour; Urinary Retention | Escitalopram Oxalate            |                    |                    | S               | Oral                                  | 20 Mg (20 Mg, 1 In 1 D),Oral      |                 | Not Reported |                |
|                                                                                                                         | Abilify                         |                    |                    | S               | Oral                                  | 5 Mg (5 Mg, 1 In 1 D) ,Oral       |                 | Not Reported |                |
|                                                                                                                         | Valdoxan (Agomelatin) (Tablets) |                    |                    | C               |                                       |                                   |                 | Not Reported |                |
|                                                                                                                         | Imovane                         |                    |                    | C               |                                       |                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                |   |              |
|------------------------------------------------|---|--------------|
| (Zopiclone)(Tabl.Ets)(Zopiclone)<br>Xanax      | C | Not Reported |
| (Alprazolam)(Tablets)(Alprazolam)              |   |              |
| Noctran (Noctran) (Tablets)<br>(Noctran)       | C | Not Reported |
| Tercian (Cyamemazine)(Tab<br>Ets)(Cyamemazine) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-May-2011              | 7960586       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000020424           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression;                                                                                                      | Lexapro           |              |            | S           | Oral         | (Once),Oral        |                 | Not Reported |
| Electrocardiogram Qt                                                                                             | Lithium Carbonate |              |            | S           | Oral         | (Once),Oral        |                 | Not Reported |
| Prolonged; Intentional<br>Overdose; Lethargy;<br>Mental Status Changes;<br>Sinus Bradycardia;<br>Suicide Attempt | Alcohol (Ethanol) |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-May-2011              | 7964232       | EXPEDITED (15-DAY) | N                  | HO              | 1000020702           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-May-2011              | 7964928       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020689           |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Maternal Drugs Affecting<br>Foetus; Neonatal<br>Respiratory Distress | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Ventricular  
Septal Defect

| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 10-May-2011                                                                        | 7964948        | EXPEDITED (15-DAY) | N                  | CA              | 1000020694           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Exomphalos; Hernia;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------|-----------------|--------------|----------------|
| 11-May-2011                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 6728114                              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000000353           |                                        |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Anxiety; Apathy;<br>Blood Electrolytes<br>Decreased; Condition<br>Aggravated; Crying;<br>Depression; Disease<br>Recurrence; Eczema;<br>Eyelid Oedema; Fatigue;<br>Feeling Abnormal; Feeling<br>Cold; Food Craving;<br>Hyperphagia;<br>Hypersomnia; Insomnia;<br>Mood Swings; Neutrophil<br>Count Increased; Renal<br>Impairment; Suicidal<br>Ideation; Tear<br>Discolouration; Vomiting;<br>Weight Increased; White<br>Blood Cell Count<br>Increased | Escitalopram Oxalate                 |                    |                    | S               | Oral                 | Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Topamax (Topiramate)<br>(Topiramate) |                    |                    | C               | Oral                 | Oral; 20 Mg (20 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Lithium                              |                    |                    | C               |                      |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|---------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------------|-----------------|--------------|----------------|
| 11-May-2011                                                | 7940752             | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20110501028 |                                     | 55 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypotension; Intentional Overdose; Intentional Self-Injury | Invega              |                    |                    | S               | Oral                  | Unknown Dose Of 6 Mg Tablets        |                 | Not Reported |                |
|                                                            | Ciprallex           |                    |                    | S               | Unknown               |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2011                                                | 7941167             | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011ES38580       |                                     | 68 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia                            | Diovan              |                    |                    | S               | Oral                  | 160 Mg, Unk                         |                 | Novartis     |                |
|                                                            | Ciprallex           |                    |                    | S               | Oral                  | 30 Mg Daily                         |                 | Not Reported |                |
|                                                            | Hydrochlorothiazide |                    |                    | S               | Oral                  | 50 Mg, Unk                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2011                                                | 7954525             | DIRECT             | Y                  | OT              |                       |                                     | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Mydriasis                                                  | Cymbalta            |                    |                    | S               | Oral                  | 1 Tab 30 Mg 1 Tab Qhs Po            |                 | Not Reported |                |
|                                                            | Lexapro             |                    |                    | S               | Oral                  | 1/2 Tab 10 Mg -5 Mg- 1/2 Tab Qhs Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2011                                                | 7955307             | DIRECT             | N                  | HO              |                       |                                     | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Increased; Heart Rate Increased;            | Lexapro             |                    |                    | S               | Oral                  | 5 Mg To Be Increased To             |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Panic Attack; Psychotic Disorder

10 Mg 1 Per Day Po

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-May-2011              | 7966092       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020761           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------------------------|-----------------|--------------|
| Maternal Drugs Affecting Fetus; Neonatal Respiratory Distress Syndrome | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D), Transplacental   |                 | Not Reported |
|                                                                        | Zyprexa              |              |            | S           | Transplacental | 2.5 Mg (2.5 Mg, 1 In 1 D), Transplacental |                 | Not Reported |
|                                                                        | Diazepam             |              |            | C           |                |                                           |                 | Not Reported |
|                                                                        | Folic Acid           |              |            | C           |                |                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-May-2011              | 7943934       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010086429 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Decreased Appetite; Headache; Hot Flush; Hyperhidrosis | Celebrex       |              |            | S           | Oral         | Unk, 1x/Day        |                 | Pfizer       |
|                                                        | Lexapro        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                        | Zolpidem       |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-May-2011              | 7971165       | EXPEDITED (15-DAY) | N                  | OT              | 1000020724           |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Impaired Driving Ability; Sedation; Somnolence | Lexapro                   |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                | Norco (Vicodin) (Vicodin) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2011              | 7675654       | EXPEDITED (15-DAY) | N                  | HO, OT          | PHHY2010BR75692      |                      |            | Male       | BRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>        |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------|-----------------------------------------------|-----------------|-------------------|----------------|
| Cerebrovascular Accident;<br>Depression; Shock                                                                                             | Diovan Hct              |                    |                    | S               |                                    | 320 Mg Valsartan /25mg<br>Hydrochlorothiazide |                 | Novartis          |                |
|                                                                                                                                            | Lexapro                 |                    |                    | S               |                                    | 10 Mg, Unk                                    |                 | Not Reported      |                |
|                                                                                                                                            | Trileptal               |                    |                    | C               |                                    | 600 Mg, Unk                                   |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 16-May-2011                                                                                                                                | 7960362                 | DIRECT             | Y                  | OT              |                                    |                                               | 13 YR           | Female            | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>        |                |
| Disease Recurrence;<br>Suicidal Ideation                                                                                                   | Lexapro                 |                    |                    | S               | Oral                               | 10 Mg Qd Po                                   |                 | Forest            |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 17-May-2011                                                                                                                                | 7660983                 | EXPEDITED (15-DAY) | N                  | OT              |                                    | US-RB-016370-10                               | 36 YR           | Male              | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>        |                |
| Diabetes Mellitus; Drug<br>Dependence; Drug<br>Withdrawal Syndrome;<br>Insomnia; Overdose; Self-<br>Injurious Ideation;<br>Substance Abuse | Suboxone                |                    |                    | S               | Sublingual                         |                                               |                 | Reckitt Benckiser |                |
|                                                                                                                                            | Suboxone                |                    |                    | S               | Sublingual                         | Sublingual Film                               |                 | Reckitt Benckiser |                |
|                                                                                                                                            | Lexapro                 |                    |                    | S               | Oral                               | Dosing Information<br>Unknown                 |                 | Not Reported      |                |
|                                                                                                                                            | Abilify                 |                    |                    | C               | Unknown                            |                                               |                 | Not Reported      |                |
|                                                                                                                                            | Metformin Hydrochloride |                    |                    | C               | Unknown                            | Dosing Information<br>Unknown                 |                 | Not Reported      |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>        | <u>Country</u> |
| 17-May-2011                                                                                                                                | 7948471                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-SANOFI-AVENTIS-<br>2011SA029640 |                                               | 84 YR           | Male              | FRA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>        |                |
| Condition Aggravated;<br>Hyponatraemia;<br>Somnolence                                                                                      | Fludex (Indapamide)     |                    |                    | S               | Oral                               |                                               |                 | Not Reported      |                |
|                                                                                                                                            | Effexor                 |                    |                    | S               | Oral                               |                                               |                 | Not Reported      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                             |   |      |              |
|--|-----------------------------|---|------|--------------|
|  | Escitalopram Oxalate        | S | Oral | Not Reported |
|  | Escitalopram Oxalate        | S | Oral | Not Reported |
|  | Esomeprazole Magnesium      | S | Oral | Not Reported |
|  | Doxazosin                   | C |      | Not Reported |
|  | Pravastatin                 | C |      | Not Reported |
|  | Avodart                     | C |      | Not Reported |
|  | Trimetazidine Hydrochloride | C |      | Not Reported |
|  | Foradil                     | C |      | Not Reported |
|  | Spiriva                     | C |      | Not Reported |
|  | Domperidone                 | C |      | Not Reported |
|  | Mianserin Hydrochloride     | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2011              | 7975243       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020817           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Blood Calcium Decreased;<br>Mouth Ulceration | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                              |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2011              | 7975259       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020818           |                      | 22 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Increased Tendency To<br>Bruise; Vaginal<br>Haemorrhage | Escitalopram Oxalate             |              |            | S           |              |                    |                 | Not Reported |
|                                                         | Cox-2 Inhibitor (Cox-2) (-Cox-2) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2011              | 7975619       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020790           |                      | 84 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|                       |                |              |            |             |              |                    |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                    |                            |   |      |                                      |              |
|------------------------------------|----------------------------|---|------|--------------------------------------|--------------|
| Drug Interaction;<br>Hyponatraemia | Escitalopram Oxalate       | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     | Not Reported |
|                                    | Escitalopram Oxalate       | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     | Not Reported |
|                                    | Effexor                    | S | Oral | 37.5 Mg (37.5 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                    | Fludex (Indapamide)        | S | Oral | 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Oral   | Not Reported |
|                                    | Inexium (Esomeprazole)     | S | Oral | 40 Mg (40 Mg, 1 In 1 D),<br>Oral     | Not Reported |
|                                    | Erythromycin               | C |      |                                      | Not Reported |
|                                    | Macrolides (Macrolides)    | C |      |                                      | Not Reported |
|                                    | Pravastatin                | C |      |                                      | Not Reported |
|                                    | Zoxan (Doxazosin Mesilate) | C |      |                                      | Not Reported |
|                                    | Avodart                    | C |      |                                      | Not Reported |
|                                    | Vastarel                   | C |      |                                      | Not Reported |
|                                    | Foradil                    | C |      |                                      | Not Reported |
|                                    | Spiriva                    | C |      |                                      | Not Reported |
|                                    | Biperidys (Domperidone)    | C |      |                                      | Not Reported |
|                                    | Atorvastatin Calcium       | C |      |                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-May-2011              | 7976222       | EXPEDITED (15-DAY) | Y                  | OT              | 2011SP020484         |                      | 9 YR       | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|-----------------------------|--------------------|-----------------|--------------|
| Aggression            | Nasonex        |              |            | S           | Respiratory<br>(inhalation) | Inh                |                 | Not Reported |
|                       | Asmanex        |              |            | S           |                             |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |                             |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2011              | 7865627       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000018954           |                      | 31 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cyclic Neutropenia    | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dianette (Cyproterone Acetate,  
Ethinylestradiol)(Cyproterone  
Acetate, Ethinylestradiol)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2011              | 7981377       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020921           |                      | 68 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Hyponatraemia         | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (15 Mg,2 In 1 D),Oral    |                 | Not Reported |
|                       | Hydrochlorothiazide  |              |            | S           | Oral         | 50 Mg (50 Mg, 1 In 1 D),Oral   |                 | Not Reported |
|                       | Diovan               |              |            | S           | Oral         | 160 Mg (160 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       | Atenolol             |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-May-2011              | 7985424       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2011SP021824         |                      | 22 YR      | Female     | NOR            |

| <u>Preferred Term</u>                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Dehydration; Fluid Intake<br>Reduced; Hyponatraemia;<br>Hypophagia; Pericarditis | Mirtazapine    |              |            | S           | Oral         | 15 Mg Po           |                 | Not Reported |
|                                                                                                     | Ciprallex      |              |            | S           | Oral         | 5 Mg Po            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2011              | 7889089       | EXPEDITED (15-DAY) | Y                  | DE              | 1000019160           |                      | 76 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                              | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------------|-----------------|--------------|
| Cerebral Haemorrhage;<br>Depressed Level Of<br>Consciousness; Dizziness;<br>Drug Interaction; Fall;<br>Hypotension; Nausea;<br>Skin Laceration; Urinary | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),Oral,<br>10 Mg (10 Mg, 1 In<br>11d),Oral, 20 Mg (20 Mg, 1<br>In 11d),Oral |                 | Not Reported |
|                                                                                                                                                         |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),Oral,<br>10 Mg (10 Mg, 1 In                                               |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |                                                            |   |      |      |                                                                                        |              |
|-----------------|------------------------------------------------------------|---|------|------|----------------------------------------------------------------------------------------|--------------|
| Tract Infection |                                                            |   |      |      | 11d),Oral, 20 Mg (20 Mg, 1 In 11d),Oral                                                |              |
|                 |                                                            |   |      | Oral | 5 Mg (5 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 11d),Oral, 20 Mg (20 Mg, 1 In 11d),Oral |              |
|                 | Keppra                                                     | S | Oral |      | 1000 Mg (1000 Mg,1 In 1 D),Oral                                                        | Not Reported |
|                 | Bisoprolol Fumarate                                        | S | Oral |      | 5 Mg (5 Mg, 1 In 1 D) , Oral, For A Long Time                                          | Not Reported |
|                 | Torseamide                                                 | S | Oral |      | 10 Mg (10 Mg, 1 In 1 D), Oral, For A Long Time                                         | Not Reported |
|                 | Aspirin                                                    | S |      |      | 100 Mg (100 Mg,1 In 1 D),Oral For A Longer Time                                        | Not Reported |
|                 | Pantozol (Pantoprazole Sodium)                             | C |      |      |                                                                                        | Not Reported |
|                 | Mcp                                                        | C |      |      |                                                                                        | Not Reported |
|                 | Ferro Sanol (Ferrous Sulfate) (Capsules) (Ferrous Sulfate) | C |      |      |                                                                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-May-2011              | 7966078       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020767           |                      | 30 YR      | Male       | DNK            |

| <u>Preferred Term</u>                               | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|--------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Aggression;<br>Hyperthyroidism; Weight<br>Decreased | Escitalopram Oxalate                                         |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                     | Seroquel (Quetiapine Fumarate)(Tablets)(Quetiapine Fumarate) |              |            | C           |              |                              |                 | Not Reported |
|                                                     | Camcolit (Lithium Carbonate) (Tablets)(Lithium Carbonate)    |              |            | C           |              |                              |                 | Not Reported |
|                                                     | Abilify (Aripiprazole)(Tablets)(Aripiprazole)                |              |            | C           |              |                              |                 | Not Reported |
|                                                     | Lithium (Lithium) (Tablets) (Lithium)                        |              |            | C           |              |                              |                 | Not Reported |
|                                                     | Zyprexa                                                      |              |            | C           |              |                              |                 | Not Reported |
|                                                     |                                                              |              |            |             |              |                              |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------|-----------------------|-----------------|--------------|----------------|
| 23-May-2011                                                                | 7891489                  | EXPEDITED (15-DAY) | Y                  | DS, HO, LT, OT  | AU-PFIZER INC-2011068790        |                       | 44 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury                                                        | Pristiq Extended Release |                    |                    | S               | Oral                            | 50 Mg, 1x/Day         | 16 DAY          | Pfizer       |                |
|                                                                            | Lexapro                  |                    |                    | S               | Oral                            | 20 Mg, Unk            | 46 DAY          | Not Reported |                |
|                                                                            | Karvezide                |                    |                    | C               | Oral                            | 12.5 Mg/150mg, 1x/Day |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2011                                                                | 7906599                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | HR-PFIZER INC-2011082006        |                       | 41 YR           | Female       | HRV            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Flushing; Hypersensitivity; Suffocation Feeling; Tongue Oedema | Sertraline Hydrochloride |                    |                    | S               |                                 | 25 Mg, Single         |                 | Pfizer       |                |
|                                                                            | Sertraline Hydrochloride |                    |                    | S               |                                 |                       |                 | Pfizer       |                |
|                                                                            | Escitalopram Oxalate     |                    |                    | S               |                                 | 5 Mg, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2011                                                                | 7955154                  | EXPEDITED (15-DAY) | Y                  | OT              | IT-EISAI INC-E3810-04676-SPO-IT |                       | 69 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Intentional Self-Injury; Sopor                       | Pariet (Rabeprazole)     |                    |                    | S               | Oral                            | Unknown               |                 | Not Reported |                |
|                                                                            | Ciprallex                |                    |                    | S               | Oral                            |                       |                 | Not Reported |                |
|                                                                            | Flurazepam Hydrochloride |                    |                    | S               |                                 |                       |                 | Not Reported |                |
|                                                                            | Promazine Hydrochloride  |                    |                    | S               | Oral                            |                       |                 | Not Reported |                |
|                                                                            | Tavor (Lorazepam)        |                    |                    | S               | Oral                            |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2011                                                                | 7955737                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-MERCK-1105USA02948           |                       | 79 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                        |   |         |                         |       |              |
|---------------------------------------------------|------------------------|---|---------|-------------------------|-------|--------------|
| International Normalised Ratio Increased; Melaena | Noroxin                | S | Oral    |                         | 4 DAY | Merck        |
|                                                   | Escitalopram Oxalate   | S | Oral    |                         |       | Not Reported |
|                                                   | Previscan (Fluindione) | S | Oral    | 3/4-1/4 (1 Dosage Form) |       | Not Reported |
|                                                   | Aspirin                | S | Oral    |                         |       | Not Reported |
|                                                   | Bisoprolol Fumarate    | S | Unknown |                         |       | Not Reported |
|                                                   | Pravastatin Sodium     | S | Oral    |                         |       | Not Reported |
|                                                   | Levothyrox             | S | Oral    |                         |       | Not Reported |
|                                                   | Inexium                | C | Oral    |                         |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2011              | 7957223       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020580           |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Gynaecomastia         | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Pravastatin          |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2011              | 7986892       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2011MA005626         |                      | 21 YR      | Female     | AUS            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged;<br>Electrocardiogram T Wave Inversion; Overdose;<br>Serotonin Syndrome;<br>Toxicity To Various Agents | Tramadol Hydrochloride    |              |            | S           |              | 3 Gr;              |                 | Purepac      |
|                                                                                                                                       | Quetiapine Fumarate       |              |            | S           |              | 15 G;              |                 | Not Reported |
|                                                                                                                                       | Escitalopram Oxalate      |              |            | S           |              | 560 Mg;            |                 | Not Reported |
|                                                                                                                                       | Mirtazapine (Mirtazapine) |              |            | S           |              | 315 Mg;            |                 | Not Reported |
|                                                                                                                                       | Fluoxetine                |              |            | S           |              | 1.1 G;             |                 | Not Reported |
|                                                                                                                                       | Risperidone (Risperidone) |              |            | S           |              | 120 Mg;            |                 | Not Reported |
|                                                                                                                                       | Lithium (Lithium)         |              |            | S           |              | 13 G;              |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|--------------|----------------|
| 23-May-2011                                                                                                                                                                                                                                           | 7997917                 | NON-EXPEDITED      | N                  | OT              | DSA_44810_2011               |                         | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;<br>Drug Interaction; Tinnitus;<br>Tremor; Urinary Tract<br>Infection                                                                                                                                                        | Aplenzin                |                    |                    | S               | Oral                         | (348 Mg Qd Oral)        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Lexapro                 |                    |                    | S               | Oral                         | (40 Mg Qd Oral)         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Trazodone Hydrochloride |                    |                    | C               |                              |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Oxycodone               |                    |                    | C               |                              |                         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Xanax                   |                    |                    | C               |                              |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                                                                                                                                                                                                                           | 7238457                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | AU-PFIZER INC-<br>2009290743 |                         | 29 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Bradyphrenia;<br>Crying; Dizziness; Drug<br>Ineffective; Dyspnoea;<br>Fatigue; Generalised<br>Tonic-Clonic Seizure;<br>Headache; Hyperreflexia;<br>Nausea; Pain; Pyrexia;<br>Respiratory Arrest;<br>Seizure; Somnolence;<br>Syncope; Tremor | Lyrica                  |                    |                    | S               | Oral                         | 300 Mg, 2x/Day          |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                       | Lyrica                  |                    |                    | S               | Oral                         | 150 Mg, 2x/Day          |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                       | Tramadol Hydrochloride  |                    |                    | S               | Oral                         | 150 Mg, 2x/Day          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Escitalopram Oxalate    |                    |                    | S               | Oral                         | 20 Mg, 1x/Day Nocte     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Oxycontin               |                    |                    | C               | Oral                         | 20 Mg, 1x/Day Nocte     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Diazepam                |                    |                    | C               | Oral                         | 5 Mg, 3x/Day            |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Temazepam               |                    |                    | C               | Oral                         | 10 Mg, Nocte As Needed  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Oxynorm                 |                    |                    | C               | Oral                         | 10 Mg, 2x/Day As Needed |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Codeine Phosphate       |                    |                    | C               |                              | 1 3x/Day                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Paracetamol             |                    |                    | C               |                              | 500 Mg, 3x/Day          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                                                                                                                                                                                                                           | 7843684                 | EXPEDITED (15-DAY) | Y                  | DE, HO, LT      | CA-ROCHE-763039              |                         | 43 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Hypotension; Hypoxia;                                                                                                                                                                                                              | Clonazepam              |                    |                    | S               | Unknown                      |                         |                 | Roche        |                |

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|                      |                           |   |         |              |              |
|----------------------|---------------------------|---|---------|--------------|--------------|
| Intentional Overdose | Clonazepam                | S | Unknown | Overdose     | Roche        |
|                      | Apixaban                  | S | Oral    |              | Not Reported |
|                      | Warfarin Sodium           | S | Oral    |              | Not Reported |
|                      | Ativan                    | S | Unknown | As Necessary | Not Reported |
|                      | Ativan                    | S | Unknown | Overdose     | Not Reported |
|                      | Cipralex                  | S | Unknown |              | Not Reported |
|                      | Metoprolol                | S | Unknown |              | Not Reported |
|                      | Metoprolol                | S | Unknown | Overdose     | Not Reported |
|                      | Propafenone Hydrochloride | S | Unknown |              | Not Reported |
|                      | Propafenone Hydrochloride | S | Unknown | Overdose     | Not Reported |
|                      | Metformin Hydrochloride   | C |         |              | Not Reported |
|                      | Gliclazide                | C |         |              | Not Reported |
|                      | Ezetrol                   | C |         |              | Not Reported |
|                      | Venlafaxine Hydrochloride | C |         |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 24-May-2011              | 7872047       | EXPEDITED (15-DAY) | N                  | OT              | BR-PFIZER INC-BR-WYE-H15150010 |                      | 44 YR      | Female     | BRA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Body Mass Index Increased; Fluid Retention; Swelling; Weight Decreased; Weight Fluctuation; Weight Increased; Weight Loss Poor | Pristiq Extended Release                                       |              |            | S           | Oral         | 50 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                                                | Pristiq Extended Release                                       |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                                                                | Lexapro                                                        |              |            | S           |              | 10 Mg, 1x/Day      | 666 DAY         | Not Reported |
|                                                                                                                                | Euthyrox                                                       |              |            | C           | Oral         | 100 Ug, 1x/Day     |                 | Not Reported |
|                                                                                                                                | Pariet                                                         |              |            | C           |              | 20 Mg, 1x/Day      | 91 DAY          | Not Reported |
|                                                                                                                                | Cellulase\Dehydrocholic Acid\Metoclopramide\Pancreatin \Pepsin |              |            | C           |              | 1 Df, 1x/Day       | 30 DAY          | Not Reported |
|                                                                                                                                | Cellulase\Dehydrocholic Acid\Metoclopramide\Pancreatin \Pepsin |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                | Pantoprazole                                                   |              |            | C           |              | 40 Mg, 1x/Day      | 91 DAY          | Not Reported |
|                                                                                                                                | Lorazepam                                                      |              |            | C           |              | 1 Mg, Weekly       |                 | Not Reported |
|                                                                                                                                | Fluconazole                                                    |              |            | C           |              | 150 Mg, 1x/Day     |                 | Not Reported |

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|  |                                    |   |                      |        |              |
|--|------------------------------------|---|----------------------|--------|--------------|
|  | Celebrex                           | C | 200 Mg, Occasionally |        | Not Reported |
|  | Levocetirizine                     | C | 1 Df, 1x/Day         | 15 DAY | Not Reported |
|  | Biofenac (Diclofenac Diethylamine) | C | 75 Mg, 1x/Day        | 7 DAY  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------|-----------------|--------------|----------------|
| 24-May-2011              | 7933763                  | EXPEDITED (15-DAY) | Y                  | HO              | DE-WATSON-2011-06067 |                                   | 76 YR           | Male         | DEU            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Mania                    | Galantamine Hydrobromide |                    |                    | S               | Unknown              | 8 -16 Mg, Then Increased To 16 Mg |                 | Watson       |                |
|                          | Escitalopram Oxalate     |                    |                    | S               |                      |                                   |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|------------------------|------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 24-May-2011                | 7943440                | NON-EXPEDITED    | Y                  | DE              | US-JNJFOC-20110505289 |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents | Ibuprofen              |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Oxycodone              |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Cocaine                |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Morphine               |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Unspecified Ingredient |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Hydroxyzine            |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Escitalopram Oxalate   |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Quetiapine             |                  |                    | S               |                       |                      |                 | Not Reported |                |
|                            | Unspecified Ingredient |                  |                    | S               |                       |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 24-May-2011                                               | 7958842              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | US-ROXANE LABORATORIES, INC.-2011-RO-00687RO |                      | 33 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Overdose; Suicide Attempt | Lithium Carbonate    |                    |                    | S               | Oral                                         |                      |                 | Roxane       |                |
|                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |

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| Alcohol                                                                                                           |                          |                    | S                  |                 | Oral                 |                          |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                                                                                       | 7977416                  | DIRECT             | N                  | DE              |                      |                          | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Depression; Drug<br>Ineffective; Gun Shot<br>Wound; Insomnia; Product<br>Substitution Issue | Lexapro                  |                    |                    | S               | Oral                 | 10 Mg 2 Per Day Oral     |                 | Forest       |                |
|                                                                                                                   | Levaquin                 |                    |                    | S               | Oral                 | 500mg 1 Per Day Oral     |                 | Janssen      |                |
|                                                                                                                   | Ciprofloxacin            |                    |                    | S               |                      |                          |                 | Cobalt       |                |
|                                                                                                                   | Bactrin                  |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Doxycycline              |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Levaquin                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Zolpidem                 |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Flomax                   |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Actos                    |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Amlodipine               |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Benazepril Hydrochloride |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Crestor                  |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Metformin Hydrochloride  |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Docusate Sodium          |                    |                    | C               |                      |                          |                 | Not Reported |                |
|                                                                                                                   | Ibuprofen                |                    |                    | C               |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                                                                                       | 7987451                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021021           |                          |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                         | Escitalopram Oxalate     |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D), |                 | Not Reported |                |
|                                                                                                                   |                          |                    |                    |                 | Oral                 | Oral; Oral               |                 |              |                |
|                                                                                                                   |                          |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D), | 2 YR            |              |                |
|                                                                                                                   | Prazepam                 |                    |                    | C               |                      | Oral; Oral               |                 |              |                |
|                                                                                                                   |                          |                    |                    |                 |                      |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                                                                                       | 7987497                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000021065           |                          | 70 YR           | Female       | DNK            |

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| <u>Preferred Term</u>                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|
| Tubulointerstitial Nephritis                            | Escitalopram Oxalate                                          |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |
|                                                         | Tahor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium) |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         | Prazepam                                                      |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         | Tardyferon (Ferrous Sulfate) (Ferrous Sulfate)                |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         | 1-Alpha (Alfacalcidol) (Alfacalcidol)                         |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         | Kenzen (Candesartan Cilexetil) (Candesartan Cilexetil)        |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         |                                                               |                    |                    |                 |                      |                                         |                 |              |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2011                                             | 7989315                                                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020974           |                                         | 41 YR           | Male         | USA            |
|                                                         |                                                               |                    |                    |                 |                      |                                         |                 |              |                |
| <u>Preferred Term</u>                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Depression; Drug Interaction; Suicidal Ideation | Lexapro                                                       |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |
|                                                         | Fentanyl Patches                                              |                    |                    | S               | Transdermal          | Transdermal                             |                 | Not Reported |                |
|                                                         | Oxycodone (Oxycodone)                                         |                    |                    | C               |                      |                                         |                 | Not Reported |                |
|                                                         |                                                               |                    |                    |                 |                      |                                         |                 |              |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2011                                             | 7765575                                                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000017837           |                                         | 87 YR           | Male         | DNK            |
|                                                         |                                                               |                    |                    |                 |                      |                                         |                 |              |                |
| <u>Preferred Term</u>                                   | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Failure; Pancytopenia                       | Escitalopram Oxalate                                          |                    |                    | S               | Oral                 | 5 Mg, As Required, Oral                 |                 | Not Reported |                |
|                                                         | Ramipril                                                      |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D)                 |                 | Not Reported |                |
|                                                         | Nifedipine                                                    |                    |                    | S               | Oral                 | 30 Mg (3 Mg, 1 In 1 D), Oral            |                 | Not Reported |                |
|                                                         | Inipomp                                                       |                    |                    | S               | Oral                 | 40 Mg, Oral                             |                 | Not Reported |                |
|                                                         | Acetaminophen                                                 |                    |                    | S               | Oral                 | 3 Gram (1 Gm, 3 In 1 D), Oral           |                 | Not Reported |                |
|                                                         | Diclofenac Sodium                                             |                    |                    | S               | Cutaneous            | 1 Dosage Forms, As Required), Cutaneous |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2011              | 7856111       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000018857           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Adjustment Disorder;<br>Cardiac Arrest; Condition<br>Aggravated; Decreased<br>Appetite; Depressed Level<br>Of Consciousness;<br>Hypotension; Hypoxia;<br>Intentional Overdose;<br>Psychiatric Symptom;<br>Restlessness; Stress;<br>Suicide Attempt | Escitalopram Oxalate      |              |            | S           | Oral         | Oral; 30 Mg, Oral; Once,<br>Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                    |                           |              |            |             | Oral         | Oral; 30 Mg, Oral; Once,<br>Oral   |                 |              |
|                                                                                                                                                                                                                                                    | Apixaban                  |              |            | S           | Oral         | Oral                               |                 | Not Reported |
|                                                                                                                                                                                                                                                    |                           |              |            |             | Oral         | Oral                               |                 |              |
|                                                                                                                                                                                                                                                    | Ativan                    |              |            | S           |              | 1 Mg, As Required); Once           |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Clonazepam                |              |            | S           |              | 1.5 Mg (0.5 Mg, 3 In 1 D);<br>Once |                 | Not Reported |
|                                                                                                                                                                                                                                                    |                           |              |            |             |              | 1.5 Mg (0.5 Mg, 3 In 1 D);<br>Once |                 |              |
|                                                                                                                                                                                                                                                    | Metoprolol Tartrate       |              |            | S           |              | 100 Mg (50 Mg, 2 In 1 D);<br>Once  |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Propafenone Hydrochloride |              |            | S           |              | 450 Mg (150 Mg, 3 In 1 D);<br>Once |                 | Not Reported |
|                                                                                                                                                                                                                                                    |                           |              |            |             |              | 450 Mg (150 Mg, 3 In 1 D);<br>Once |                 |              |
|                                                                                                                                                                                                                                                    | Metformin Hydrochloride   |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Gliclazide                |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Effexor                   |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Vitamin D Nos             |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                    | Warfarin Sodium           |              |            | S           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 25-May-2011              | 7942433       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-<br>2011SE27587 |                      | 84 YR      | Male       | FRA            |

| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia;<br>Somnolence | Effexor              |              |            | S           | Oral         |                    | 26 DAY          | Not Reported |
|                                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    | 3 DAY           | Not Reported |
|                                                   | Escitalopram Oxalate |              |            | S           | Oral         |                    | 10 DAY          | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |      |        |              |
|-------------------------|---|------|--------|--------------|
| Fludex (Indapamide)     | S | Oral | 19 DAY | Not Reported |
| Ciprofloxacin           | C |      |        | Not Reported |
| Mianserin Hydrochloride | C |      |        | Not Reported |
| Avodart                 | C |      |        | Not Reported |
| Vastarel                | C |      |        | Not Reported |
| Foradil                 | C |      |        | Not Reported |
| Spiriva                 | C |      |        | Not Reported |
| Domperidone             | C |      |        | Not Reported |
| Pravastatin             | C |      |        | Not Reported |
| Inexium                 | S | Oral |        | Astrazeneca  |
| Erythromycin            | S |      |        | Not Reported |
| Tahor                   | S |      |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 25-May-2011              | 7960557                              | EXPEDITED (15-DAY) | N                  | DS, HO, LT, OT  | GR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15750904 |                      | 36 YR           | Female       | GRC            |
| <u>Preferred Term</u>    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Cholestatic    | Captopril And<br>Hydrochlorothiazide |                    |                    | S               | Oral                                            | Tab                  |                 | Apothecon    |                |
|                          | Cipraxel                             |                    |                    | S               | Oral                                            | Tab;1df=1/Litre      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 25-May-2011              | 7975237              | EXPEDITED (15-DAY) | Y                  | HO              | 1000020816           |                      | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased; | Escitalopram Oxalate |                    |                    | S               | Oral                 | (10 Mg), Oral        |                 | Not Reported |                |
| Hepatic Steatosis;       | Chloramphenicol      |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| Hepatitis Cholestatic;   | Neurontin            |                    |                    | S               |                      | (300 Mg),Oral        |                 | Not Reported |                |
| Hepatosplenomegaly;      |                      |                    |                    |                 |                      |                      |                 |              |                |
| Platelet Count Decreased |                      |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-May-2011              | 7991529        | EXPEDITED (15-DAY) | Y                  | LT              | 1000020992           |                      |                 | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                           |                                                                      |   |                         |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|---|-------------------------|--------------|
| Aggression; Anxiety;<br>Decreased Appetite;<br>Dysgeusia; Emotional<br>Disorder; Feeling<br>Abnormal; Insomnia;<br>Suicidal Ideation; Weight<br>Decreased | Escitalopram Oxalate                                                 | S | 20 Mg (20 Mg, 1 In 1 D) | Not Reported |
|                                                                                                                                                           | Propavan (Propiomazine<br>Maleate)(Tablets)(Propiomazine<br>Maleate) | C |                         | Not Reported |
|                                                                                                                                                           | Stilnoct (Zolpidem<br>Tartrate)(Tablets)(Zolpidem<br>Tartrate)       | C |                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-May-2011              | 7991677       | EXPEDITED (15-DAY) | Y                  | OT              | 1000021001           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-----------------------------------------------------------------------------------------|-----------------|--------------|
| Crying; Drug Withdrawal<br>Syndrome Neonatal;<br>Maternal Drugs Affecting<br>Foetus | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental; 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |
|                                                                                     |                      |              |            |             | Transplacental | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental; 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2011              | 7743901       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017482           |                      | 35 YR      | Female     | DNK            |

| <u>Preferred Term</u>                  | <u>Product</u>                                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Maternal Exposure During<br>Pregnancy; | Escitalopram Oxalate                                                                           |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
| Oligohydramnios;<br>Pregnancy          | Cymbalta                                                                                       |              |            | S           | Oral         | 60 Mg (60 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                        | Yasminelle (Drospirenone,<br>Ethinyl Estradiol) (Tablets)<br>(Drospirenone, Ethinyl Estradiol) |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2011              | 7743907       | EXPEDITED (15-DAY) | Y                  | CA              | 1000017492           |                      |            | Unknown    | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                             | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------------------|-----------------|--------------|----------------|
| Amniotic Fluid Volume Decreased; Caesarean Section; Maternal Exposure During Pregnancy; Pregnancy | Escitalopram Oxalate                                                           |                    |                    | S               | Transplacental            | 20 Mg (20 Mg,1 In 1 D),Transplacental  |                 | Not Reported |                |
|                                                                                                   | Cymbalta                                                                       |                    |                    | S               | Transplacental            | 60 Mg (60 Mg, 1 In 1 D),Transplacental |                 | Not Reported |                |
|                                                                                                   | Yasminelle (Drospirenone, Ethinyl Estradiol) (Drospirenone, Ethinyl Estradiol) |                    |                    | C               |                           |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2011                                                                                       | 7963155                                                                        | NON-EXPEDITED      | N                  |                 | US-MYLANLABS-2010S1011986 |                                        | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite; Headache; Hot Flush; Hyperhidrosis                                            | Zolpidem Tartrate                                                              |                    |                    | S               | Oral                      |                                        |                 | Not Reported |                |
|                                                                                                   | Lexapro                                                                        |                    |                    | S               | Oral                      |                                        |                 | Alphapharm   |                |
|                                                                                                   | Celebrex                                                                       |                    |                    | S               |                           |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                          | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-May-2011                                                                                       | 7990247                                                                        | EXPEDITED (15-DAY) | Y                  | LT              | 1000021067                |                                        | 64 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                                | Escitalopram Oxalate                                                           |                    |                    | S               | Oral                      | Oral                                   |                 | Not Reported |                |
|                                                                                                   | Methylene Blue                                                                 |                    |                    | S               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Alendronic Acid (Alendronic Acid) (Alendronic Acid)                            |                    |                    | C               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Atorvastatin (Atorvastatin) (Atorvastatin)                                     |                    |                    | C               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Dihydrocodeine (Dihydrocodeine) (Dihydrocodeine)                               |                    |                    | C               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Felodipine (Felodipine) (Felodipne)                                            |                    |                    | C               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Gaviscon (Gaviscon /00237601/) (Gaviscon /00237601/)                           |                    |                    | C               |                           |                                        |                 | Not Reported |                |
|                                                                                                   | Losartin (Losartan Potassium)                                                  |                    |                    | C               |                           |                                        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |              |
|--------------------------------|---|--------------|
| (Losartan Potassium)           |   |              |
| Metformin Hydrochloride        | C | Not Reported |
| Omeprazole                     | C | Not Reported |
| Paracetamol (Paracetamol)      | C | Not Reported |
| (Paracetamol)                  |   |              |
| Salbutamol (Salbutamol )       | C | Not Reported |
| (Salbutamol)                   |   |              |
| Seretide (Seretide /01420901/) | C | Not Reported |
| (Seretide /01420901/)          |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-May-2011              | 7993837       | EXPEDITED (15-DAY) | Y                  | HO              | DSA_46713_2011       |                      | 82 YR      | Female     | SWE            |

| <u>Preferred Term</u>                                                   | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Fatigue; General Physical Health Deterioration; Hyponatraemia | Enalapril Maleate |              |            | S           | Oral         | (5 Mg Qd Oral)     |                 | Not Reported |
|                                                                         | Ciprallex         |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                         | Pamol             |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Acetylcysteine    |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Zolpidem Tartrate |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Ipramol           |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Cocillana-Etyfin  |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Diazepam          |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Fenantoin         |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Imovane           |              |            | C           |              |                    |                 | Not Reported |
|                                                                         | Diazepan          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2011              | 7815615       | EXPEDITED (15-DAY) | N                  | DE, HO, LT, OT  | B0699992A            |                      | 42 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|-----------------|
| Cardiac Arrest; Decreased Appetite; Depressed Level Of Consciousness; Hypotension; Hypoxia; Mental Disorder; Mental Impairment; Overdose; Suicidal Ideation; Suicide Attempt | Rythmol             |              |            | S           | Unknown      | 150mg Three Times Per Day |                 | Glaxosmithkline |
|                                                                                                                                                                              | Ciprallex           |              |            | S           | Oral         | 30mg Per Day              |                 | Not Reported    |
|                                                                                                                                                                              | Metoprolol Tartrate |              |            | S           | Unknown      | 50mg Twice Per Day        |                 | Not Reported    |
|                                                                                                                                                                              | Clonazepam          |              |            | S           | Unknown      | .5mg Three Times Per Day  |                 | Glaxosmithkline |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |         |                   |         |                 |
|---------------------------|---|---------|-------------------|---------|-----------------|
| Ativan                    | S | Unknown | 1mg As Required   |         | Not Reported    |
| Placebo                   | S | Oral    |                   |         | Glaxosmithkline |
| Warfarin Sodium           | S | Oral    | 7mg Per Day       |         | Glaxosmithkline |
| Apixaban                  | S | Oral    | 5mg Twice Per Day | 497 DAY | Not Reported    |
| Metformin Hydrochloride   | C |         |                   |         | Glaxosmithkline |
| Gliclazide                | C |         |                   |         | Not Reported    |
| Ezetimibe                 | C |         |                   |         | Glaxosmithkline |
| Venlafaxine Hydrochloride | C |         |                   |         | Glaxosmithkline |
| Vitamin D Nos             | C |         |                   |         | Not Reported    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2011              | 7892725       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019334           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                         | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Anger; Anxiety; Bruxism;<br>Depressed Mood;                                                                                                                                         | Escitalopram Oxalate                    |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
| Dyskinesia; Emotional<br>Disorder; Headache;<br>Impulsive Behaviour;<br>Insomnia; Irritability; Loss<br>Of Libido; Paranoia;<br>Sedation; Sexual<br>Dysfunction; Suicidal<br>Ideation; Withdrawal<br>Syndrome | Escitalopram Oxalate                    |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                               | Prozac (Fluoxetine) (Fluoxetine)        |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                               | Duloxetine (Duloxetine)<br>(Duloxetine) |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                                                                                                                               | Sertraline (Sertraline)<br>(Sertraline) |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2011              | 7924371       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019785           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aortic Valve Incompetence | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
|                           | Dexfenfluramine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                           | Benfluorex Hydrochloride      |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------------|-----------------|--------------|----------------|
| 27-May-2011                                                                                                                                                                                                                                                                                 | 7944007                         | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020235                 |                                 |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy                                                                                                                                                                                                                                                                                    | Escitalopram Oxalate            |                    |                    | S               | Oral                       | 5 Mg (5 Mg,1 In 1 D), Oral      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Tergretol Cr (Carbamazepine)    |                    |                    | C               |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2011                                                                                                                                                                                                                                                                                 | 7964820                         | EXPEDITED (15-DAY) | Y                  | HO              | TR-ASTRAZENECA-2011SE29706 |                                 | 54 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction;<br>Rhabdomyolysis                                                                                                                                                                                                                                                         | Quetiapine                      |                    |                    | S               | Oral                       |                                 |                 | Zeneca       |                |
|                                                                                                                                                                                                                                                                                             | Metoprolol                      |                    |                    | C               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Olmesartan Medoxomil            |                    |                    | C               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Acetylsalicylic Acid            |                    |                    | C               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Quetiapine                      |                    |                    | S               | Oral                       |                                 |                 | Zeneca       |                |
|                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate            |                    |                    | S               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Escitalopram Oxalate            |                    |                    | S               |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-May-2011                                                                                                                                                                                                                                                                                 | 7970559                         | EXPEDITED (15-DAY) | Y                  | DE              | 1000020789                 |                                 | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Coma;<br>Disseminated<br>Intravascular Coagulation;<br>Hepatic Cirrhosis; Hepatic<br>Failure; Hepatic<br>Neoplasm; Hyperthermia;<br>Miosis; Neuroleptic<br>Malignant Syndrome;<br>Neuropathy Peripheral;<br>Overdose; Poisoning<br>Deliberate; Portal<br>Hypertension; Product | Escitalopram Oxalate            |                    |                    | S               |                            | 20 Mg (20 Mg,1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Abilify                         |                    |                    | S               |                            | 30 Mg (15 Mg,2 In 1 D)          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | Gardenal (Phenobarbital)        |                    |                    | C               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | (Phenobarbital)                 |                    |                    |                 |                            |                                 |                 |              |                |
|                                                                                                                                                                                                                                                                                             | Kepra (Levetiracetam) (Tablets) |                    |                    | C               |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                             | (Levetiracetam)                 |                    |                    |                 |                            |                                 |                 |              |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Dose Omission;  
Rhabdomyolysis; Status  
Epilepticus; Varices  
Oesophageal

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-May-2011              | 7987445       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000021008           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Blood Bilirubin Increased; | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D), Oral   |                 | Not Reported |
| Blood Chloride             | Mirtazapine          |              |            | S           | Oral         | 15 Mg (15 Mg,1 In 1 D), Oral |                 | Not Reported |
| Decreased; Blood Iron      |                      |              |            |             |              |                              |                 |              |
| Decreased; Blood           |                      |              |            |             |              |                              |                 |              |
| Magnesium Decreased;       |                      |              |            |             |              |                              |                 |              |
| Cardiac Arrest;            |                      |              |            |             |              |                              |                 |              |
| Dehydration; Gamma-        |                      |              |            |             |              |                              |                 |              |
| Glutamyltransferase        |                      |              |            |             |              |                              |                 |              |
| Increased; Haemoglobin     |                      |              |            |             |              |                              |                 |              |
| Decreased; Hypophagia;     |                      |              |            |             |              |                              |                 |              |
| International Normalised   |                      |              |            |             |              |                              |                 |              |
| Ratio Increased;           |                      |              |            |             |              |                              |                 |              |
| Oligodipsia; Pericarditis; |                      |              |            |             |              |                              |                 |              |
| Serum Ferritin Increased   |                      |              |            |             |              |                              |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-May-2011              | 7644766       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000015683           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Caesarean Section; Colitis | Escitalopram Oxalate         |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral | 2 YR            | Not Reported |
| Ulcerative; Maternal       |                              |              |            |             |              |                               |                 |              |
| Exposure During            | Cortison (Cortisone Acetate) |              |            | C           |              |                               |                 | Not Reported |
| Pregnancy; Pregnancy       | (Cortisone Acetate)          |              |            |             |              |                               |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-May-2011              | 7964249       | EXPEDITED (15-DAY) | Y                  | CA, DS, HO      | 1000020668           |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                 |                                      |   |                |                                            |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|---|----------------|--------------------------------------------|--------------|
| Atrial Septal Defect;<br>Caesarean Section;<br>Congenital Pulmonary<br>Valve Disorder; Drug<br>Withdrawal Syndrome<br>Neonatal; Maternal Drugs<br>Affecting Foetus; Renal<br>Aplasia; Selective Eating<br>Disorder; Small For Dates<br>Baby; Temperature<br>Regulation Disorder | Escitalopram Oxalate                 | S | Transplacental | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental | Not Reported |
|                                                                                                                                                                                                                                                                                 | Cortisone (Cortisone)<br>(Cortisone) | C |                |                                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 31-May-2011              | 7966455       | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-<br>20110509701 |                      | 42 YR      | Female     | ITA            |

| <u>Preferred Term</u>                            | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Intentional Self-Injury | Topamax           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                  | Cipraxex          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Tavor (Lorazepam) |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-May-2011              | 7967609       | EXPEDITED (15-DAY) | Y                  | HO, OT          | GXKR2011DE01832      |                      | 31 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Hypertension; Maternal<br>Exposure During<br>Pregnancy; Oedema; Pre-<br>Eclampsia; Premature<br>Baby; Proteinuria | Mirtazapine             |              |            | S           | Oral         | 30 Mg/Day Until Gw 8.5,<br>Rest Of Pregnancy 15<br>Mg/Day | 255 DAY         | Novartis     |
|                                                                                                                   | Cipraxex                |              |            | S           | Oral         | 10 Mg, Qd (Gw 0 To 8.5)                                   | 62 DAY          | Not Reported |
|                                                                                                                   | Paracetamol             |              |            | C           | Oral         | 500 Mg, Qd (Gw 9.2 To<br>9.5)                             | 4 DAY           | Not Reported |
|                                                                                                                   | Amoxicillin\Clavulanate |              |            | C           | Oral         | 1 Df, Bid (Gw 9.2 To 9.3)                                 | 2 DAY           | Not Reported |
|                                                                                                                   | Potassium<br>Folic Acid |              |            | C           | Oral         | 0.8 Mg/Day (Gw 5 To<br>12.6)                              | 52 DAY          | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 31-May-2011                                                                                    | 7967677                           | EXPEDITED (15-DAY) | Y                  | HO, OT          | GXKR2011DE01842      |                                                                               | 31 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Premature Baby                                             | Mirtazapine                       |                    |                    | S               | Transplacental       | Maternal Dose: 30 Mg/Day Until Gw 8.5 And 15 Mg/Day For The Rest Of Pregnancy |                 | Novartis     |                |
|                                                                                                | Ciprallex                         |                    |                    | S               | Transplacental       | Maternal Dose: 10 Mg/Day, O To 8.5 Gw                                         |                 | Not Reported |                |
|                                                                                                | Paracetamol                       |                    |                    | C               | Transplacental       | Maternal Dose: 500 Mg/Day                                                     | 4 DAY           | Not Reported |                |
|                                                                                                | Amoxicillin\Clavulanate Potassium |                    |                    | C               | Transplacental       | Maternal Dose: 2 Df/Day                                                       | 2 DAY           | Not Reported |                |
|                                                                                                | Folic Acid                        |                    |                    | C               | Transplacental       | 0.8 Mg/Day                                                                    | 52 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2011                                                                                    | 7985669                           | DIRECT             | N                  | CA, RI          |                      |                                                                               | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness Congenital; Maternal Drugs Affecting Foetus                                           | Lexapro                           |                    |                    | S               |                      |                                                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-May-2011                                                                                    | 7995960                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000021155           |                                                                               | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Hyperhidrosis; Nausea; Sleep Disorder; Treatment Noncompliance; Withdrawal Syndrome | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral                                                 |                 | Not Reported |                |
|                                                                                                | Zyprexa                           |                    |                    | S               | Oral                 | 20 Mg (10 Mg, 2 In 1 D), Oral                                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 31-May-2011                    | 8029073                     | NON-EXPEDITED      | Y                  | OT              | US-001845                             |                                                              | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged | Trazodone Hydrochloride     |                    |                    | S               | Oral                                  | (Oral)                                                       |                 | Not Reported |                |
|                                | Telavancin Hydrochloride    |                    |                    | S               | Intravenous (not otherwise specified) | (10 Mg/Kg, Total Dose Intravenous (Not Otherwise Specified)) |                 | Not Reported |                |
|                                | Lexapro                     |                    |                    | S               | Oral                                  | (Oral)                                                       |                 | Not Reported |                |
|                                | Metoclopramide              |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Warfarin Sodium             |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Novolin R                   |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Hydromorphone Hydrochloride |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Metoprolol                  |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Lisinopril                  |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Sitagliptin                 |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Imdur                       |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Lasix                       |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Cilostazol                  |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Colecalciferol              |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Calcium Citrate             |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Omeprazole                  |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Zolpidem                    |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Lipitor                     |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Fentanyl                    |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
|                                | Lantus                      |                    |                    | C               |                                       |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>       | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jun-2011                    | 7969553                     | EXPEDITED (15-DAY) | Y                  | OT              | DE-TEVA-283724GER                     |                                                              |                 | Female       | DEU            |
| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Pre-Eclampsia                  | Mirtazapine                 |                    |                    | S               | Oral                                  | 30 Milligram;                                                | 255 DAY         | Not Reported |                |
|                                | Mirtazapine                 |                    |                    | S               | Oral                                  |                                                              | 255 DAY         | Not Reported |                |
|                                | Cipralex                    |                    |                    | S               | Oral                                  | 10 Milligram;                                                |                 | Not Reported |                |
|                                | Paracetamol                 |                    |                    | C               | Oral                                  | 500 Milligram;                                               |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |   |      |                                                               |              |
|-----------------------------------|---|------|---------------------------------------------------------------|--------------|
| Amoxicillin\Clavulanate Potassium | C | Oral | 250 Mg/D (2x125) Clavulanate + 1750 Mg /D (2x875) Amoxicillin | Not Reported |
| Folio Forte                       | C | Oral | .8 Milligram; 52 DAY                                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7969556       | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | DE-TEVA-283726GER    |                      | < 1 DAY    | Female     | DEU            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|----------------|-------------------------------------------------------------------|-----------------|--------------|
| Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Premature Baby; Selective Eating Disorder | Mirtazapine                       |              |            | S           | Transplacental |                                                                   | 255 DAY         | Teva         |
|                                                                                                 | Mirtazapine                       |              |            | S           | Transplacental |                                                                   | 255 DAY         | Teva         |
|                                                                                                 | Ciprallex                         |              |            | S           | Transplacental | 10 Milligram;                                                     |                 | Not Reported |
|                                                                                                 | Paracetamol                       |              |            | C           | Transplacental | 500 Milligram;                                                    |                 | Not Reported |
|                                                                                                 | Amoxicillin\Clavulanate Potassium |              |            | C           | Transplacental | 250 [Mg/D (2x125) ] Clavulanate + 1750 [Mg/D (2x875) ]Amoxicillin |                 | Not Reported |
|                                                                                                 | Folio Forte                       |              |            | C           | Transplacental | .8 Milligram;                                                     | 52 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7969951       | EXPEDITED (15-DAY) | Y                  | HO, OT          | ES-PFIZER INC-2011112319 |                      | 43 YR      | Male       | ESP            |

| <u>Preferred Term</u>                                                                                                                | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gamma-Glutamyltransferase Increased; Hepatitis Cholestatic | Neurontin         |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                                                                      | Calcium Carbimide |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                      | Ciprallex         |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7969953       | EXPEDITED (15-DAY) | N                  | OT              | DE-PFIZER INC-2011116108 |                      |            | Male       | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                           |                                               |             |                                        |
|---------------------------------------------------------------------------|-----------------------------------------------|-------------|----------------------------------------|
| Confusional State; Feeling Of Despair; Heart Rate Increased; Hypertension | Champix<br>Doxepin Hydrochloride<br>Ciprallex | S<br>S<br>S | Pfizer<br>Not Reported<br>Not Reported |
|---------------------------------------------------------------------------|-----------------------------------------------|-------------|----------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7986371       | DIRECT           | N                  | LT              |                      |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depressed Mood; Emotional Disorder; Suicidal Behaviour | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7996116       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021229           |                      | 46 YR      | Male       | DNK            |

| <u>Preferred Term</u>               | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|--------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Drug Interaction; Fall; Hypotension | Lexapro                        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 I N 1 D), Oral  |                 | Not Reported |
|                                     | Quetiapine Fumarate            |              |            | S           |              | 100 Mg (100 Mg, 1 In 1 D)       |                 | Not Reported |
|                                     | Hydrochlorothiazide/Irbesartan |              |            | S           |              | 1 Df (1 Dosage Forms, 1 I N1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jun-2011              | 7996212       | EXPEDITED (15-DAY) | N                  | HO              | 1000021195           |                      | 55 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                           | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|---------------------------|-----------------|------------------------------|
| Balance Disorder; Dysstasia; Fall; Feeling Cold; Gait Disturbance; Headache; Hypoacusis; Ill-Defined Disorder; Malaise; Neck Pain; Restless Legs Syndrome; Sleep Disorder; Syncope; Visual Impairment; Vomiting | Escitalopram Oxalate<br>Xalatan |              |            | S<br>C      | Oral         | 10 Mg Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------------------------|----------------------|-----------------|--------------|----------------|
| 01-Jun-2011                                                                        | 7997197              | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000021166                                   |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Rate Decreased;<br>Hemiplegia; Migraine;<br>Seizure; Speech Disorder         | Lexapro              |                    |                    | S               |                                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2011                                                                        | 7952890              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | DE-ABBOTT-11P-062-0725894-00                 |                      | 19 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose; Loss Of Consciousness; Somnolence; Suicide Attempt; Vomiting | Valproate Sodium     |                    |                    | S               | Oral                                         | Overdose             |                 | Not Reported |                |
|                                                                                    | Ciprallex            |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                                                                    | Dimethindene         |                    |                    | S               | Oral                                         | Overdose: 1 Bottle   |                 | Not Reported |                |
|                                                                                    | Alcohol              |                    |                    | S               | Other                                        | Unknown Amount       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2011                                                                        | 7971737              | EXPEDITED (15-DAY) | Y                  | OT              | FR-BAXTER-2011BH017738                       |                      | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                          | Cyclophosphamide     |                    |                    | S               | Intravenous (not otherwise specified)        |                      |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate |                    |                    | S               | Oral                                         |                      |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate |                    |                    | S               | Unknown                                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jun-2011                                                                        | 7971837              | EXPEDITED (15-DAY) | Y                  | LT, OT          | US-ROXANE LABORATORIES, INC.-2011-RO-00742RO |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |                             |   |  |              |       |  |  |              |
|----------------------------------|-----------------------------|---|--|--------------|-------|--|--|--------------|
| Cardiac Arrest; Long Qt Syndrome | Ondansetron                 | S |  |              |       |  |  | Roxane       |
|                                  | Succinylcholine             | S |  |              |       |  |  | Not Reported |
|                                  | Nortriptyline Hydrochloride | S |  |              | 25 Mg |  |  | Not Reported |
|                                  | Atorvastatin                | S |  |              | 20 Mg |  |  | Not Reported |
|                                  | Escitalopram Oxalate        | S |  |              | 10 Mg |  |  | Not Reported |
|                                  | Topiramate                  | S |  |              | 25 Mg |  |  | Not Reported |
|                                  | Baby Aspirin                | S |  |              |       |  |  | Not Reported |
|                                  | Heparin                     | S |  | Subcutaneous |       |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jun-2011              | 7989493       | DIRECT           | Y                  |                 |                      |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------|-----------------|--------------|
| Fatigue; Insomnia     | Lexapro        |              |            | S           | Oral         | 10 Qd Po (Dates Of Use: Unknown, Several Months)       |                 | Not Reported |
|                       | Venlafaxine    |              |            | S           | Oral         | 37.5 Mg Bid Po (Dates Of Use: Unknown, Several Months) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jun-2011              | 7998076       | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | 2011SP024112         |                      | 1 DAY      | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Caesarean Section; Haemangioma Congenital; Hyperbilirubinaemia Neonatal; Maternal Death Affecting Foetus; Premature Baby; Selective Eating Disorder | Mirtazapine               |              |            | S           | Transplacental | Trpl               |                 | Not Reported |
|                                                                                                                                                     | Ciprallex                 |              |            | S           | Transplacental | Trpl               |                 | Not Reported |
|                                                                                                                                                     | Paracetamol               |              |            | C           |                |                    |                 | Not Reported |
|                                                                                                                                                     | Amoxicillin & Clavulanate |              |            | C           |                |                    |                 | Not Reported |
|                                                                                                                                                     | Potassium                 |              |            |             |                |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Jun-2011              | 7962949       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020675           |                      | 49 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Diabetic Ketoacidotic<br>Hyperglycaemic Coma;<br>Rash Maculo-Papular                                                 | Escitalopram Oxalate                                                      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral    |                 | Not Reported |                |
|                                                                                                                      | Alprazolam                                                                |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                      | Prazepam (Prazepam)<br>(Prazepam)                                         |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                      | Neocodion (Codeine,<br>Sulfogaiacol) (Tablets) (Codeine,<br>Sulfogaiacol) |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2011                                                                                                          | 7982837                                                                   | EXPEDITED (15-DAY) | Y                  | HO, LT, RI, OT  | 1000020940           |                                     | 19 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Intentional Overdose; Loss<br>Of Consciousness;<br>Somnolence; Suicide<br>Attempt; Vomiting | Escitalopram Oxalate                                                      |                    |                    | S               | Oral                 | 30 Mg, Once, Oral                   |                 | Not Reported |                |
|                                                                                                                      | Valproate Sodium                                                          |                    |                    | S               | Oral                 | 3300 Mg, Once, Oral                 |                 | Not Reported |                |
|                                                                                                                      | Dimethindene Maleate                                                      |                    |                    | S               | Oral                 | 1 Bottle (Single Dosage),<br>Oral   |                 | Not Reported |                |
|                                                                                                                      | Alcohol (Ethanol)                                                         |                    |                    | S               | Oral                 | Oral                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jun-2011                                                                                                          | 7987060                                                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000020950           |                                     | 80 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Sopor                                                                                                                | Memantine                                                                 |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D),            |                 | Not Reported |                |
|                                                                                                                      | Escitalopram Oxalate                                                      |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D),            |                 | Not Reported |                |
|                                                                                                                      | Fentanyl                                                                  |                    |                    | S               |                      | 1 Df (1 Dosage Forms, 1<br>In 1 D); |                 | Not Reported |                |
|                                                                                                                      | Tamsulosine Hydrochloride                                                 |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                      | Dutasteride                                                               |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                      | Foline (Folic Acid)                                                       |                    |                    | C               |                      |                                     |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| 06-Jun-2011                                                                                                                                                                                      | 7976491                     | NON-EXPEDITED      | N                  |                 | US-BAYER-201028563NA |                                                            | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity; Swelling Face; Swollen Tongue                                                                                                                                                  | Avelox                      |                    |                    | S               | Oral                 | 400 Mg, Qd                                                 | 1 DAY           | Bayer        |                |
|                                                                                                                                                                                                  | Ibuprofen                   |                    |                    | C               |                      | Unk Unk, Prn                                               |                 | Bayer        |                |
|                                                                                                                                                                                                  | Lexapro                     |                    |                    | S               | Oral                 | 10 Mg, Qd                                                  |                 | Not Reported |                |
|                                                                                                                                                                                                  | Nicoderm Cq                 |                    |                    | S               |                      | Unk                                                        | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2011                                                                                                                                                                                      | 8001462                     | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | AUR-APL-2011-01870   |                                                            | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Ejection Fraction Decreased; Fibrosis; Incision Site Haemorrhage; Long Qt Syndrome; Procedural Haemorrhage; Sinus Bradycardia; Ventricular Fibrillation; Ventricular Tachycardia | Ondansetron                 |                    |                    | S               |                      |                                                            |                 | Not Reported |                |
|                                                                                                                                                                                                  | Nortriptyline Hydrochloride |                    |                    | S               |                      | 25mg                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                  | Atorvastatin                |                    |                    | S               |                      | 20mg                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               |                      | 10 Mg                                                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Suxmethonium Chloride       |                    |                    | C               |                      | 25 Mg                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Jun-2011                                                                                                                                                                                      | 8006330                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021410           |                                                            | 51 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                                                                                                        | Escitalopram Oxalate        |                    |                    | S               | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                  |                             |                    |                    |                 | Oral                 | 40 Mg (40 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1), Oral |                 |              |                |

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Cyclophosphamide

S

Intravenous (not  
otherwise specified)

1180 Mg (1180 Mg, 1 In 1  
D), Intravenous (Not  
Otherwise Specified)

Not Reported

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 07-Jun-2011                       | 8006336                | EXPEDITED (15-DAY)        | N                           | DE                       | 1000021283                    |                               | < 1 DAY             | Female              | USA                     |

| <a href="#">Preferred Term</a>                                                                                                                                                                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Aortic Occlusion; Cardiac<br>Ventricular Disorder; Heart<br>Disease Congenital; Left<br>Ventricular Failure;<br>Maternal Drugs Affecting<br>Foetus; Obstruction; Post<br>Procedural Complication | Lexapro                 |                       |                     | S                    | Transplacental        | Transplacental              |                          | Not Reported        |
|                                                                                                                                                                                                  | Zoloft                  |                       |                     | S                    | Transplacental        | Transplacental              |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 08-Jun-2011                       | 7934541                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000020064                    |                               | 45 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>     | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|---------------------------------|--------------------------|---------------------|
| Mastitis                       | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 08-Jun-2011                       | 7980181                | NON-EXPEDITED             | Y                           |                          | US-PFIZER INC-<br>2011121825  |                               | 55 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>  | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|--------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Feeling Jittery                | Pristiq Extended Release |                       |                     | S                    |                       | 50 Mg                       |                          | Pfizer              |
|                                | Lexapro                  |                       |                     | S                    |                       | Unk                         |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 08-Jun-2011                       | 7980744                | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | DE-MYLANLABS-<br>2011S1010952 |                               | 31 YR               | Female              | DEU                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                                      |   |      |                                                                    |         |              |
|----------------------------------------------------------------------------|--------------------------------------|---|------|--------------------------------------------------------------------|---------|--------------|
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pre-Eclampsia | Mirtazapine                          | S | Oral | 30 [Mg/D ] / Until Gw 8.5<br>30 Mg/D, Rest Of<br>Pregnancy 15 Mg/D | 255 DAY | Not Reported |
|                                                                            | Mirtazapine                          | S | Oral | 30 [Mg/D ] / Until Gw 8.5<br>30 Mg/D, Rest Of<br>Pregnancy 15 Mg/D | 255 DAY | Not Reported |
|                                                                            | Cipralext                            | S | Oral | 10 [Mg/D ]                                                         | 62 DAY  | Not Reported |
|                                                                            | Paracetamol                          | C | Oral | 500 [Mg/D ]                                                        |         | Not Reported |
|                                                                            | Amoxicillin\Clavulanate<br>Potassium | C | Oral | 250 [Mg/D (2x125) ] / 17502 DAY<br>[Mg/D (2x875) ]                 |         | Not Reported |
|                                                                            | Folic Acid                           | C | Oral | 0.8 [Mg/D ]                                                        | 52 DAY  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 08-Jun-2011              | 7980751       | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | DE-MYLANLABS-<br>2011S1010960 |                      | < 1 DAY    | Female     | DEU            |

| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|--------------------------------------------------------------------|-----------------|--------------|
| Haemangioma Congenital;<br>Hyperbilirubinaemia<br>Neonatal; Maternal<br>Exposure During<br>Pregnancy; Premature<br>Baby; Selective Eating<br>Disorder | Mirtazapine                          |              |            | S           | Transplacental | 30 [Mg/D ] / Until Gw 8.5<br>30 Mg/D, Rest Of<br>Pregnancy 15 Mg/D | 255 DAY         | Not Reported |
|                                                                                                                                                       | Cipralext                            |              |            | S           | Transplacental | 10 [Mg/D ]                                                         | 62 DAY          | Not Reported |
|                                                                                                                                                       | Paracetamol                          |              |            | C           | Transplacental | 500 [Mg/D ]                                                        | 1 DAY           | Not Reported |
|                                                                                                                                                       | Amoxicillin\Clavulanate<br>Potassium |              |            | C           | Transplacental | 250 [Mg/D (2x125) ] / 17502 DAY<br>[Mg/D (2x875) ]                 |                 | Not Reported |
|                                                                                                                                                       | Folic Acid\Potassium Iodide          |              |            | C           | Transplacental | 0.8 [Mg/D ]                                                        | 52 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jun-2011              | 8003834       | EXPEDITED (15-DAY) | Y                  | CA, HO, RI, OT  | 1000021415           |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------------------------------|-----------------|--------------|
| Caesarean Section;<br>Congenital Anomaly;<br>Haemangioma Congenital;<br>Hyperbilirubinaemia;<br>Maternal Drugs Affecting | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1<br>D),Transplacental       |                 | Not Reported |
|                                                                                                                          | Mirtazapine          |              |            | S           | Transplacental | 30 Mg (30 Mg, 1 In 1<br>D),Transplacenta, 15 Mg |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetus; Premature Baby;  
Selective Eating Disorder

(15 Mg, 1 In 1  
D),Transplacen

|                                       |   |              |
|---------------------------------------|---|--------------|
| Paracetamol                           | C | Not Reported |
| (Paracetamol)(Paracetamol)            |   |              |
| Amoxicillin\Clavulanate               | C | Not Reported |
| Potassium                             |   |              |
| Folio Forte (Folic Acid) (Folic Acid) | C | Not Reported |

| <u>FDA Received Date</u>                                                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-----------------------|------------------------|-----------------|--------------|----------------|
| 09-Jun-2011                                                                       | 7904077        | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-20110403801 |                        | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Apnoea; Bradycardia;<br>Hypotonia; Metabolic<br>Acidosis; Respiratory<br>Distress | Topamax        |                    |                    | S               | Transplacental        |                        |                 | Not Reported |                |
|                                                                                   | Topamax        |                    |                    | S               | Transplacental        | Start Date- 19-Oct     |                 | Not Reported |                |
|                                                                                   | Lexapro        |                    |                    | S               | Transplacental        | On Therapy For 7 Weeks |                 | Not Reported |                |
|                                                                                   | Elavil         |                    |                    | S               | Transplacental        |                        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------|
| 09-Jun-2011                                                                                                                                                                                                                                     | 7983512              | EXPEDITED (15-DAY) | N                  | HO              | B0723312A            |                      | 53 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Blister; Cheilitis; Condition<br>Aggravated; Conjunctivitis;<br>Erythema Multiforme;<br>Mouth Ulceration;<br>Oropharyngeal<br>Discomfort; Pharyngitis;<br>Protein Total Abnormal;<br>Pyrexia; Rash; Skin<br>Lesion; Stevens-Johnson<br>Syndrome | Lamictal             |                    |                    | S               | Oral                 | 25mg Per Day         | 24 DAY          | Glaxosmithkline |                |
|                                                                                                                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20mg Per Day         | 24 DAY          | Unknown         |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Jun-2011              | 7997433       | DIRECT           | Y                  |                 |                      |                      | 65 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                   |                |
|--------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------|-----------------|------------------------------|----------------|
| Fatigue; Insomnia                                      | Lexapro                   |                    |                    | S               | Oral                 | 10 Qd Po                                                   |                 | Not Reported                 |                |
|                                                        | Venlafaxine Hydrochloride |                    |                    | S               | Oral                 | 37.5mg Bid Po                                              |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Jun-2011                                            | 8007717                   | EXPEDITED (15-DAY) | N                  | CA              | 1000021289           |                                                            | 1 DAY           | Male                         | USA            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Maternal Drugs Affecting Foetus; Vascular Malformation | Lexapro                   |                    |                    | S               | Transplacental       | 20 Mg (20 Mg,1 In 1 D),Transplacental                      |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Jun-2011                                            | 8008406                   | EXPEDITED (15-DAY) | Y                  | LT              | 1000021428           |                                                            | 46 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Road Traffic Accident; Somnolence                      | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                              |                 | Not Reported                 |                |
|                                                        | Nisis Tranxene T-Tab      |                    |                    | C<br>C          |                      |                                                            |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                               | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 09-Jun-2011                                            | 8008590                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021440           |                                                            | 40 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>                   |                |
| Epilepsy                                               | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                |                 | Not Reported                 |                |
|                                                        | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported                 |                |
|                                                        |                           |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral; 5 Mg (5 Mg, 1 In 1 D), Oral |                 |                              |                |
|                                                        | Trileptal                 |                    |                    | C               |                      |                                                            |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| 09-Jun-2011                                                                                                       | 8008608                  | EXPEDITED (15-DAY)        | N                           | RI, OT                   | 1000021438                    |                                                              | 2 YR                     | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                  | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child                                                                           | Escitalopram Oxalate     |                           |                             | S                        | Oral                          | 1 Drop In A Small Amount Of Orange Juice, Oral               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Jun-2011                                                                                                       | 8009100                  | EXPEDITED (15-DAY)        | Y                           | HO, RI, OT               | 1000021439                    |                                                              | 31 YR                    | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                  | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Caesarean Section; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery; Urinary Tract Infection | Escitalopram Oxalate     |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                          | Not Reported        |                         |
|                                                                                                                   | Mirtazapine              |                           |                             | S                        | Oral                          | 30 Mg (30 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                                                                                                   |                          |                           |                             |                          | Oral                          | 30 Mg (30 Mg, 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral |                          |                     |                         |
|                                                                                                                   | Folio Forte (Folic Acid) |                           |                             | C                        |                               |                                                              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Jun-2011                                                                                                       | 8009110                  | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000021443                    |                                                              | 14 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                  | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Breast Pain; Contusion; Petechiae                                                                                 | Lexapro                  |                           |                             | S                        |                               |                                                              |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Jun-2011                                                                                                       | 8018388                  | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000021420                    |                                                              |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                  | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Angina Pectoris; Balance Disorder; Extrasystoles; Fatigue; Vomiting      Escitalopram Oxalate      S      Oral      10 Mg (10 Mg,1 In 1 D),Oral      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2011              | 7869905       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20110307442 |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Blood Pressure Increased; Decreased Appetite; Hallucination; Headache; Incorrect Product Administration Duration; Occipital Neuralgia | Tylenol                          |              | Y          | S           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Tylenol                          |              |            | S           | Oral         | 1000mg 3-4 Times Day  |                 | Not Reported |
|                                                                                                                                       | Lexapro                          |              |            | S           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Lexapro                          |              |            | S           | Oral         | 8-10 Years            |                 | Not Reported |
|                                                                                                                                       | Methylprednisolone               |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Atenolol                         |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Levothyrox                       |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Valsartan W/ Hydrochlorothiazide |              |            | C           | Oral         | 81mg/25mg, 8-10 Years |                 | Not Reported |
|                                                                                                                                       | Ocuvite Nos                      |              |            | C           | Oral         | 6-7 Years             |                 | Not Reported |
|                                                                                                                                       | Vitamins                         |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Bayer Aspirin                    |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Lovaza                           |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Vitamin D2                       |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Calcium Carbonate                |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Omeprazole                       |              |            | C           | Oral         |                       |                 | Not Reported |
|                                                                                                                                       | Ubidecarenone                    |              |            | C           | Oral         |                       |                 | Not Reported |
| Fish Oil                                                                                                                              |                                  |              | C          | Oral        |              |                       | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Jun-2011              | 7986589       | EXPEDITED (15-DAY) | Y                  | OT              | DE-ABBOTT-11P-062-0730947-00 |                      | 21 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |                               |   |      |                   |              |
|--------------------------------------------------|-------------------------------|---|------|-------------------|--------------|
| Dizziness; Intentional Overdose; Suicide Attempt | Ciprallex                     | S | Oral | 7-20mg Tabs Once  | Not Reported |
|                                                  | Ibuprofen                     | S | Oral | 7-500mg Tabs Once | Not Reported |
|                                                  | Paracetamol                   | S | Oral |                   | Not Reported |
|                                                  | Famotidine                    | S | Oral |                   | Not Reported |
|                                                  | Prednisolone                  | S | Oral | 10-20mg Tabs Once | Not Reported |
|                                                  | Methylphenidate Hydrochloride | S | Oral |                   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2011              | 8009709       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021495           |                      | 77 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Creatinine Increased; Blood Urea Increased; Drug Ineffective; Glomerular Filtration Rate Decreased | Lexapro                             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                          | Pristiq Extended Release            |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                          | Cartia (Diltiazem Hydrochloride)    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                          | (Tablets) (Diltiazem Hydrochloride) |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2011              | 8009714       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021510           |                      | 69 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Intentional Overdose; Intentional Self-Injury; Sopor | Escitalopram Oxalate     |              |            | S           | Oral         | (560 Mg, Once), Oral |                 | Not Reported |
|                                                      | Rabeprazole Sodium       |              |            | S           | Oral         | (Once), Oral         |                 | Not Reported |
|                                                      | Flurazepam Hydrochloride |              |            | S           |              | (900 Mg, Once)       |                 | Not Reported |
|                                                      | Promazine Hydrochloride  |              |            | S           | Oral         | 30 MI (Once), Oral   |                 | Not Reported |
|                                                      | Tavor (Lorazepam)        |              |            | S           | Ophthalmic   | (100 Mg, Once), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2011              | 8009722       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021521           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                         |                                                                 |   |       |                               |              |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|---|-------|-------------------------------|--------------|
| Amyotrophic Lateral Sclerosis; Dysarthria; Dysphagia; Muscle Contractions Involuntary; Tongue Atrophy; Weight Decreased | Escitalopram Oxalate                                            | S | Oral  | 15 Mg (15 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                                         | Influenza Virus Vaccine Nos                                     | S | Other | (0.5 MI), Other               | Not Reported |
|                                                                                                                         | Almogran (Almotriptan Malate) (Tablets) (Almotriptan Malate)    | C |       |                               | Not Reported |
|                                                                                                                         | Levaxin (Levothyroxine Sodium) (Tablets) (Levothyroxine Sodium) | C |       |                               | Not Reported |
|                                                                                                                         | Treo (Anacin /00141001/) (Tablets) (Anacin /00141001/)          | C |       |                               | Not Reported |
|                                                                                                                         | Citodon (Co-Dafalgan) (Tablets) (Co-Dafalgan)                   | C |       |                               | Not Reported |
|                                                                                                                         | Imovane (Zopiclone) (Tablets) (Zopiclone)                       | C |       |                               | Not Reported |
|                                                                                                                         | Naprosyn (Naproxen) (Tablets) (Naproxen)                        | C |       |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 13-Jun-2011              | 7963584        | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020645           |                              |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                  | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D), Oral |                 | Not Reported |                |
|                          | Carbamazepine  |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                          | Propranolol    |                    |                    | C               |                      |                              |                 | Not Reported |                |

| <u>FDA Received Date</u>                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| 13-Jun-2011                                   | 7987761                 | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-15810377 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Multiple Sclerosis; Overdose; Suicide Attempt | Trazodone Hydrochloride |                    |                    | S               |                                          | Half A Bottle                    |                 | Apothecon    |                |
|                                               | Abilify                 |                    |                    | S               |                                          | For A While But Not For Two Days |                 | Not Reported |                |
|                                               | Lexapro                 |                    |                    | S               |                                          | Half A Bottle                    |                 | Not Reported |                |
|                                               | Copaxone                |                    |                    | C               |                                          |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------------------|----------------|
| 13-Jun-2011                                                                                                                                                                              | 7987972                              | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2011GB48979      |                         | 21 YR           | Female                   | GBR            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>               |                |
| Oculogyric Crisis                                                                                                                                                                        | Risperidone<br>Ciprallex             |                    |                    | S<br>S          | Oral                 | 20 Mg, Qd               |                 | Novartis<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 13-Jun-2011                                                                                                                                                                              | 8012023                              | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2011-02107   |                         | 31 YR           | Female                   |                |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>               |                |
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Oedema; Pre-<br>Eclampsia; Proteinuria;<br>Urinary Tract Infection                                                          | Mirtazapine                          |                    |                    | S               | Oral                 | 30mg-Daily-Oral         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Mirtazapine                          |                    |                    | S               | Oral                 | 15mg-Daily-Oral         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Ciprallex                            |                    |                    | S               | Oral                 | 10mg-Daily-Oral         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Amoxicillin\Clavulanate<br>Potassium |                    |                    | C               |                      |                         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Folio Forte (Folic Acid)             |                    |                    | C               |                      |                         |                 | Not Reported             |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 13-Jun-2011                                                                                                                                                                              | 8016386                              | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | AUR-APL-2011-02111   |                         | < 1 DAY         | Female                   | USA            |
| <u>Preferred Term</u>                                                                                                                                                                    | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>               |                |
| Caesarean Section;<br>Haemangioma Congenital;<br>Hyperbilirubinaemia<br>Neonatal; Maternal Drugs<br>Affecting Foetus; Pre-<br>Eclampsia; Premature<br>Baby; Selective Eating<br>Disorder | Mirtazapine                          |                    |                    | S               | Transplacental       | 30-15mg -Daily-Transpla |                 | Not Reported             |                |
|                                                                                                                                                                                          | Ciprallex                            |                    |                    | S               |                      | 10mg-Daily-Transplacent |                 | Not Reported             |                |
|                                                                                                                                                                                          | Paracetamol                          |                    |                    | C               |                      |                         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Amoxicillin\Clavulanate<br>Potassium |                    |                    | C               |                      |                         |                 | Not Reported             |                |
|                                                                                                                                                                                          | Folio Forte (Folic Acid)             |                    |                    | C               |                      |                         |                 | Not Reported             |                |
| <u>FDA Received Date</u>                                                                                                                                                                 | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>               | <u>Country</u> |
| 14-Jun-2011                                                                                                                                                                              | 7794508                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000017750           |                         | 43 YR           | Female                   | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                           | <u>Product</u>                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                                                                                                                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|---------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Akathisia; Restlessness;<br>Withdrawal Syndrome | Lexapro                                                 |              |            | S           |              | 15 Mg (15 Mg, 1 In 1 D) 10<br>Mg (10 Mg, 1 In 1 D) 5 Mg<br>(5 Mg, 1 In 1 D)<br>15 Mg (15 Mg, 1 In 1 D) 10<br>Mg (10 Mg, 1 In 1 D) 5 Mg<br>(5 Mg, 1 In 1 D)<br>15 Mg (15 Mg, 1 In 1 D) 10<br>Mg (10 Mg, 1 In 1 D) 5 Mg<br>(5 Mg, 1 In 1 D) |                 | Not Reported |
|                                                 | Lexapro                                                 |              |            | S           |              | 5 Mg (5 Mg, 1 In 1 D)                                                                                                                                                                                                                     |                 | Not Reported |
|                                                 | Risperidone                                             |              |            | C           |              |                                                                                                                                                                                                                                           |                 | Not Reported |
|                                                 | Seroquel (Quetiapine Fumarate)<br>(Quetiapine Fumarate) |              |            | C           |              |                                                                                                                                                                                                                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 14-Jun-2011              | 7990155       | EXPEDITED (15-DAY) | N                  | HO, LT          | CA-NAPPMUNDI-CAN-<br>2011-0001971 |                      | 29 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Oxycodone Hydrochloride |              |            | S           |              | 80 Mg, Qid         |                 | Purdue       |
|                       | Ciprallex               |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jun-2011              | 8014745       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2011SP025896         |                      | 67 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                            | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Bradycardia; Device<br>Related Infection;<br>Diarrhoea; Disorientation;<br>Dyspnoea; General<br>Physical Health<br>Deterioration;<br>Hyperkalaemia;<br>Hypotension; Lactic<br>Acidosis; Pallor; Pyrexia; | Mirtazapine                   |              |            | S           |              | 15 Mg;Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                  | Candesartan                   |              |            | S           | Oral         | 16 Mg;Qd;Po        |                 | Not Reported |
|                                                                                                                                                                                                                                  | Cilexetil\Hydrochlorothiazide |              |            | S           | Oral         | 850 Mg;Tid;Po      |                 | Teva         |
|                                                                                                                                                                                                                                  | Metformin Hydrochloride       |              |            | S           | Oral         | 50 Mg;Tid;Po       |                 | Not Reported |
|                                                                                                                                                                                                                                  | Acarbose                      |              |            | S           | Oral         | 60 Mg;Tid;Po       |                 | Not Reported |
|                                                                                                                                                                                                                                  | Urapidil                      |              |            | S           | Oral         | 100 Mg;Qd;Po Po    |                 | Teva         |



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|                                                          |                         |   |      |                 |              |
|----------------------------------------------------------|-------------------------|---|------|-----------------|--------------|
| Septic Shock;<br>Staphylococcal<br>Bacteraemia; Vomiting | Verapamil Hydrochloride | S | Oral | 100 Mg;Qd;Po Po | Teva         |
|                                                          | Ciprofibrate            | S | Oral | 240 Mg;Qd;Po    |              |
|                                                          | Escitalopram Oxalate    | S |      | 100 Mg;Qd;Po    |              |
|                                                          |                         |   |      | 10 Mg;Qd;Po     |              |
|                                                          | Xanax                   | S | Oral | 10 Mg;Qd;Po     |              |
|                                                          |                         |   |      | 0.25 Mg;Tid;Po  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 7932653       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000019955           |                      | 68 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                            | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Anaemia; Extradural<br>Haematoma; International<br>Normalised Ratio<br>Increased | Escitalopram Oxalate                                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                  | Fluindione                                          |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                  | Kardegic (Acetylsalicylate<br>Lysine)               |              |            | S           | Oral         | 160 Mg (160 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                  | Urbanyl                                             |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                  | Lasilix (Furosemide) (Tablets)<br>(Furosemide)      |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                  | Keppra (Levetiracetam)<br>(Tablets) (Levetiracetam) |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                  | Omeprazole                                          |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 7942702       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020199           |                      | 44 YR      | Male       | DNK            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Generalised Tonic-Clonic<br>Seizure; Tremor | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                             | Aspirin              |              |            | C           |              |                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 15-Jun-2011                                                                                                                                                                          | 7945754                                                                | EXPEDITED (15-DAY) | N                  | DS              | 1000020196           |                                  | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Pruritus; Arthralgia;<br>Bursa Disorder; Gait<br>Disturbance;<br>Haemorrhoidal<br>Haemorrhage; Myalgia;<br>Product Quality Issue;<br>Pruritus; Varicose Vein;<br>Vision Blurred | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral        |                 | Not Reported |                |
|                                                                                                                                                                                      | Calcium And Magnesium<br>(Calcium, Magnesium) (Calcium,<br>Magnesium)  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Eltroxin (Levothyroxine Sodium)<br>(Tablets) (Levothyroxine<br>Sodium) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Lecithin (Lecithin) (Lecithin)                                         |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Lipitac (Omega-3) (Omega-3)                                            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | One A Day (Multivitamins)<br>(Multivitamins)                           |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Vitamin B 50 (Thiamine<br>Hydrochloride) (Thiamine<br>Hydrochloride)   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Vitamin C (Ascorbic Acid)<br>(Ascorbic Acid)                           |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Vitamin E (Tocopherol)<br>(Tocopherol)                                 |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Alcohol (Ethanol) (Ethanol)                                            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2011                                                                                                                                                                          | 7947753                                                                | EXPEDITED (15-DAY) | N                  | DS, HO, LT      | 1000020285           |                                  | 58 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;<br>Presyncope                                                                                                                                                   | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                      | Asa (Acetylsalicylic Acid)<br>(Acetylsalicylic Acid)                   |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Calcium (Calcium) (Calcium)                                            |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Eltroxin (Levothyroxine Sodium)<br>(Tablets) (Levothyroxine<br>Sodium) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                                                                                                      | Fosavance (Alendronic Acid,                                            |                    |                    | C               |                      |                                  |                 | Not Reported |                |

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|                                                                    |   |              |
|--------------------------------------------------------------------|---|--------------|
| Cholecalciferol (Tablets)<br>(Alendronic Acid,<br>Cholecalciferol) | C | Not Reported |
| Magnesium (Magnesium)<br>(Magnesium)                               | C | Not Reported |
| Vitamin-D (Ergocalciferol)<br>(Ergocalciferol)                     | C | Not Reported |
| Alcohol (Ethanol) (Ethanol)                                        | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 7981998       | EXPEDITED (15-DAY) | Y                  | DS              | FR-ABBOTT-11P-056-0730612-00 |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Dyskinesia; Fall;<br>Hypomania; Nuclear<br>Magnetic Resonance<br>Imaging Brain Abnormal | Depakote               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Lithium Carbonate      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Propranolol            |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Previscan (Fluindione) |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Ramipril               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                              | Lasix                  |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 7992956       | EXPEDITED (15-DAY) | N                  | DE              | US-ABBOTT-11P-163-0731364-00 |                      | 4 YR       | Female     | USA            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Cardiovascular<br>Anomaly; Left Ventricular<br>Failure; Maternal<br>Exposure During<br>Pregnancy | Lexapro        |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                                             | Zoloft         |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 7994598       | EXPEDITED (15-DAY) | Y                  | HO              | ES-MYLANLABS-2011S1011547 |                      | 65 YR      | Male       | ESP            |

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| <u>Preferred Term</u>        | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Tubulointerstitial Nephritis | Escitalopram Oxalate           |              |            | S           | Oral         |                    |                 | Alphapharm   |
|                              | Lioresal                       |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Hydrochlorothiazide            |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Acetylsalicylic Acid           |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Amlodipine Besylate\Olmesartan |              |            | S           | Oral         |                    |                 | Not Reported |
|                              | Medoxomil                      |              |            |             |              |                    |                 |              |
|                              | Cyanocobalamin\Folic Acid      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 8014531       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000021541           |                      | 66 YR      | Female     | DNK            |

| <u>Preferred Term</u>                 | <u>Product</u>                                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|--------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Fall; Head Injury; Subdural Haematoma | Escitalopram Oxalate                                                     |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                       | Roactemra (Tocilizumab) (Solution) (Tocilizumab)                         |              |            | C           |              |                             |                 | Not Reported |
|                                       | Methotrexate (Methotrexate) (Methotrexate)                               |              |            | C           |              |                             |                 | Not Reported |
|                                       | Cortancyl (Prednisone) (Tablets) (Prednisone)                            |              |            | C           |              |                             |                 | Not Reported |
|                                       | Kestin (Ebastine) (Tablets) (Ebastine)                                   |              |            | C           |              |                             |                 | Not Reported |
|                                       | Adartrel (Ropinirole Hydrochloride) (Tablets) (Ropinirole Hydrochloride) |              |            | C           |              |                             |                 | Not Reported |
|                                       | Bonviva (Ibandronic Acid) (Tablets) (Ibandronic Acid)                    |              |            | C           |              |                             |                 | Not Reported |
|                                       |                                                                          |              |            |             |              |                             |                 |              |
|                                       |                                                                          |              |            |             |              |                             |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jun-2011              | 8014551       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021543           |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------|-----------------|--------------|----------------|
| 15-Jun-2011                                                                                                                                                                                                                                                                                                                                                     | 8014698                                          | EXPEDITED (15-DAY) | Y                  | DE              | 1000021538                   |                                    | 48 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Abnormal Sleep-Related<br>Event; Bipolar Disorder;<br>Depression; Drowning;<br>Hallucination, Auditory;<br>Psychotic Disorder;<br>Somnambulism                                                                                                                                                                                           | Lexapro                                          |                    |                    | S               |                              | 1 Df (1 Dosage Forms, 1<br>In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Codeine\Ibuprofen                                |                    |                    | S               |                              |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Acetaminophen\Codeine<br>Phosphate               |                    |                    | S               |                              |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Zolpidem Tartrate                                |                    |                    | S               |                              | 10 Mg (10 Mg, 1 In 1 D)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jun-2011                                                                                                                                                                                                                                                                                                                                                     | 8134444                                          | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-<br>2011123070 |                                    | 67 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                           | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Acute<br>Kidney Injury; Blood<br>Bicarbonate Decreased;<br>Blood Ph Decreased;<br>Bradycardia; Diarrhoea;<br>Disorientation; Drug Level<br>Increased; Dyspnoea;<br>General Physical Health<br>Deterioration;<br>Hyperkalaemia;<br>Hypotension; Lactic<br>Acidosis; Pallor; Pyrexia;<br>Septic Shock;<br>Staphylococcal<br>Bacteraemia; Vomiting | Xanax                                            |                    |                    | S               | Oral                         | 0.25 Mg, 3x/Day                    |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Candesartan Cilexetil And<br>Hydrochlorothiazide |                    |                    | S               | Oral                         | 16/12.5mg Per Day                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Metformin Hydrochloride                          |                    |                    | S               | Oral                         | 850 Mg, 3x/Day                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Acarbose                                         |                    |                    | S               | Oral                         | 50 Mg, 3x/Day                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Urapidil                                         |                    |                    | S               | Oral                         | 60 Mg, 3x/Day                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Atenolol                                         |                    |                    | S               | Oral                         | 100 Mg, 1x/Day                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Atenolol                                         |                    |                    | S               |                              | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Verapamil Hydrochloride                          |                    |                    | S               | Oral                         | 240 Mg, 1x/Day                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Ciprofibrate                                     |                    |                    | S               | Oral                         | 100 Mg, 1x/Day                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate                             |                    |                    | S               | Oral                         | 10 Mg, 1x/Day                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Escitalopram Oxalate                             |                    |                    | S               |                              | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                 | Mirtazapine                                      |                    |                    | S               | Oral                         | 15 Mg, 1x/Day                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                        | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2011                                                                                                                                                                                                                                                                                                                                                     | 7993930                                          | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2011131333 |                                    |                 | Male         | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Liver Function Test Abnormal                                                                                                                                                                                                    | Chantix                  |                    |                    | S               |                      | Unk                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                 | Lexapro                  |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2011                                                                                                                                                                                                                     | 7994855                  | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2011HR50016      |                      | 41 YR           | Female       | HRV            |
| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Asphyxia; Diarrhoea; Flushing; Hypersensitivity; Insomnia; Pruritus; Rash; Tongue Oedema; Urticaria; Weight Increased                                                                                               | Alprazolam               |                    |                    | S               |                      | 0.5 Mg, Unk          |                 | Novartis     |                |
|                                                                                                                                                                                                                                 | Escitalopram Oxalate     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                 | Sertraline Hydrochloride |                    |                    | S               |                      | 25 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2011                                                                                                                                                                                                                     | 8007556                  | DIRECT             | N                  |                 |                      |                      | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Asthenia; Confusional State; Coordination Abnormal; Depression; Dizziness; Euphoric Mood; Fatigue; Heart Rate Increased; Hyperhidrosis; Impulsive Behaviour; Insomnia; Libido Decreased; Somnolence; Visual Impairment | Lexapro                  |                    |                    | S               | Oral                 | 1 Tablet Daily Po    |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Jun-2011                                                                                                                                                                                                                     | 8007635                  | DIRECT             |                    | OT              |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                                                                |                   |        |  |  |  |  |  |  |                              |
|----------------------------------------------------------------|-------------------|--------|--|--|--|--|--|--|------------------------------|
| Female Orgasmic Disorder; Libido Decreased; Sexual Dysfunction | Lexapro<br>Zoloft | S<br>S |  |  |  |  |  |  | Not Reported<br>Not Reported |
|----------------------------------------------------------------|-------------------|--------|--|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2011              | 8017203       | EXPEDITED (15-DAY) | N                  | CA              | 1000021589           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Anomaly; Craniosynostosis; Maternal Drugs Affecting Foetus | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2011              | 8018429       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021575           |                      | 67 YR      | Male       | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Abdominal Pain; Acute Kidney Injury;             | Escitalopram Oxalate                          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral    |                 | Not Reported |
| Bradycardia; Device Related Infection;           | Candesartan Cilexetil And Hydrochlorothiazide |              |            | S           | Oral         | 16 Mg/12.5mg, Oral               |                 | Not Reported |
| Diarrhoea; Disorientation; Drug Level Increased; | Metformin Hydrochloride                       |              |            | S           | Oral         | 2550 Mg (850 Mg, 3 In 1 D), Oral |                 | Not Reported |
| Dyspnoea; General Physical Health Deterioration; | Acarbose                                      |              |            | S           | Oral         | 150 Mg (50 Mg, 3 In 1 D), Oral   |                 | Not Reported |
| Hyperkalaemia;                                   | Urapidil                                      |              |            | S           | Oral         | 180 Mg (60 Mg, 3 In 1 D), Oral   |                 | Not Reported |
| Hypotension; Lactic Acidosis; Septic Shock;      | Atenolol                                      |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D), Oral  |                 | Not Reported |
| Staphylococcal Bacteraemia; Vomiting             | Verapamil Hydrochloride                       |              |            | S           | Oral         | 240 Mg (240 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                                                  | Ciprofibrate                                  |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                                                  | Mirtazapine                                   |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),         |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|       |   |      |                                           |              |
|-------|---|------|-------------------------------------------|--------------|
| Xanax | S | Oral | Oral<br>0.75 Mg (0.25 Mg, 3 In 1 D), Oral | Not Reported |
|-------|---|------|-------------------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 16-Jun-2011              | 8134445       | EXPEDITED (15-DAY) | Y                  | HO              | JP-ASTRAZENECA-2011SE35982 |                      | 67 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                  | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|---------------------------------------------------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Hyperkalaemia; Lactic Acidosis | Candesartan Cilexetil And Hydrochlorothiazide |              |            | S           | Oral         | Candesartan Cilexetil 16 Mg/Hydrochlorothiazide 12.5 Mg, 1 Df Daily |                 | Astrazeneca  |
|                                                        | Metformin Hydrochloride                       |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Acarbose                                      |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Urapidil                                      |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Atenolol                                      |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Atenolol                                      |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Verapamil Hydrochloride                       |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Ciprofibrate                                  |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Escitalopram Oxalate                          |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Escitalopram Oxalate                          |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Mirtazapine                                   |              |            | S           | Oral         |                                                                     |                 | Not Reported |
|                                                        | Xanax                                         |              |            | S           | Oral         |                                                                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2011              | 8348736       | EXPEDITED (15-DAY) | N                  | CA, DE          | 1000021572           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect; Congenital Anomaly; Congenital Tricuspid Valve Atresia; Hypoplastic Right Heart Syndrome; Maternal | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Drugs Affecting Foetus;  
Pulmonary Valve  
Stenosis; Ventricular  
Septal Defect

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2011              | 7893206       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000019259           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Condition Aggravated;  | Lexapro                 |              |            | S           |              | 10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |
| Drug Interaction;      | Omeprazole              |              |            | S           |              |                        |                 | Not Reported |
| Dysphagia; Neuroleptic | Amantadine (Amantadine) |              |            | C           |              |                        |                 | Not Reported |
| Malignant Syndrome;    | (Amantadine)            |              |            |             |              |                        |                 |              |
| Serotonin Syndrome;    |                         |              |            |             |              |                        |                 |              |
| Tremor                 |                         |              |            |             |              |                        |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2011              | 7967221       | EXPEDITED (15-DAY) | Y                  | DE              | 1000020738           |                      | 26 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Accident; Blood Chloride | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
| Increased; Blood Glucose | Cocaine (Cocaine)             |              |            | S           |              |                    |                 | Not Reported |
| Decreased; Blood         | Oxycodone (Oxycodone)         |              |            | S           |              |                    |                 | Not Reported |
| Potassium Increased;     | Xanax                         |              |            | S           |              |                    |                 | Not Reported |
| Blood Sodium Decreased;  | Morphine                      |              |            | S           |              |                    |                 | Not Reported |
| Blood Urea Increased;    | Cannabis Sativa Subsp. Sativa |              |            | S           |              |                    |                 | Not Reported |
| Cardiomegaly; Pulmonary  | Flowering Top                 |              |            |             |              |                    |                 |              |
| Congestion; Pulmonary    | Hydroxyzine                   |              |            | S           |              |                    |                 | Not Reported |
| Oedema; Toxicity To      | Ibuprofen (Ibuprofen)         |              |            | S           |              |                    |                 | Not Reported |
| Various Agents           | Quetiapine Fumarate           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jun-2011              | 8022562       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021626           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Drug Dependence;      | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 |                 | Not Reported |
| Vertigo; Withdrawal   |                      |              |            |             |              |                     |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Syndrome D),Oral ; 5 Mg (5 Mg,1 In 1  
D),Oral

| <a href="#">FDA Received Date</a>                                            | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Jun-2011                                                                  | 7970877                     | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | US-PFIZER INC-2011117569      |                               | 62 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                               | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Arrest; Long Qt Syndrome; Sinus Bradycardia; Ventricular Tachycardia | Ondansetron                 |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
|                                                                              | Pantoprazole                |                           |                             | S                        |                               | 20 Mg, 1x/Day                 |                          | Pfizer              |                         |
|                                                                              | Suxamethonium               |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Nortriptyline Hydrochloride |                           |                             | S                        |                               | 25 Mg, 1x/Day                 |                          | Not Reported        |                         |
|                                                                              | Escitalopram Oxalate        |                           |                             | S                        |                               | 10 Mg, 1x/Day                 |                          | Not Reported        |                         |
|                                                                              | Acetylsalicylic Acid        |                           |                             | C                        |                               | 81 Mg, 1x/Day                 |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                            | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jun-2011                                                                  | 7994183                     | EXPEDITED (15-DAY)        | Y                           | HO                       | IT-ASTRAZENECA-2011SE35006    |                               | 49 YR                    | Male                | ITA                     |
| <a href="#">Preferred Term</a>                                               | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Electrocardiogram Qt Prolonged; Sinus Bradycardia                            | Tenormin                    |                           |                             | S                        | Oral                          |                               |                          | Zeneca              |                         |
|                                                                              | Ciprallex                   |                           |                             | S                        | Oral                          |                               |                          | Not Reported        |                         |
|                                                                              | Ramipril                    |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Adalat                      |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Tareg                       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Lasix                       |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Catapresan                  |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Tavor (Lorazepam)           |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Aldactone                   |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
|                                                                              | Cardioaspirin               |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                            | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jun-2011                                                                  | 7997506                     | EXPEDITED (15-DAY)        | Y                           | OT                       | ES-PFIZER INC-2011130671      |                               | 19 YR                    | Female              | ESP                     |
| <a href="#">Preferred Term</a>                                               | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                             |   |               |                        |              |
|-------------------------------------------|-----------------------------|---|---------------|------------------------|--------------|
| Abnormal Weight Gain;<br>Drug Interaction | Medroxyprogesterone Acetate | S | Intramuscular | 150 Mg, Every 3 Months | Pfizer       |
|                                           | Ciprallex                   | S | Oral          | 30 Mg, 1x/Day          | Not Reported |
|                                           | Risperidone                 | S | Oral          | 0.5 Mg, 1x/Day         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2011              | 8021524       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000021629           |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Abdominal Pain;<br>Dyspnoea; Epilepsy;<br>Normochromic Normocytic<br>Anaemia; Seizure;<br>Subileus | Escitalopram Oxalate                     |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                    | Norfloxacin                              |              |            | S           | Oral         | 800 Mg (400 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                    | Amitriptyline Hydrochloride              |              |            | S           | Oral         | 15 Drops (40 Mg/ML), Oral          |                 | Not Reported |
|                                                                                                    | Lovenox                                  |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                    | Diamicron (Gliclazide)<br>(Gliclazide)   |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                    | Temesta (Lorazepam)<br>(Lorazepam)       |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                    | Forlax (Macrogol) (Powder)<br>(Macrogol) |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                    | Debridat (Trimebutine)<br>(Trimebutine)  |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                    | Spasfon /00765801/                       |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jun-2011              | 8021613       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021630           |                      | 45 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Hyperhidrosis;<br>Hyperthermia;<br>Hypotension; Loss Of<br>Consciousness; Pain In<br>Extremity; Tachycardia | Escitalopram Oxalate                           |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 D),<br>Oral   |                 | Not Reported |
|                                                                                                             | Tramadol Hydrochloride                         |              |            | S           | Oral         | 300 Mg (150 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                             | Lexomil (Bromazepam) (Tablets)<br>(Bromazepam) |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                             | Tercian (Cyamemazine)                          |              |            | C           |              |                                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

(Cyamemazine)  
Xylocaine Viscous  
Dafalgan Codein (Panadeine  
Co) (Tablets) (Panadeine Co)

C  
C

Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2011              | 7419086       | EXPEDITED (15-DAY) | Y                  | OT              | CH-PFIZER INC-CH-WYE-G06220510 |                      |            | Male       | CHE            |

| <u>Preferred Term</u>                                                                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|----------------|-------------------------------|-----------------|--------------|
| Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy; Respiratory Disorder Neonatal | Effexor Xr              |              |            | S           | Transplacental | 75 Mg, 1x/Day                 |                 | Pfizer       |
|                                                                                                    | Buspar                  |              |            | S           | Transplacental | 10 Mg, 3x/Day                 |                 | Not Reported |
|                                                                                                    | Cipralelex              |              |            | S           | Transplacental | 40 Mg, 1x/Day                 |                 | Not Reported |
|                                                                                                    | Cipralelex              |              |            | S           | Transplacental | 5 Mg, 1x/Day                  |                 | Not Reported |
|                                                                                                    | Oxazepam                |              |            | S           | Transplacental | 15 Mg, 1x/Day                 |                 | Not Reported |
|                                                                                                    | Trazodone Hydrochloride |              |            | S           | Transplacental | 50 Mg, 1x/Prn                 |                 | Not Reported |
|                                                                                                    | Alcohol                 |              |            | S           | Unknown        | Occasionally During Pregnancy |                 | Not Reported |
|                                                                                                    | Cannabis                |              |            | C           | Transplacental | Unk                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 21-Jun-2011              | 7419093       | EXPEDITED (15-DAY) | Y                  | OT              | CH-PFIZER INC-CH-WYE-G06220410 |                      | 34 YR      | Female     | CHE            |

| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Postpartum Haemorrhage | Effexor Xr              |              |            | S           |              | 75 Mg, 1x/Day                     |                 | Pfizer       |
|                        | Buspar                  |              |            | S           |              | 10 Mg, 3x/Day                     |                 | Not Reported |
|                        | Cipralelex              |              |            | S           | Unknown      | 10 Mg, 1x/Day                     |                 | Not Reported |
|                        | Cipralelex              |              |            | S           | Unknown      | 5 Mg, 1x/Day                      |                 | Not Reported |
|                        | Oxazepam                |              |            | S           |              | 15 Mg, 1x/Day                     |                 | Not Reported |
|                        | Trazodone Hydrochloride |              |            | S           |              | 50 Mg, 1x/Prn                     |                 | Not Reported |
|                        | Alcohol                 |              |            | S           | Unknown      | Episodically During The Pregnancy |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Cannabis                                                                                                                                        |                      |                    | C                  |                 | Unknown                  |                               |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2011                                                                                                                                     | 8001195              | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011133481 |                               | 18 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Behaviour;<br>Toxicity To Various Agents                                                                                               | Xanax                |                    |                    | S               | Oral                     | 0.25 Mg, 1x/Day If Needed     |                 | Pfizer       |                |
|                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                     | Unk                           |                 | Not Reported |                |
|                                                                                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                     | Unk                           | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2011                                                                                                                                     | 8014319              | DIRECT             | N                  | LT, RI          |                          |                               | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Decreased Activity; Discomfort; Dyspnoea; Hyperphagia; Increased Appetite; Product Quality Issue; Weight Increased | Lexapro              |                    |                    | S               | Oral                     | Varied 10 Mg To 20mg Daily Po |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Jun-2011                                                                                                                                     | 8014493              | DIRECT             | N                  | OT              |                          |                               | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous; Feeling Abnormal; Maternal Exposure During Pregnancy; Paraesthesia                                                        | Lexapro              |                    |                    | S               | Oral                     | 10mg Daily Po                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                                                                                                     | 7998113              | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2011SP024114             |                               | 31 YR           | Female       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------|------------------------------------------|-----------------|--------------|----------------|
| Caesarean Section;<br>Maternal Exposure During<br>Pregnancy; Pain; Pre-<br>Eclampsia; Premature<br>Delivery; Urinary Tract<br>Infection | Mirtazapine              |                    |                    | S               |                           | 30 Mg;Qd; 15 Mg;Qd<br>30 Mg;Qd; 15 Mg;Qd |                 | Not Reported |                |
|                                                                                                                                         | Ciprallex                |                    |                    | S               | Oral                      | 10 Mg;Qd;Po                              |                 | Not Reported |                |
|                                                                                                                                         | Paracetamol              |                    |                    | C               |                           |                                          |                 | Not Reported |                |
|                                                                                                                                         | Amoxicillin\Clavulanate  |                    |                    | C               |                           |                                          |                 | Not Reported |                |
|                                                                                                                                         | Potassium<br>Folio Forte |                    |                    | C               |                           |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                                                                                             | 8001832                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020548                |                                          | 45 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Non-Hodgkin'S<br>Lymphoma; Pancytopenia                                                                                                 | Escitalopram Oxalate     |                    |                    | S               |                           |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                                                                                             | 8001908                  | EXPEDITED (15-DAY) | Y                  | LT              | GB-JNJFOC-<br>20110606702 |                                          | 38 YR           | Female       | GBR            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure;<br>Syncope                                                                                                   | Tramadol Hydrochloride   |                    |                    | S               | Oral                      |                                          | 63 DAY          | Not Reported |                |
|                                                                                                                                         | Tramadol Hydrochloride   |                    |                    | S               | Oral                      |                                          | 63 DAY          | Not Reported |                |
|                                                                                                                                         | Chlorpromazine           |                    |                    | C               |                           |                                          |                 | Not Reported |                |
|                                                                                                                                         | Co-Codamol               |                    |                    | C               |                           |                                          |                 | Not Reported |                |
|                                                                                                                                         | Nexium                   |                    |                    | C               |                           |                                          |                 | Not Reported |                |
|                                                                                                                                         | Escitalopram Oxalate     |                    |                    | S               | Unknown                   |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                                                                                             | 8018445                  | DIRECT             | N                  | OT              |                           |                                          | 51 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Dependence;<br>Paraesthesia                                                                                                        | Lexapro                  |                    |                    | S               | Oral                      | 20 Mg 1.5 Daily Oral                     |                 | Forest       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                  | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------|-----------------|--------------|----------------|
| 22-Jun-2011                                                               | 8024840                                                                                              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021649           |                                                                  | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder;<br>Headache; Vertigo                                  | Escitalopram Oxalate                                                                                 |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                               | 8024938                                                                                              | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000021654           |                                                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Drug Ineffective; Long Qt<br>Syndrome Congenital | Escitalopram Oxalate                                                                                 |                    |                    | S               |                      |                                                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                               | 8027929                                                                                              | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000021585           |                                                                  | 47 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Hypocapnia;<br>Sexual Dysfunction;<br>Weight Increased           | Lexapro                                                                                              |                    |                    | S               | Oral                 | Oral                                                             |                 | Not Reported |                |
|                                                                           |                                                                                                      |                    |                    |                 | Oral                 | Oral                                                             |                 |              |                |
|                                                                           | Venlafaxine Hydrochloride                                                                            |                    |                    | S               | Oral                 | 37.5 Mg (37.5 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                           |                                                                                                      |                    |                    |                 | Oral                 | 37.5 Mg (37.5 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                           | Prozac                                                                                               |                    |                    | S               | Oral                 | (1 In 1 D), Oral                                                 |                 | Not Reported |                |
|                                                                           | Trazodone (Trazodone) (50 Milligram, Tablets) (Trazodone)                                            |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |
|                                                                           | Z-Dex 12d (Dextromethorphan, Chlorpheniramine, Phenylephrine) (Dextromethorphan, Chlorpheniramine, P |                    |                    | C               |                      |                                                                  |                 | Not Reported |                |

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|                                                                                               |                      | Sominex (Methapyrilene Hydrochloride, Salicylamide, Scopolamine Aminoxide Hydrobromide) (Methapyrile) |                    | C               |                          |                               |                 |              | Not Reported   |
|-----------------------------------------------------------------------------------------------|----------------------|-------------------------------------------------------------------------------------------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>                                                                                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Jun-2011                                                                                   | 8027932              | EXPEDITED (15-DAY)                                                                                    | N                  | RI, OT          | 1000021622               |                               | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>                                                                                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Petit Mal Epilepsy; Weight Increased | Lexapro              |                                                                                                       |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                               | Zyrtec               |                                                                                                       |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>                                                                                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2011                                                                                   | 7984444              | EXPEDITED (15-DAY)                                                                                    |                    | OT              | TW-PFIZER INC-2011123616 |                               | 52 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>                                                                                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Extrapyrimal Disorder; Multiple System Atrophy; Parkinsonism                       | Sertraline Hcl       |                                                                                                       |                    | S               |                          |                               |                 | Pfizer       |                |
|                                                                                               | Escitalopram Oxalate |                                                                                                       |                    | S               |                          |                               |                 | Not Reported |                |
|                                                                                               | Fluoxetine           |                                                                                                       |                    | S               |                          |                               |                 | Not Reported |                |
|                                                                                               | Duloxetine           |                                                                                                       |                    | S               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>                                                                                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2011                                                                                   | 8003995              | NON-EXPEDITED                                                                                         | Y                  | OT              | US-PFIZER INC-2011133845 |                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>                                                                                          | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                                                                                     | Zoloft               |                                                                                                       |                    | S               |                          | Unk                           |                 | Pfizer       |                |
|                                                                                               | Lexapro              |                                                                                                       |                    | S               |                          | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u>                                                                                      | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Jun-2011                                                                                   | 8006934              | EXPEDITED (15-DAY)                                                                                    | Y                  | HO              | FR-PFIZER INC-2011131911 |                               | 39 YR           | Male         | FRA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Poisoning;<br>Merycism; Suicidal<br>Behaviour; Toxicity To<br>Various Agents | Xanax                                       |              |            | S           |              | Unk                | 91 DAY          | Pfizer       |
|                                                                                      | Escitalopram Oxalate                        |              |            | S           | Oral         | Unk                | 91 DAY          | Not Reported |
|                                                                                      | Ramipril                                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Tramadol Hydrochloride And<br>Acetaminophen |              |            | C           |              | 6 Df Unk           |                 | Not Reported |
|                                                                                      | Hydrochlorothiazide\Ramipril                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Ibuprofen                                   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Aerius (Desloratadine)                      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                      | Alcohol                                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2011              | 8028633       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021652           |                      | 42 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                          | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Intentional Overdose;<br>Suicide Attempt;<br>Unevaluable Event | Escitalopram Oxalate        |              |            | S           | Oral         | 1000 Mg, Once, Oral   |                 | Not Reported |
|                                                                | Nortriptyline Hydrochloride |              |            | S           | Oral         | 2500 Mg, Once, Oral   |                 | Not Reported |
|                                                                | Lithium Carbonate           |              |            | S           | Oral         | 45000 Mg, Once, Oral; |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jun-2011              | 8028680       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021662           |                      | 77 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Amnesia; Cerebral<br>Haemorrhage;<br>Disorientation; Face Injury;<br>Fall; Head Injury;<br>Hemiparesis; Loss Of<br>Consciousness | Escitalopram Oxalate                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                  | Plavix                              |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                  | Depakote                            |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                  | Crestor (Rosuvastatin) (Tablets)    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                  | Tercian (Cyamemazine)<br>(Capsules) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                  | Urbanyl                             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                  | Furosemide                          |              |            | C           |              |                                  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------------|-------------------------------|-----------------|--------------|----------------|
| 23-Jun-2011                                                                                                                                                                                                              | 8028782                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000021680                 |                               | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness; Nausea                                                                                                                                                          | Escitalopram Oxalate              |                    |                    | S               | Oral                       | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Aricept                           |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Langoran (Isosorbide Dinitrate)   |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Zanidip (Lercanidipine)           |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Candesartan Cilexetil             |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Aspirin                           |                    |                    | C               |                            |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Lipanthyl (Fenofibrate) (Tablets) |                    |                    | C               |                            |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Jun-2011                                                                                                                                                                                                              | 8009033                           | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011134939   |                               | 35 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt                                                                                                                                                                                                          | Xanax                             |                    |                    | S               | Oral                       | 20 Tablets, Unk               |                 | Pfizer       |                |
|                                                                                                                                                                                                                          | Escitalopram Oxalate              |                    |                    | S               | Oral                       | 10 Tablets, Unk               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                 | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2011                                                                                                                                                                                                              | 7974258                           | EXPEDITED (15-DAY) |                    | HO, OT          | US-ASTRAZENECA-2011SE32305 |                               | 82 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                    | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Cataract Operation; Cerebrovascular Accident; Cervical Vertebral Fracture; Confusional State; Coronary Artery Disease; Dehydration; Dementia Alzheimer'S Type; Ejection Fraction Decreased; Fall; Hypersomnia; | Crestor                           |                    |                    | S               | Oral                       |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                          | Lexapro                           |                    |                    | S               | Unknown                    |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Incontinence; Loss Of  
Consciousness;  
Pneumonia; Presyncope;  
Radioisotope Scan; Spinal  
Fusion Surgery; Suicidal  
Ideation; Syncope; Urinary  
Bladder Suspension;  
Urinary Tract Infection;  
Ventricular Tachycardia;  
Vomiting; Weight  
Decreased

| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| 27-Jun-2011                                        | 8010305              | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2011136800 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Withdrawal<br>Syndrome; Panic Attack | Geodon               |                    |                    | S               |                              | 60 Mg, Unk                       |                 | Pfizer       |                |
|                                                    | Lexapro              |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Jun-2011                                        | 8033027              | EXPEDITED (15-DAY) | Y                  | DS              | 1000021711                   |                                  | 54 YR           | Female       | DNK            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Gait Inability; Neuralgia;<br>Pain In Extremity    | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2011                                        | 8023459              | DIRECT             | N                  | LT, OT          |                              |                                  | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Heat Exhaustion; Heat<br>Stroke                    | Lexapro              |                    |                    | S               | Oral                         | 10mg Daily Po                    | 2 YR            | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|--------------|----------------|
| 28-Jun-2011                                                                                              | 8033037                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000021712               |                          | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Confusional State; Dyspnoea; Hyponatraemia; Pallor                                           | Escitalopram Oxalate                   |                    |                    | S               | Oral                     | Oral                     |                 | Not Reported |                |
|                                                                                                          | Lisinopril                             |                    |                    | C               |                          |                          |                 | Not Reported |                |
|                                                                                                          | Lorazepam                              |                    |                    | C               |                          |                          |                 | Not Reported |                |
|                                                                                                          | Mirtazapine                            |                    |                    | C               |                          |                          |                 | Not Reported |                |
|                                                                                                          | Simvastatin (Simvastatin) (Simvasatin) |                    |                    | C               |                          |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Jun-2011                                                                                              | 8036210                                | EXPEDITED (15-DAY) | Y                  | HO              | 1000021734               |                          |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Leukocytosis; Pancreatitis Acute                                                                         | Lexapro                                |                    |                    | S               |                          |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2011                                                                                              | 7807609                                | EXPEDITED (15-DAY) |                    | CA, DE, OT      | FR-PFIZER INC-2011029215 |                          |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari Malformation; Congenital Foot Malformation; Foetal Exposure During Pregnancy; Spina Bifida | Atarax                                 |                    |                    | S               | Transplacental           | 25 Mg Or 50 Mg, Weekly   |                 | Pfizer       |                |
|                                                                                                          | Escitalopram Oxalate                   |                    |                    | S               | Transplacental           | Unknown                  |                 | Not Reported |                |
|                                                                                                          | Versatis                               |                    |                    | S               | Transplacental           | 0.5 Df Qod, Drug Plaster |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jun-2011                                                                                              | 7951977                                | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000019289               |                          | 44 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicide Attempt; Trance                                                                                  | Escitalopram Oxalate                   |                    |                    | S               |                          | 5 Mg (5 Mg,1 In 1 D)     |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |   |              |
|----------------------------------------------------------------------------------------|---|--------------|
| Effexor Xr (Venlafaxine Hydrochloride) (Capsules)                                      | C | Not Reported |
| Novo Venlafaxine Xr (Venlafaxine Hydrochloride) (Capsules) (Venlafaxine Hydrochloride) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
|--------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------|-----------------|---------------------------------|----------------|
| 29-Jun-2011              | 8014342                                                    | NON-EXPEDITED      | N                  |                 | A0859251A            |                                                                   |                 | Unknown                         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>                      |                |
| Libido Decreased         | Zyban<br>Lexapro                                           |                    |                    | S<br>S          |                      |                                                                   |                 | Glaxosmithkline<br>Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 29-Jun-2011              | 8014811                                                    | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000019332           |                                                                   | 44 YR           | Male                            | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>                      |                |
| Suicide Attempt; Trance  | Escitalopram Oxalate                                       |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral                                         |                 | Not Reported                    |                |
|                          | Teva-Venlafaxine Xr (Venlafaxine) (Capsules) (Venlafaxine) |                    |                    | C               |                      |                                                                   |                 | Not Reported                    |                |
|                          | Novo-Venlafaxine Xr (Venlafaxine) (Capsules) (Venlafaxine) |                    |                    | C               |                      |                                                                   |                 | Not Reported                    |                |
| <u>FDA Received Date</u> | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                              | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 29-Jun-2011              | 8024544                                                    | DIRECT             | N                  | DS              |                      |                                                                   | 46 YR           | Male                            | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>                      |                |
| Ear Discomfort; Tinnitus | Lexapro                                                    |                    |                    | S               | Oral<br>Oral<br>Oral | 2.5 Mg 3 Times Oral<br>2.5 Mg 3 Times Oral<br>2.5 Mg 3 Times Oral |                 | Not Reported                    |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Jun-2011              | 7749643       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2010182248 |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Altered State Of Consciousness; Anxiety; Drug Ineffective; Drug Intolerance; Dysphagia; Insomnia; Mental Disorder; Nervous System Disorder; Post-Traumatic Stress Disorder; Sedation; Suffocation Feeling | Effexor Xr     |              |            | S           | Oral         | 75 Mg, Daily       |                 | Pfizer       |
|                                                                                                                                                                                                                      | Effexor Xr     |              |            | S           | Oral         | 120 Mg, Unk        |                 | Pfizer       |
|                                                                                                                                                                                                                      | Effexor Xr     |              |            | S           | Oral         | 150 Mg, Daily      |                 | Pfizer       |
|                                                                                                                                                                                                                      | Effexor Xr     |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                      | Prozac         |              |            | S           | Oral         | 20 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                                      | Valium         |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                                      | Zyprexa        |              |            | S           | Oral         | 1 Mg, 1x/Day       |                 | Not Reported |
|                                                                                                                                                                                                                      | Zyprexa        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                      | Lexapro        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                      | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                      | Calcium        |              |            | C           | Oral         | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                      | Multivitamins  |              |            | C           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jun-2011              | 7913139       | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-ROCHE-772674      |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------|--------------|------------|-------------|---------------------------------------|------------------------------|-----------------|--------------|
| Drug Interaction; Gastrointestinal Haemorrhage | Rocephin       |              |            | S           | Intravenous (not otherwise specified) |                              |                 | Roche        |
|                                                | Humalog        |              |            | C           | Subcutaneous                          | Start Date : For A Long Time |                 | Not Reported |
|                                                | Lantus         |              |            | C           | Subcutaneous                          | Start Date : For A Long Time |                 | Not Reported |
|                                                | Aprovel        |              |            | C           | Oral                                  | Start Date : For A Long Time |                 | Not Reported |
|                                                | Propranolol    |              |            | C           | Oral                                  | Start Date : For A Long Time |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |                      |                        |                    |                 |                      |                                         |                              |            |                |
|---------------------------------------------|----------------------|------------------------|--------------------|-----------------|----------------------|-----------------------------------------|------------------------------|------------|----------------|
|                                             |                      | Cortancyl              | C                  | Oral            |                      |                                         | Time                         |            | Not Reported   |
|                                             |                      | Alendronic Acid        | C                  | Oral            |                      |                                         |                              |            | Not Reported   |
|                                             |                      | Lercanidipine          | C                  | Oral            |                      |                                         |                              |            | Not Reported   |
|                                             |                      | Omeprazole             | C                  | Oral            |                      |                                         |                              |            | Not Reported   |
|                                             |                      | Previscan (Fluindione) | S                  | Oral            |                      |                                         | Start Date : For A Long Time |            | Not Reported   |
|                                             |                      | Escitalopram Oxalate   | S                  | Oral            |                      |                                         |                              |            | Not Reported   |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>                   | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2011                                 | 8036522              | EXPEDITED (15-DAY)     | Y                  | DE              | 1000021713           |                                         |                              | Female     | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>           | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u>              | <u>Mfr</u> |                |
| Maternal Drugs Affecting Foetus; Stillbirth | Escitalopram Oxalate |                        |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D), Transplacental |                              |            | Not Reported   |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>                   | <u>Sex</u> | <u>Country</u> |
| 01-Jul-2011                                 | 7916221              | EXPEDITED (15-DAY)     | Y                  | RI, OT          | 1000019741           |                                         | 51 YR                        | Male       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>           | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u>              | <u>Mfr</u> |                |
| Intraocular Pressure Increased              | Escitalopram Oxalate |                        |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral             |                              |            | Not Reported   |
|                                             | Escitalopram Oxalate |                        |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral             |                              |            | Not Reported   |
|                                             |                      |                        |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral           |                              |            | Not Reported   |
|                                             |                      |                        |                    |                 | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral           |                              |            | Not Reported   |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>       | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>                   | <u>Sex</u> | <u>Country</u> |
| 01-Jul-2011                                 | 8018819              | EXPEDITED (15-DAY)     | Y                  | OT              | HR-WATSON-2011-09547 |                                         | 41 YR                        | Female     | HRV            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>           | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u>              | <u>Mfr</u> |                |
| Angioedema; Diarrhoea;                      | Alprazolam           |                        |                    | S               |                      | 0.5 Mg, Daily Once Or                   |                              |            | Watson         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Urticaria

Sertraline Hydrochloride  
Escitalopram Oxalate

S  
S

Twice A Week  
25 Mg, Unk  
5 Mg, Unk

Watson  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Jul-2011              | 8018897       | EXPEDITED (15-DAY) | Y                  | HO              | TW-MYLANLABS-2011S1013122 |                      | 52 YR      | Female     | TWN            |

| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Multiple System Atrophy;<br>Parkinsonism | Fluoxetine Hcl           |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                          | Sertraline Hydrochloride |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                          | Escitalopram Oxalate     |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                          | Duloxetine               |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2011              | 8031408       | DIRECT           | Y                  | DE              |                      |                      | 3 DAY      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Disorder; Cardio-Respiratory Arrest<br>Neonatal; Death Neonatal;<br>Foetal Hypokinesia;<br>Hepatic Steatosis;<br>Hypoperfusion; Maternal<br>Drugs Affecting Foetus;<br>Metabolic Acidosis;<br>Vacuum Extractor Delivery | Lexapro                  |              |            | S           | Oral         | Po                 |                 | Forest       |
|                                                                                                                                                                                                                                 | Ampicillin Sodium        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Ceftotaxime              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Lasix                    |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Gentamicin               |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Potassium Chloride       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Na Bicarb                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Midazolam                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Morphine                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Dobutamine Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Dopamine                 |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Epinephrine              |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Milrinone                |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                 | Tpn                      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Jul-2011              | 8044787       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021775           |                      | 39 YR      | Male       | DNK            |



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| <u>Preferred Term</u>                                                         | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| Anxiety; Coma Scale Abnormal; Gamma-Glutamyltransferase Increased             | Escitalopram Oxalate                     |                    |                    | S               | Oral                  | Oral                                          |                 | Not Reported |                |
|                                                                               | Xanax                                    |                    |                    | S               | Oral                  | Overdose, Oral                                |                 | Not Reported |                |
|                                                                               | Alcohol (Ethanol)                        |                    |                    | S               |                       |                                               |                 | Not Reported |                |
|                                                                               | Ramipril                                 |                    |                    | C               |                       |                                               |                 | Not Reported |                |
|                                                                               | Tramadol Hydrochloride And Acetaminophen |                    |                    | C               |                       |                                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Jul-2011                                                                   | 8044800                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000021776            |                                               | 18 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Incorrect Dose Administered; Partner Stress               | Escitalopram Oxalate                     |                    |                    | S               | Oral                  | Oral Overdose Of Escitalopram                 |                 | Not Reported |                |
|                                                                               |                                          |                    |                    |                 | Oral                  | Oral Overdose Of Escitalopram                 |                 |              |                |
|                                                                               | Xanax                                    |                    |                    | S               |                       | (0.25 Mg, If Necessary), Oral Overdose (Once) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                      | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jul-2011                                                                   | 7947888                                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-JNJFOC-20110506107 |                                               |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Apgar Score Low; Bradycardia; Hypotonia; Infantile Apnoea; Metabolic Acidosis | Topamax                                  |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Topamax                                  |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Lexapro                                  |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Omeprazole                               |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Ampicillin Sodium                        |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Gentamicin                               |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Clindamycin                              |                    |                    | S               | Transplacental        |                                               |                 | Not Reported |                |
|                                                                               | Elavil                                   |                    |                    | C               | Transplacental        |                                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2011              | 8021800       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011TW56904      |                      | 52 YR      | Female     | TWN            |

| <u>Preferred Term</u>                                                                                                                                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Akathisia; Balance Disorder; Extrapyramidal Disorder; Gait Disturbance; Multiple System Atrophy; Muscle Rigidity; Orthostatic Hypotension; Parkinsonism; Psychomotor Retardation; Tremor; Urinary Incontinence | Fluoxetine Hcl           |              |            | S           |              |                    |                 | Novartis     |
|                                                                                                                                                                                                                | Sertraline Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                | Duloxetine               |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jul-2011              | 8041032       | EXPEDITED (15-DAY) | N                  | HO              | 2011SP030151         |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Feeling Abnormal; Panic Attack; Somnolence | Remeron        |              |            | S           | Oral         | 45 Mg;Qd;Po        |                 | Not Reported |
|                                                     | Lexapro        |              |            | S           |              | 2.5 Mg ; 5 Mg      |                 | Not Reported |
|                                                     | Cymbalta       |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Abilify        |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Allopurinol    |              |            | C           |              |                    |                 | Not Reported |
|                                                     | Ramipril       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2011              | 8024126       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021667           |                      | 62 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Atrioventricular Block First Degree; Cardiac Arrest; Fibrosis; Gastric Bypass; Left Ventricular | Escitalopram Oxalate        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                                                                                 | Escitalopram Oxalate        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                                                                                 | Nortriptyline Hydrochloride |              |            | S           |              | 25 Mg (25 Mg, 1 In 1 D) |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                             |                                         |        |  |  |  |  |  |  |                              |
|---------------------------------------------------------------------------------------------|-----------------------------------------|--------|--|--|--|--|--|--|------------------------------|
| Hypertrophy; Long Qt Syndrome; Sinus Bradycardia; Ventricular Tachycardia; Weight Increased | Succinylcholine Chloride<br>Ondansetron | S<br>S |  |  |  |  |  |  | Not Reported<br>Not Reported |
|---------------------------------------------------------------------------------------------|-----------------------------------------|--------|--|--|--|--|--|--|------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2011              | 8044829       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000021905           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Benign Congenital Hypotonia; Bradycardia; Cardiac Murmur; Congenital Anomaly; Congenital Choroid Plexus Cyst; Foetal Distress Syndrome; Maternal Drugs Affecting Foetus; Neonatal Respiratory Depression; Neural Tube Defect; Overdose; Premature Baby | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                        | Folic Acid           |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2011              | 8044863       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000021824           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abscess Oral; Weight Increased | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2011              | 8044970       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021937           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Arthralgia; Headache; Hemiparesis; Muscular Weakness; Pain In | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Extremity; Vertigo

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Jul-2011              | 8730557       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Asthma;<br>Lymphadenopathy; Rash;<br>Urticaria | Lexapro 10 Forest Laboratories |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2011              | 7957176       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020562           |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                       | <u>Product</u>                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------|------------|-------------|------------------------------------------|--------------------------------------------------|-----------------|--------------|
| Cerebrovascular Accident;<br>Drug Interaction;<br>Gastrointestinal<br>Haemorrhage;<br>Haemoglobin Decreased;<br>International Normalised<br>Ratio Increased | Escitalopram Oxalate                                                               |              |            | S           | Oral                                     | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                             | Fluindione                                                                         |              |            | S           |                                          | Long-Standing Treatment -<br>03/16/2011          |                 | Not Reported |
|                                                                                                                                                             | Ceftriaxone Sodium                                                                 |              |            | S           | Intravenous (not<br>otherwise specified) | Intravenous (Not<br>Otherwise Specified)         |                 | Not Reported |
|                                                                                                                                                             | Lantus                                                                             |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Aprovel ( Irbesartan) (150<br>Milligram) ( Irbesartan)                             |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Avlocardyl                                                                         |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | (Propranolol)(Propranolol)                                                         |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Cortancyl (Prednisone) (20<br>Milligram) (Prednisone)                              |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Fosavance (Alendronic Acid,<br>Colecalciferol)(Alendronic Acid,<br>Colecalciferol) |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Lercan (Lercanidipine<br>Hydrochloride) (Lercanidipine<br>Hydrochloride)           |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Mopral (Omeprazole)<br>(Omeprazole)                                                |              |            | C           |                                          |                                                  |                 | Not Reported |
|                                                                                                                                                             | Humalog (Insulin) (Insulin)                                                        |              |            | C           |                                          |                                                  |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Jul-2011              | 7999365       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021207           |                      | 63 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Psoriatic Arthropathy | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |
|                       | Fluoxetine Hydrochloride |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|------------|------------|----------------|
| 08-Jul-2011              | 8025943       | EXPEDITED (15-DAY) | Y                  | DS              | GB-EISAI INC-E2020-09407-SPO-GB |                      | 87 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Facial Paralysis;     | Aricept        |              |            | S           | Oral         |                    |                 | Not Reported |
| Myoclonus; Tardive    | Ciprallex      |              |            | S           | Oral         |                    |                 | Not Reported |
| Dyskinesia            |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-Jul-2011              | 8026810       | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2011147693 |                      | 85 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Fall                  | Xanax                  |              |            | S           | Oral         | 0.25 Mg, Unk         |                 | Pfizer       |
|                       | Xanax                  |              |            | S           |              | 0.25mg, (1/2-0-1/2)  |                 | Pfizer       |
|                       | Zopiclone              |              |            | S           | Oral         | 7.5 Mg, 1x/Day       |                 | Not Reported |
|                       | Zopiclone              |              |            | S           |              | 7.5 Mg, (0-0-1/2)    |                 | Not Reported |
|                       | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg, Unk           |                 | Not Reported |
|                       | Tramadol Hydrochloride |              |            | S           |              |                      |                 | Not Reported |
|                       | Actonel                |              |            | C           | Oral         | 75 Mg, 150mg Monthly |                 | Not Reported |
|                       | Paracetamol            |              |            | C           |              | Unk                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2011              | 8027048       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2011FR57394      |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                      |   |           |        |              |
|-------------------------|----------------------|---|-----------|--------|--------------|
| Leukopenia; Neutropenia | Zometa               | S | 4 Mg, Unk |        | Novartis     |
|                         | Rocephin             | S | 1 G, Qd   | 16 DAY | Not Reported |
|                         | Lasix                | S | 20 Mg, Qd | 31 DAY | Not Reported |
|                         | Escitalopram Oxalate | S |           |        | Not Reported |
|                         | Rivotril             | C |           |        | Not Reported |
|                         | Xanax                | C |           |        | Not Reported |
|                         | Aspirin              | C |           |        | Not Reported |
|                         | Aprovel              | C |           |        | Not Reported |
|                         | Esomeprazole         | C |           |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2011              | 8031809       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021683           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>                                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Anxiety; Condition Aggravated; Road Traffic Accident; Seizure | Escitalopram Oxalate                                                                    |              |            | S           | Oral         | 5 Mg (5 Mg,1 In 1 D),Oral   |                 | Not Reported |
|                                                               | Mirtazapine                                                                             |              |            | S           | Oral         | 15 Mg (15 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                               | Theralen Oral Drops (Alimemazine Tartrate) (Drops(For Oral Use)) (Alimemazine Tartrate) |              |            | C           |              |                             |                 | Not Reported |
|                                                               | Atarax (Hydroxyzine) (Tablets) (Hydroxyzine)                                            |              |            | C           |              |                             |                 | Not Reported |
|                                                               | Panocod (Acetaminophen, Codeine Phosphate) (Tablets) (Acetaminophen, Codeine Phosphate) |              |            | C           |              |                             |                 | Not Reported |
|                                                               | Diklofenak (Diclofenac Sodium) (Tablets) (Diclofenac Sodium)                            |              |            | C           |              |                             |                 | Not Reported |
|                                                               | Panodil Forte (Paracetamol) (Paracetamol)                                               |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Jul-2011              | 8046972       | EXPEDITED (15-DAY) | Y                  | DE, HO          | AUR-APL-2011-03696   |                      | 69 YR      | Female     | POL            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                           |   |          |              |
|---------------------------|---------------------------|---|----------|--------------|
| Antiphospholipid          | Paroxetine Hydrochloride  | S | (20 Mg)  | Not Reported |
| Antibodies Positive;      | Sertraline Hydrochloride  | S | (100 Mg) | Not Reported |
| Condition Aggravated;     | Mirtazapine (Mirtazapine) | S | (30 Mg)  | Not Reported |
| Deep Vein Thrombosis;     | Venlafaxine               | S | (225 Mg) | Not Reported |
| Depression; International | Reboxetine                | S | (4 Mg)   | Not Reported |
| Normalised Ratio          | Escitalopram Oxalate      | S | (20 Mg)  | Not Reported |
| Abnormal; Pulmonary       | Quetiapine Fumarate       | S | (100 Mg) | Not Reported |
| Embolism                  | Olanzapine (Olanzapine)   | S | (5 Mg)   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2011              | 8029110       | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2011GB60248      |                      | 60 DAY     | Female     | GBR            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cardiac Septal Defect;  | Citalopram           |              |            | S           | Transplacental | 20 Mg, Qd          |                 | Novartis     |
| Congenital Pulmonary    | Escitalopram Oxalate |              |            | S           |                | 20 Mg, Qd          |                 | Not Reported |
| Valve Atresia; Maternal |                      |              |            |             |                |                    |                 |              |
| Exposure During         |                      |              |            |             |                |                    |                 |              |
| Pregnancy               |                      |              |            |             |                |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2011              | 8029554       | EXPEDITED (15-DAY) | Y                  | CA, DE          | GB-TEVA-289675ISR    |                      | 60 DAY     | Female     | GBR            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Pulmonary    | Citalopram           |              |            | S           | Transplacental | 20 Milligram;      |                 | Ivax         |
| Valve Atresia; Maternal | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Milligram;      |                 | Not Reported |
| Exposure During         |                      |              |            |             |                |                    |                 |              |
| Pregnancy               |                      |              |            |             |                |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2011              | 8049629       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021936           |                      | 83 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Leukopenia; Neutropenia | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                              |   |                                       |                                                            |              |
|--------------------------------------------------------------|---|---------------------------------------|------------------------------------------------------------|--------------|
| Zometa                                                       | S | Intravenous (not otherwise specified) | 4 Mg (4 Mg,1 In 1 D),Intravenous (Not Otherwise Specified) | Not Reported |
| Furosemide                                                   | S | Oral                                  | 20 Mg (20 Mg,1 In 1 D),Oral                                | Not Reported |
| Rocephin                                                     | S | Oral                                  | 1 Gram (1 Gm,1 In 1 D),Oral                                | Not Reported |
| Rivotril (Clonazepam) (Clonazepam)                           | C |                                       |                                                            | Not Reported |
| Xanax                                                        | C |                                       |                                                            | Not Reported |
| Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine) | C |                                       |                                                            | Not Reported |
| Aprovel (Irbesartan) (Irbesartan)                            | C |                                       |                                                            | Not Reported |
| Inexium (Esomeprazole Magnesium)                             | C |                                       |                                                            | Not Reported |
| Transipeg (Macrogol)                                         | C |                                       |                                                            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2011              | 8050637       | EXPEDITED (15-DAY) | Y                  | OT              | DSA_47076_2011       |                      | 28 YR      | Male       | CAN            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache; Nausea; Photophobia; Vision Blurred | Wellbutrin XI  |              |            | S           |              | (150 Mg Qd)        |                 | Not Reported |
|                                               | Cipraxel       |              |            | S           |              | (Df)               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Jul-2011              | 8050729       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2011MA008042         |                      | 62 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Drug Dependence; Incorrect Dose Administered; Withdrawal Syndrome | Zolpidem Tartrate         |              |            | S           |              | 180 Mg, Qd;        |                 | Not Reported |
|                                                                             | Escitalopram Oxalate      |              |            | S           |              | 10 Mg, Qd;         |                 | Not Reported |
|                                                                             | Acetaminophen\Domperidone |              |            | S           |              | Qd;                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2011              | 7987763       | EXPEDITED (15-DAY) | N                  | HO, OT          | AT-BRISTOL-MYERS SQUIBB COMPANY- |                      | 24 YR      | Female     | AUT            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

15812548

| <u>Preferred Term</u>                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pulmonary Embolism;<br>Suicidal Ideation | Trazodone Hydrochloride |              |            | S           | Oral         |                    |                 | Apothecon    |
|                                          | Abilify                 |              |            | S           |              |                    |                 | Not Reported |
|                                          | Cipralex                |              |            | S           |              | 10mg               |                 | Not Reported |
|                                          | Chlorprothixene         |              |            | S           |              | 30mg               |                 | Not Reported |
|                                          | Lorazepam               |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Jul-2011              | 8026162       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2011152599 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Headache;<br>Hypersensitivity;<br>Intervertebral Disc<br>Disorder; Urticaria | Pristiq Extended Release |              |            | S           | Oral         | 76 Mg, Daily       | 35 DAY          | Pfizer       |
|                                                                              | Lexapro                  |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |
|                                                                              | Klonopin                 |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                              | Calcium                  |              |            | C           |              | 1200 Mg, Daily     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2011              | 8032837       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021710           |                      | 33 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------|-----------------|--------------|
| Feeling Abnormal; Muscle<br>Twitching; Overdose;<br>Weight Increased;<br>Withdrawal Syndrome | Escitalopram Oxalate                        |              |            | S           | Oral         | 30 Mg (30 Mg,1 In 1<br>D),Oral,Dosage Reduced<br>(Unknown Dosage),Oral |                 | Not Reported |
|                                                                                              | Temesta Expidet<br>(Astemizole)(Astemizole) |              |            | C           |              |                                                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jul-2011              | 8053336       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021996           |                      | 31 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Alanine Aminotransferase Increased; Depression; Drug Interaction; Oedema Peripheral | Escitalopram Oxalate                                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral; 20 Mg (20 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
|                                                                                     |                                                                  |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral; 20 Mg (20 Mg, 1 In 1 D), Oral                                |                 |              |                |
|                                                                                     | Mirtazapine                                                      |                    |                    | S               | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                     |                                                                  |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                     |                                                                  |                    |                    |                 | Oral                 | 15 Mg (15 Mg, 1 In 1 D),Oral; 30 Mg (30 Mg, 1 In 1 D), Oral; 45 Mg (45 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                     | Atosil (Promethazine Hydrochloride) (Promethazine Hydrochloride) |                    |                    | C               |                      |                                                                                            |                 | Not Reported |                |
|                                                                                     | Marcumar (Phenprocoumon) (Phenprocoumon)                         |                    |                    | C               |                      |                                                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jul-2011                                                                         | 8053838                                                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021969           |                                                                                            | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                               | <u>Product</u>                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Mitral Valve Incompetence                                                 | Escitalopram Oxalate                                             |                    |                    | S               | Oral                 | (10 Mg),Oral                                                                               |                 | Not Reported |                |
|                                                                                     | Benfluorex                                                       |                    |                    | S               | Oral                 | (1 Dosage Forms),Oral, (2 Dosage Forms),Oral, (3 Dosage Forms),Oral                        |                 | Not Reported |                |
|                                                                                     | Levothyroxine                                                    |                    |                    | S               | Oral                 | (50 Mcg),Oral, (75 Mcg),Oral                                                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                              | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------|--------------------------------------------------------------------------------|--------------------|--------------------|--------------------|--------------------------|-------------------------|-----------------|--------------|----------------|
| 13-Jul-2011                                           | 6868092                                                                        | EXPEDITED (15-DAY) | Y                  | DE, HO             | US-PFIZER INC-2008153681 |                         | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Celecoxib                                                                      |                    |                    | S                  | Oral                     | Unk                     |                 | Pfizer       |                |
|                                                       | Unspecified Ingredient                                                         |                    |                    | S                  | Oral                     | Unk                     |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate                                                           |                    |                    | S                  | Oral                     | Unk                     |                 | Not Reported |                |
|                                                       | Meloxicam                                                                      |                    |                    | S                  | Oral                     | Unk                     |                 | Not Reported |                |
|                                                       | Propoxyphene Hydrochloride And Acetaminophen                                   |                    |                    | S                  | Oral                     | Unk                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jul-2011                                           | 7975195                                                                        | EXPEDITED (15-DAY) | Y                  | HO                 | 1000020821               |                         | 78 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Myoclonus                                             | Escitalopram Oxalate                                                           |                    |                    | S                  |                          | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                                       | Aspirin                                                                        |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       | Dipyridamol (Dipyridamole) (Dipyridamole)                                      |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       | Metoprolol (Metoprolol) (Metoprolol)                                           |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       | Pantoprazole (Pantoprazole) (Pantoprazole)                                     |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       | Insulin (Insulin) (Insulin)                                                    |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       | Nitroglycerine (Glyceryl Trinitrate) (Poultice Or Patch) (Glyceryl Trinitrate) |                    |                    | C                  |                          |                         |                 | Not Reported |                |
|                                                       |                                                                                |                    |                    |                    |                          |                         |                 |              |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jul-2011                                           | 7995783                                                                        | EXPEDITED (15-DAY) | Y                  | DS, HO, LT, RI, OT | 1000021094               |                         | 36 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                 | <u>Product</u>                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Acute; Toxicity To Various Agents           | Escitalopram Oxalate                                                           |                    |                    | S                  |                          | 1 Dosage Form (1 Dosage |                 | Not Reported |                |

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|                    |   |      |                                                   |              |
|--------------------|---|------|---------------------------------------------------|--------------|
| Hydroxycitric Acid | S |      | Forms, 1 In D)                                    | Not Reported |
| Capozide           | S | Oral | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2011              | 8046971       | DIRECT           | N                  | OT              |                      |                      | 36 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                        | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Acne; Alopecia; Delusion;<br>Depersonalisation/Derealisation Disorder; Dry Mouth; Grandiosity; Hair Growth Abnormal; Imprisonment; Impulsive Behaviour; Irritability; Kleptomania; Mania; Mood Altered; Muscle Twitching; Nail Growth Abnormal; Onychoclasia; Somnolence; Weight Increased; Weight Loss Poor | Lexapro                          |              |            | S           | Oral         | 20 Mg Lexapro 1x Daily Oral Tablet |                 | Forest       |
|                                                                                                                                                                                                                                                                                                              | Naproxen Sodium                  |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Maxcide                          |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Celexa                           |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Thyroid Hormone Therapy          |              |            | C           |              |                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                              | Tahiti Trim Female Hormone Cream |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2011              | 8055022       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-03877   |                      | 40 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents | Amlodipine              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                           | Atenolol (Atenolol)     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                           | Trazodone Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                           | Escitalopram Oxalate    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                           | Duloxetine              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                           | Losartan Potassium      |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2011              | 8056154       | EXPEDITED (15-DAY) | Y                  | DE, HO          | AUR-APL-2011-03797   |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents | Meloxicam                                    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                               | Propoxyphene Hydrochloride And Acetaminophen |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                               | Escitalopram Oxalate                         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                               | Celecoxib                                    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                               | Benzodiazepine                               |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jul-2011              | 8056905       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 2011SP031846         |                      | 38 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Alcohol Use; Autoimmune Hepatitis; Hepatic Steatosis; Hepatitis Acute; Reye'S Syndrome; Toxicity To Various Agents | Mirtazapine          |              |            | S           | Oral         | 15 Mg;Qd;Po ; 90 Mg;Once;Po                |                 | Not Reported |
|                                                                                                                    |                      |              |            |             | Oral         | 15 Mg;Qd;Po ; 90 Mg;Once;Po                |                 |              |
|                                                                                                                    | Xanax                |              |            | S           | Oral         | 0.5 Mg;Qd;Po ; 7.5 Mg;Once.Po              |                 | Not Reported |
|                                                                                                                    |                      |              |            |             | Oral         | 0.5 Mg;Qd;Po ; 7.5 Mg;Once.Po              |                 |              |
|                                                                                                                    |                      |              |            | S           | Oral         | 40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po |                 | Not Reported |
|                                                                                                                    | Propranolol          |              |            |             | Oral         | 40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po |                 |              |
|                                                                                                                    |                      |              |            |             | Oral         | 40 Mg;Qd;Po ; 320 Mg;Once;Po ; 40 Mg;Qd;Po |                 |              |
|                                                                                                                    |                      |              |            | S           | Oral         | 20 Mg;Qd;Po ; 120 Mg;Once;Po               |                 | Not Reported |
|                                                                                                                    | Escitalopram Oxalate |              |            | S           | Oral         |                                            |                 | Not Reported |

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## Freedom of Information Act (FOIA)

### Detailed Report

Oral  
20 Mg;Qd;Po ; 120  
Mg;Once;Po

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2011              | 8009773       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021519           |                      | 45 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                         | <u>Product</u>                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Fall; Generalised Tonic-Clonic Seizure; Loss Of Consciousness | Escitalopram Oxalate                                       |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D), Oral |                 | Not Reported |
|                                                               | Calcium D3 (Calcium D3 /01483701/) (Calcium D3 /01483701/) |              |            | C           |              |                              |                 | Not Reported |
|                                                               | Atilnox (Zolpidem) (Tablets) (Zolpidem)                    |              |            | C           |              |                              |                 | Not Reported |
|                                                               | Xanax (Alprazolam) (Tablets) (Alprazolam)                  |              |            | C           |              |                              |                 | Not Reported |
|                                                               | Tercian (Cyamemazine) (Solution) (Cyamemazine)             |              |            | C           |              |                              |                 | Not Reported |
|                                                               | Sertraline (Sertraline) (Capsules) (Sertraline)            |              |            | C           |              |                              |                 | Not Reported |
|                                                               |                                                            |              |            |             |              |                              |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2011              | 8056539       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022064           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Neurogenic Bladder    | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Jul-2011              | 8057222       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022028           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Acidosis; Alcohol Poisoning; Cardiac Failure; Somnolence; Syncope; Toxicity To Various Agents | Escitalopram Oxalate |              |            | S           | Oral         | (200 Mg,Once), Oral |                 | Not Reported |
|                                                                                               | Alcohol              |              |            | S           |              |                     |                 | Not Reported |

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| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Jul-2011                                                          | 8059297                                                              | EXPEDITED (15-DAY) | Y                  | HO, LT          | IDA-00559            |                                                                                 | 38 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Steatosis;<br>Hepatitis Acute; Toxicity<br>To Various Agents | Propranolol                                                          |                    |                    | S               | Oral                 | 8 Tablets Of 40mg Once<br>Oral Formulation:<br>Tablet/Oral                      | 1 DAY           | Not Reported |                |
|                                                                      | Xanax                                                                |                    |                    | S               | Oral                 | 15 Tablets Of 0.5mg Oral<br>Formulation: Tablet/ Oral<br>Formulation: Tablet    | 4 DAY           | Not Reported |                |
|                                                                      | Escitalopram Oxalate                                                 |                    |                    | S               | Oral                 | 6 Tablets Of 15mg Once<br>Oral Formulation: Tablet/<br>Oral Formulation: Tablet | 8 MTH           | Not Reported |                |
|                                                                      | Mirtazapine                                                          |                    |                    | S               | Oral                 | Oral Formulation: Tablet/<br>Oral Formulation: Tablet                           | 7 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                             | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Jul-2011                                                          | 8032217                                                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000021526           |                                                                                 | 82 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Haemorrhage;<br>Headache; Hyponatraemia                     | Escitalopram Oxalate                                                 |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral                 |                 | Not Reported |                |
|                                                                      |                                                                      |                    |                    |                 | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral                 |                 |              |                |
|                                                                      | Zestril                                                              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1d),<br>Oral                                                 |                 | Not Reported |                |
|                                                                      | Stilnox (Zolpidem) (Tablets)<br>(Zolpidem)                           |                    |                    | C               |                      |                                                                                 |                 | Not Reported |                |
|                                                                      | Pravalotin (Pravastatin Sodium)<br>(Tablets) (Pravastatin)           |                    |                    | C               |                      |                                                                                 |                 | Not Reported |                |
|                                                                      | Motilium (Domperidone Maleate)<br>(Tablets) (Domperidone<br>Maleate) |                    |                    | C               |                      |                                                                                 |                 | Not Reported |                |

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Marcumar (Phenprocoumon)  
(Tablets) (Phenprocoumon)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2011              | 8037802       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ALLERGAN-1109514US |                      | 73 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cognitive Disorder; Dry Mouth; Fall; Memory Impairment | Trospium Chloride       |              |            | S           | Oral         | 20 Mg, Qd          |                 | Indevus      |
|                                                        | Ditropan                |              |            | S           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                        | Escitalopram Oxalate    |              |            | S           | Oral         | 10 Mg, Qd          |                 | Not Reported |
|                                                        | Zopiclone               |              |            | S           | Oral         | 7.5 Mg, Qd         |                 | Not Reported |
|                                                        | Xanax                   |              |            | C           |              | Unk                |                 | Not Reported |
|                                                        | Amlodipine Besylate     |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Mianserin Hydrochloride |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Crestor                 |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Levothyrox              |              |            | C           |              |                    |                 | Not Reported |
|                                                        | Lovenox                 |              |            | C           |              |                    |                 | Not Reported |
| Alendronate Sodium                                     |                         |              | C          |             |              |                    | Not Reported    |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2011              | 8058148       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022091           |                      | 42 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                   | <u>Product</u>                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Generalised Tonic-Clonic Seizure; Loss Of Consciousness | Escitalopram Oxalate                                     |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                         | L-Thyroxin (Levothyroxine Sodium) (Levothyroxine Sodium) |              |            | C           |              |                               |                 | Not Reported |
|                                                         | Budesonid (Budesonide) (Budesonide)                      |              |            | C           |              |                               |                 | Not Reported |
|                                                         | Omeprazol (Omeprazole)                                   |              |            | C           |              |                               |                 | Not Reported |
|                                                         | Omeprazole                                               |              |            |             |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Jul-2011              | 8058692       | EXPEDITED (15-DAY) | Y                  | DS              | 1000022088           |                      | 87 YR      | Male       | DNK            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>           |                |
|-----------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|---------------------------------|-----------------|----------------------|----------------|
| Myoclonus; Tardive Dyskinesia                 | Escitalopram Oxalate |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported         |                |
|                                               | Aricept              |                    |                    | S               | Oral                                                | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported         |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 18-Jul-2011                                   | 8060650              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022122                                          |                                 | 28 YR           | Male                 | DNK            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>           |                |
| Headache; Nausea; Photophobia; Vision Blurred | Escitalopram Oxalate |                    |                    | S               | Oral                                                | Oral                            |                 | Not Reported         |                |
|                                               | Wellbutrin XI        |                    |                    | S               | Oral                                                | 150 Mg (150 Mg, 1 In 1 D), Oral |                 | Not Reported         |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 19-Jul-2011                                   | 8042836              | NON-EXPEDITED      | N                  |                 | US-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2011-BP-17 |                                 | 83 YR           | Female               | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>           |                |
| Fatigue                                       | Pradaxa              |                    |                    | S               | Oral                                                | 300 Mg                          |                 | Boehringer Ingelheim |                |
|                                               | Lexapro              |                    |                    | S               | Oral                                                | 10 Mg                           |                 | Not Reported         |                |
|                                               | Coreg                |                    |                    | C               | Oral                                                | 25 Mg                           |                 | Not Reported         |                |
|                                               | Lisinopril           |                    |                    | C               | Oral                                                | 20 Mg                           |                 | Not Reported         |                |
|                                               | Lasix                |                    |                    | C               | Oral                                                | 40 Mg                           |                 | Not Reported         |                |
|                                               | Amiodarone           |                    |                    | C               | Oral                                                | 200 Mg                          |                 | Not Reported         |                |
|                                               | Aspirin              |                    |                    | C               | Oral                                                | 81 Mg                           |                 | Not Reported         |                |
|                                               | Folic Acid           |                    |                    | C               | Oral                                                | 1 Mg                            |                 | Not Reported         |                |
|                                               | Xanax                |                    |                    | C               | Oral                                                |                                 |                 | Not Reported         |                |
|                                               | Fosamax              |                    |                    | C               | Oral                                                |                                 |                 | Not Reported         |                |
|                                               | Calcium Carbonate    |                    |                    | C               | Oral                                                | 1000 Mg                         |                 | Not Reported         |                |
|                                               | Synthroid            |                    |                    | C               | Oral                                                | 75 Mg                           |                 | Not Reported         |                |

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|                                                             |                          |                    |                    |                 |                                 |                      |                 |              |                |
|-------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| Vitamin B12                                                 |                          |                    | C                  |                 | Intramuscular                   |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2011                                                 | 8043845                  | EXPEDITED (15-DAY) | Y                  | OT              | TW-WATSON-2011-10301            |                      | 52 YR           | Female       | TWN            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Extrapyramidal Disorder;<br>Multiple System Atrophy         | Fluoxetine Hcl           |                    |                    | S               | Unknown                         |                      |                 | Watson       |                |
|                                                             | Sertraline Hydrochloride |                    |                    | S               | Unknown                         |                      |                 | Watson       |                |
|                                                             | Escitalopram Oxalate     |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2011                                                 | 8043958                  | NON-EXPEDITED      | N                  |                 | US-KINGPHARMUSA00001-K201000880 |                      | 62 YR           | Female       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression;<br>Hyperthyroidism;<br>Thyroxine Free Increased | Levoxyl                  |                    |                    | S               | Oral                            | 162 Mcg, Qd          |                 | King         |                |
|                                                             | Levoxyl                  |                    |                    | S               | Oral                            | 137 Mcg, Qd          |                 | King         |                |
|                                                             | Levoxyl                  |                    |                    | S               | Oral                            | 150 Mcg, Qd          |                 | King         |                |
|                                                             | Lexapro                  |                    |                    | S               | Oral                            | 20 Mg, Qd            |                 | Not Reported |                |
|                                                             | Lipitor                  |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
|                                                             | Atenolol                 |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
|                                                             | Ambien                   |                    |                    | C               |                                 | Unk                  |                 | Not Reported |                |
|                                                             | Klonopin                 |                    |                    | C               |                                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Jul-2011                                                 | 8044030                  | NON-EXPEDITED      | N                  |                 | US-KINGPHARMUSA00001-K201001061 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Fatigue                         | Levoxyl                  |                    |                    | S               | Oral                            | 125 Mcg, Unk         |                 | King         |                |
|                                                             | Lexapro                  |                    |                    | S               |                                 | 10 Mg, Unk           |                 | Not Reported |                |
|                                                             | Metformin Hydrochloride  |                    |                    | C               |                                 |                      |                 | Not Reported |                |

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| Byetta                                                     |                         |                    | C                  |                 |                          | Not Reported         |                 |              |                |
|------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2011                                                | 7247068                 | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2010000996 |                      | 56 YR           | Male         | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                          | Phenytoin               |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                            | Pregabalin              |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                            | Metformin Hcl           |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                            | Ondansetron Hcl         |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                            | Escitalopram Oxalate    |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Phenobarbital           |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Quetiapine              |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Trazodone               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Emtricitabine/Tenofovir |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Oxycodone               |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Methylphenidate         |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Zolpidem                |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                            | Metoclopramide          |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Jul-2011                                                | 8045223                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | HR-JNJFOC-20110501972    |                      | 29 YR           | Male         | HRV            |
| <u>Preferred Term</u>                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Schizophrenia; Substance Abuse; Toxicity To Various Agents | Risperidone             |                    |                    | S               | Intramuscular            |                      |                 | Not Reported |                |
|                                                            | Risperidone             |                    |                    | S               | Intramuscular            |                      |                 | Not Reported |                |
|                                                            | Risperidone             |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                            | Risperidone             |                    |                    | S               | Unknown                  | 1/2,0,1              |                 | Not Reported |                |
|                                                            | Risperidone             |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |
|                                                            | Risperidone             |                    |                    | S               | Unknown                  |                      |                 | Not Reported |                |

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|                                   |   |         |              |              |
|-----------------------------------|---|---------|--------------|--------------|
| Akineton                          | S | Unknown |              | Not Reported |
| Akineton                          | S | Unknown |              | Not Reported |
| Thioridazine Hydrochloride        | S | Unknown | 1,1,2        | Not Reported |
| Leponex                           | S | Unknown |              | Not Reported |
| Leponex                           | S | Unknown | 1/2,0,1      | Not Reported |
| Cipralex                          | S | Unknown |              | Not Reported |
| Xanax                             | S | Unknown | 3x1 Tablet   | Not Reported |
| Xanax                             | S | Unknown | 3x1/2 Tablet | Not Reported |
| Xanax                             | S | Unknown | 3x1 Tablet   | Not Reported |
| Xanax                             | S | Unknown | 3x1/2 Tablet | Not Reported |
| Xanax                             | S | Unknown | 3x1 Tablet   | Not Reported |
| Xanax                             | S | Unknown | 3x1/2 Tablet | Not Reported |
| Xanax                             | S | Unknown | 3x1/2 Tablet | Not Reported |
| Xanax                             | S | Unknown | 3x1 Tablet   | Not Reported |
| Paroxetine Hydrochloride          | S |         | 1,0,0        | Not Reported |
| Paroxetine Hydrochloride          | S |         | 1,0,0        | Not Reported |
| Paroxetine Hydrochloride          | S |         | 1,0,0        | Not Reported |
| Paroxetine Hydrochloride          | S |         | 1,0,0        | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Diazepam                          | S |         |              | Not Reported |
| Prazine (Promazine Hydrochloride) | S |         |              | Not Reported |
| Prazine (Promazine Hydrochloride) | S |         |              | Not Reported |
| Promazine Hydrochloride           | S |         |              | Not Reported |
| Promazine Hydrochloride           | S |         |              | Not Reported |
| Zolpidem Tartrate                 | S | Unknown |              | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |         |              |
|-------------------|---|---------|--------------|
| Zolpidem Tartrate | S | Unknown | Not Reported |
| Zolpidem Tartrate | S | Unknown | Not Reported |
| Zolpidem Tartrate | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 20-Jul-2011              | 8045923       | EXPEDITED (15-DAY) | N                  | HO, OT          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15898638 |                      | 82 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                            | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Cerebrovascular Accident;<br>Depression;<br>Hyponatraemia;<br>Overdose; Vomiting | Irbesartan And<br>Hydrochlorothiazide |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                                                                  | Digoxin                               |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                                                  | Escitalopram Oxalate                  |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                                                  | Acenocoumarol                         |              |            | C           | Oral         | Tablet             |                 | Not Reported         |
|                                                                                  | Lansoprazole                          |              |            | C           | Oral         | Tablet             |                 | Not Reported         |
|                                                                                  | Crestor                               |              |            | C           | Oral         | Tablet             |                 | Not Reported         |
|                                                                                  | Amlodipine Besylate                   |              |            | C           | Oral         | It Is A Capsule    |                 | Not Reported         |
|                                                                                  | Noroxin                               |              |            | C           | Oral         |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 20-Jul-2011              | 8046063       | EXPEDITED (15-DAY) | Y                  | CA, DE          | GB-MYLANLABS-<br>2011S1013999 |                      | 60 DAY     | Female     | GBR            |

| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Pulmonary<br>Valve Atresia; Maternal<br>Exposure During<br>Pregnancy | Citalopram           |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                                 | Escitalopram Oxalate |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Jul-2011              | 8062560       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022237           |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                                      |   |                                                                                                                          |              |
|---------------------------------------|--------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------|--------------|
| Paraesthesia; Sedation;<br>Somnolence | Escitalopram Oxalate                 | S | 10 Mg (10 Mg,1 In 1 D) ;<br>10 Mg (10 Mg,1 In 1<br>D),Oral<br>10 Mg (10 Mg,1 In 1 D) ;<br>10 Mg (10 Mg,1 In 1<br>D),Oral | Not Reported |
|                                       | Methadone (Methadone)<br>(Methadone) | C |                                                                                                                          | Not Reported |

| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 20-Jul-2011                      | 8062607              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022161           |                        |                 | Female       | DNK            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Narrow Anterior Chamber<br>Angle | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D) |                 | Not Reported |                |
|                                  | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 20-Jul-2011                                                                                  | 8083231                 | EXPEDITED (15-DAY) | Y                  | DE, OT          | 2011AP001423         |                      | 60 DAY          | Female       | GBR            |
| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Pulmonary<br>Valve Atresia; Death<br>Neonatal; Maternal Drugs<br>Affecting Foetus | Citalopram Hydrobromide |                    |                    | S               | Transplacental       | 20 Mg, Qd, Trpl      |                 | Not Reported |                |
|                                                                                              | Escitalopram Oxalate    |                    |                    | S               | Transplacental       | 20 Mg, Trpl, Qd      |                 | Not Reported |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Jul-2011                              | 8034130                  | EXPEDITED (15-DAY) |                    | OT              | TW-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR003101 |                      |                 | Unknown      | TWN            |
| <u>Preferred Term</u>                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Multiple System Atrophy;<br>Parkinsonism | Fluoxetine               |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Par          |                |
|                                          | Sertraline Hydrochloride |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
|                                          | Escitalopram Oxalate     |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |
|                                          | Duloxetine               |                    |                    | S               | Unknown                                         | Unk, Unknown         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------------------|----------------------|-----------------|-----------------|----------------|
| 21-Jul-2011                                                                  | 8047238                  | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR62540                             |                      |                 | Female          | FRA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Attention Deficit/Hyperactivity Disorder; Craniocerebral Injury; Fall; Wound | Exelon                   |                    |                    | S               | Transdermal                                 | 9.5 Mg, Unk          |                 | Novartis        |                |
|                                                                              | Leponex                  |                    |                    | S               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Leponex                  |                    |                    | S               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Escitalopram Oxalate     |                    |                    | S               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Lormetazepam             |                    |                    | S               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Sterogyl                 |                    |                    | C               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Lescol                   |                    |                    | C               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
|                                                                              | Movicol                  |                    |                    | C               |                                             | Unk Ukn, Unk         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 21-Jul-2011                                                                  | 8047503                  | EXPEDITED (15-DAY) | Y                  | DE              | PL-GLAXOSMITHKLINE-B0734223A                |                      | 69 YR           | Female          | POL            |
| <u>Preferred Term</u>                                                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Antiphospholipid Antibodies; Embolism Venous; Pulmonary Embolism             | Paroxetine Hydrochloride |                    |                    | S               | Unknown                                     |                      |                 | Glaxosmithkline |                |
|                                                                              | Quetiapine               |                    |                    | S               | Unknown                                     |                      |                 | Glaxosmithkline |                |
|                                                                              | Sertraline Hydrochloride |                    |                    | S               | Unknown                                     |                      |                 | Not Reported    |                |
|                                                                              | Venlafaxine              |                    |                    | S               | Unknown                                     |                      |                 | Glaxosmithkline |                |
|                                                                              | Mirtazapine              |                    |                    | S               | Unknown                                     |                      |                 | Not Reported    |                |
|                                                                              | Reboxetine               |                    |                    | S               | Unknown                                     |                      |                 | Not Reported    |                |
|                                                                              | Escitalopram Oxalate     |                    |                    | S               | Unknown                                     |                      |                 | Not Reported    |                |
|                                                                              | Olanzapine               |                    |                    | S               |                                             |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 21-Jul-2011                                                                  | 8048203                  | EXPEDITED (15-DAY) | Y                  | OT              | TW-TYCO HEALTHCARE/MALLIN CKRODT-T201101397 |                      | 52 YR           | Female          | TWN            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder;<br>Multiple System Atrophy;<br>Parkinsonism; Therapy<br>Non-Responder | Fluoxetine               |              |            | S           |              | Unk                |                 | Tyco         |
|                                                                                                | Sertraline Hydrochloride |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate     |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2011              | 8063218       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000022188           |                      | 38 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------|-----------------|--------------|
| Alcohol Use; Hepatic<br>Steatosis; Hepatitis Acute;<br>Incorrect Dose<br>Administered; Reye'S<br>Syndrome; Unevaluable<br>Event | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral (120 Mg, Once), Oral |                 | Not Reported |
|                                                                                                                                 |                      |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral (120 Mg, Once), Oral |                 |              |
|                                                                                                                                 | Xanax                |              |            | S           | Oral         | Oral (7.5 Mg, Once), Oral                             |                 | Not Reported |
|                                                                                                                                 |                      |              |            |             | Oral         | Oral (7.5 Mg, Once), Oral                             |                 |              |
|                                                                                                                                 | Propranolol          |              |            | S           | Oral         | Oral (320 Mg, Once), Oral                             |                 | Not Reported |
|                                                                                                                                 |                      |              |            |             | Oral         | Oral (320 Mg, Once), Oral                             |                 |              |
|                                                                                                                                 | Mirtazapine          |              |            | S           | Oral         | Oral (90 Mg, Once), Oral                              |                 | Not Reported |
|                                                                                                                                 |                      |              |            |             | Oral         | Oral (90 Mg, Once), Oral                              |                 |              |
|                                                                                                                                 | Alcohol (Ethanol)    |              |            | S           | Oral         | (1 Lit), Oral                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Jul-2011              | 8063246       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022190           |                      | 73 YR      | Female     | DNK            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------------------------|-----------------|--------------|
| Cognitive Disorder; Dry<br>Mouth; Fall | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                  |                 | Not Reported |
|                                        | Escitalopram Oxalate |              |            | S           |              | Reduced Dose, Oral                                |                 | Not Reported |
|                                        | Ditropan             |              |            | S           | Oral         | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                        | Trospium Chloride    |              |            | S           |              | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D)       |                 | Not Reported |



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|                                                |   |      |                    |              |
|------------------------------------------------|---|------|--------------------|--------------|
| Zopiclone                                      | S | Oral | (7.5 Mg), Oral     | Not Reported |
| Zopiclone                                      | S | Oral | Reduced Dose, Oral | Not Reported |
| Levothyroxine Sodium                           | C |      |                    | Not Reported |
| Lovenox                                        | C |      |                    | Not Reported |
| Crestor (Rosuvastatin)                         | C |      |                    | Not Reported |
| Fosavance (Alendronate Sodium, Colecalciferol) | C |      |                    | Not Reported |
| Amlodipine Besylate                            | C |      |                    | Not Reported |
| Xanax                                          | C |      |                    | Not Reported |
| Athymil (Mianserin Hydrochloride)              | C |      |                    | Not Reported |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2011                                                                            | 7995914        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011131979 |                      | 31 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea; Drug Ineffective; Malaise; Nausea; Product Residue Present; Stress | Effexor        |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                                                        | Effexor        |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                        | Xanax          |                  |                    | S               |                          | 0.5 Mg, Unk          |                 | Pfizer       |                |
|                                                                                        | Xanax          |                  |                    | S               |                          | 1 Mg, 1x/Day         |                 | Pfizer       |                |
|                                                                                        | Xanax          |                  |                    | S               |                          | 2 Mg, 2x/Day         |                 | Pfizer       |                |
|                                                                                        | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                                        | Lexapro        |                  |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                        | Prilosec       |                  |                    | C               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2011                            | 8048874        | EXPEDITED (15-DAY) | Y                  | HO              | FR-EISAI INC-E3810-04802-SPO-FR |                      | 82 YR           | Male         | FRA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Anaemia; Jaundice | Aciphex        |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |                                |   |      |              |
|----------------------------------|--------------------------------|---|------|--------------|
| Cholestatic;<br>Thrombocytopenia | Bactrim                        | S | Oral | Not Reported |
|                                  | Amlodipine Besylate\Olmesartan | S | Oral | Not Reported |
|                                  | Medoxomil                      | S | Oral | Not Reported |
|                                  | Escitalopram Oxalate           | S | Oral | Not Reported |
|                                  | Aspirin                        | S | Oral | Not Reported |

| <u>FDA Received Date</u>                                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Jul-2011                                                             | 8060021        | DIRECT           |                    | OT              |                      |                      | 29 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Follicle Stimulating<br>Hormone Increased;<br>Premature Menopause | Lexapro        |                  |                    | S               | Oral                 | 20 Mg Qd Po          |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                                  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2011                                                                                                               | 8065211                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-04202   |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                     | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Intentional<br>Product Misuse;<br>Respiratory Arrest;<br>Toxicity To Various Agents | Citalopram Hydrobromide |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                           | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                           | Venlafaxine             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                           | Alcohol                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Jul-2011                                      | 8066088              | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-04210   |                      | 53 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Product Misuse | Zolpidem             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Duloxetine           |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Temazepam            |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Alcohol                                                                                                       |                          |                    | S                  |                 | Oral                 |                                         | Oral            |              | Not Reported   |  |
|---------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------|-----------------|--------------|----------------|--|
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 22-Jul-2011                                                                                                   | 8066239                  | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000022223           |                                         | 60 DAY          | Female       | DNK            |  |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Congenital Pulmonary Valve Atresia; Death Neonatal; Maternal Drugs Affecting Foetus                           | Escitalopram Oxalate     |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |  |
|                                                                                                               | Citalopram               |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D), Transplacental |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 22-Jul-2011                                                                                                   | 8066457                  | EXPEDITED (15-DAY) | Y                  | DE, HO          | AUR-APL-2011-03987   |                                         | 18 YR           | Male         | USA            |  |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Cardiac Arrest; Completed Suicide; Intentional Product Misuse; Respiratory Arrest; Toxicity To Various Agents | Paroxetine Hydrochloride |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Tramadol Hydrochloride   |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Diazepam (Diazepam)      |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |
| 22-Jul-2011                                                                                                   | 8066528                  | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-04194   |                                         | 54 YR           | Female       | USA            |  |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |                |  |
| Completed Suicide; Intentional Product Misuse; Toxicity To Various Agents                                     | Metoprolol Tartrate      |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Escitalopram Oxalate     |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Carisoprodol             |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Clopidogrel              |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |
|                                                                                                               | Diazepam (Diazepam)      |                    |                    | S               | Oral                 | Oral                                    |                 | Not Reported |                |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2011              | 8067890       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-04143   |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Intentional Product<br>Misuse; Toxicity To<br>Various Agents | Metformin Hydrochloride       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Zolpidem                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Ondansetron                   |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Phenytoin                     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Phenobarbital (Phenobarbital) |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Quetiapine Fumarate           |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Trazodone Hydrochloride       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Escitalopram Oxalate          |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Emtricitabine And Tenofovir   |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Disoproxil Fumarate           |              |            |             |              |                    |                 |              |
|                                                                                    | Oxycodone (Oxycodone)         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Methylphenidate               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Pregabalin                    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                    | Metoclopramide Hydrochloride  |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2011              | 8067933       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-04204   |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest;<br>Respiratory Arrest;<br>Toxicity To Various Agents | Sertraline Hydrochloride      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                      | Doxepin Hydrochloride         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                      | Alcohol                       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                      | Clonazepam                    |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                      | Clonidine Transdermal System  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                      | Diphenhydramine Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |

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|                         |   |      |      |              |
|-------------------------|---|------|------|--------------|
| Sildenafil Citrate      | S | Oral | Oral | Not Reported |
| Duloxetine              | S | Oral | Oral | Not Reported |
| Oxybutynin (Oxybutynin) | S | Oral | Oral | Not Reported |
| Escitalopram Oxalate    | S | Oral | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2011              | 7755697       | EXPEDITED (15-DAY) | Y                  | CA, DE, OT      | AUR-APL-2010-03018   |                      | 2 YR       | Female     | GBR            |

| <u>Preferred Term</u>                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|----------------|--------------------------------------------|-----------------|--------------|
| Heart Disease Congenital;<br>Maternal Drugs Affecting<br>Foetus; Pulmonary Artery<br>Atresia | Citalopram Hydrobromide |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |
|                                                                                              | Escitalopram Oxalate    |              |            | S           | Transplacental | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 25-Jul-2011              | 8051993       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15362122 |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Rash                  | Coumadin       |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                       | Coumadin       |              |            | S           |              |                    |                 | Bristol Myers Squibb |
|                       | Lexapro        |              |            | S           | Oral         | Tabs               |                 | Not Reported         |
|                       | Protonix       |              |            | S           | Oral         | Tabs               |                 | Not Reported         |
|                       | Multivitamins  |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2011              | 8069951       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022286           |                      | 82 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Anaemia; Balanoposthitis;<br>Blood Bilirubin Increased;<br>Blood Thyroid Stimulating | Escitalopram Oxalate                        |              |            | S           | Oral         | 1 In 1 D), Oral         |                 | Not Reported |
|                                                                                                              | Bactrim                                     |              |            | S           |              | 2 In 1 D                |                 | Not Reported |
|                                                                                                              | Amlodipine Besylate\Olmesartan<br>Medoxomil |              |            | S           |              | 1 Dosage Form (1 Dosage |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                       |                                    |   |      |                                                      |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|---|------|------------------------------------------------------|--------------|
| Hormone Decreased;<br>Gamma-Glutamyltransferase Increased; Jaundice<br>Cholestatic; Platelet Count Decreased; Prostatic Specific Antigen Increased;<br>Thrombocytopenia;<br>Urinary Tract Infection<br>Staphylococcal | Kardegic (Acetylsalicylate Lysine) | S | Oral | Forms, 1 In 1 D)<br>75 Mg (75 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                                                                                                                                                       | Rabeprazole Sodium                 | C |      |                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2011              | 8070002       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022303           |                      | 37 YR      | Male       | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Agitation; Drug Interaction;<br>Hyperhidrosis | Escitalopram Oxalate           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral; 10 Mg(10 Mg, 1 In 1 D), Ora      |                 | Not Reported |
|                                               |                                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral; 10 Mg(10 Mg, 1 In 1 D), Ora      |                 |              |
|                                               | Trimipramine Maleate           |              |            | S           | Ophthalmic   | 100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                               |                                |              |            |             | Ophthalmic   | 100 Mg (100 Mg, 1 In 1 D), Oral; 75 Mg (75 Mg, 1 In 1 D), Oral |                 |              |
|                                               | Pantozol (Pantoprazole Sodium) |              |            | C           |              |                                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jul-2011              | 8091295       | EXPEDITED (15-DAY) | Y                  | HO              | DSM-2011-00697       |                      | 82 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Acute Kidney Injury;<br>Anaemia; Balanoposthitis;<br>Bladder Dilatation; Blood<br>Thyroid Stimulating | Amlodipine Besylate\Olmesartan Medoxomil |              |            | S           | Oral         | 1 Dosage Forms (1 Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                     |                                       |   |      |                                                      |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|---|------|------------------------------------------------------|--------------|
| Hormone Decreased;<br>Cholestasis; Complication<br>Associated With Device;<br>Depression; Prostatic<br>Specific Antigen<br>Increased; Streptococcal<br>Urinary Tract Infection;<br>Thrombocytopenia | Bactrim                               | S | Oral | 2 Dosage Forms (1<br>Dosage Forms, 2 In 1<br>D),Oral | Not Reported |
|                                                                                                                                                                                                     | Escitalopram Oxalate                  | S | Oral | 1 Dosage Forms (1<br>Dosage Forms,1 In 1 D),<br>Oral | Not Reported |
|                                                                                                                                                                                                     | Kardegic (Acetylsalicylate<br>Lysine) | S | Oral | 75 Mg (75 Mg, 1 In 1 D),<br>Oral                     | Not Reported |
|                                                                                                                                                                                                     | Rabeprazole Sodium                    | S |      | 20 Mg ( 20 Mg, 1 In 1 D)<br>Oral                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 27-Jul-2011              | 8057316       | EXPEDITED (15-DAY) | Y                  | HO              | PL-ARROW GEN-2011-<br>10987 |                      | 69 YR      | Female     | POL            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Pulmonary Embolism    | Sertraline Hydrochloride  |              |            | S           |              | 100 Mg, Daily        | 1095 DAY        | Watson       |
|                       | Mirtazapine               |              |            | S           |              | 30 To 45 Mg, Daily   | 1095 DAY        | Watson       |
|                       | Paroxetine Hydrochloride  |              |            | S           |              | 20 Mg, Daily         | 1095 DAY        | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           |              | 225 Mg, Daily        |                 | Not Reported |
|                       | Quetiapine                |              |            | S           |              | 100 To 300 Mg, Daily |                 | Not Reported |
|                       | Olanzapine                |              |            | S           |              | 5 Mg, Daily          |                 | Not Reported |
|                       | Reboxetine                |              |            | S           |              | 4 Mg, Daily          |                 | Not Reported |
|                       | Escitalopram Oxalate      |              |            | S           |              | 20 Mg, Daily         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Jul-2011              | 8071930       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022336           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Affect Lability; Aggression;<br>Compulsive Shopping;<br>Logorrhoea; Mania;<br>Psychomotor Hyperactivity | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                           | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|----------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------------------------------------------------------------|--------------------------|---------------------|-------------------------|
| 27-Jul-2011                                                                            | 8091427                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000022288                    |                                                                                         | < 1 DAY                  | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                             | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Caesarean Section;<br>Maternal Drugs Affecting<br>Foetus; Pulmonary<br>Oedema Neonatal | Escitalopram Oxalate    |                           |                             | S                        | Transplacental                | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental; 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                          | Not Reported        |                         |
|                                                                                        |                         |                           |                             |                          | Transplacental                | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental; 5 Mg (5<br>Mg, 1 In 1 D),<br>Transplacental |                          |                     |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                           | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Jul-2011                                                                            | 8059586                 | NON-EXPEDITED             | Y                           | OT                       | US-PFIZER INC-<br>2011170545  |                                                                                         | 45 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                             | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depression; Hyperhidrosis                                                              | Chantix                 |                           |                             | S                        |                               | Unk                                                                                     |                          | Pfizer              |                         |
|                                                                                        | Lexapro                 |                           |                             | S                        |                               | Unk                                                                                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                           | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Jul-2011                                                                            | 8079966                 | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | 1000022395                    |                                                                                         | 89 YR                    | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                             | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Decreased Appetite;<br>Dehydration; Diarrhoea;<br>Hyponatraemia                        | Escitalopram Oxalate    |                           |                             | S                        |                               | 5 Mg (5 Mg, 1 In 1 D),                                                                  |                          | Not Reported        |                         |
|                                                                                        | Cordarone               |                           |                             | C                        |                               |                                                                                         |                          | Not Reported        |                         |
|                                                                                        | Cozaar                  |                           |                             | C                        |                               |                                                                                         |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                                                           | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Jul-2011                                                                            | 8080246                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000022404                    |                                                                                         | 84 YR                    | Female              | FRA                     |
| <a href="#">Preferred Term</a>                                                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                                                             | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                    |                                  |   |      |                               |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---|------|-------------------------------|--------------|
| Asthenia; Blood Electrolytes Decreased; Creatinine Renal Clearance Decreased; Decreased Appetite; Dizziness; Hypokalaemia; Hyponatraemia; Vomiting | Escitalopram Oxalate             | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                                                                    | Alteis                           | S |      |                               | Not Reported |
|                                                                                                                                                    | Acebutolol Hydrochloride         | C |      |                               | Not Reported |
|                                                                                                                                                    | Ikorel (Nicorandil) (Nicorandil) | C |      |                               | Not Reported |
|                                                                                                                                                    | Seresta (Oxazepam) (Oxazepam)    | C |      |                               | Not Reported |
|                                                                                                                                                    | Transipeg (Macrogol)             | C |      |                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Jul-2011              | 7952858       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020378           |                      | 38 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------------------------------|-----------------|--------------|
| Agitation; Akathisia; Bacteriuria; Blood Cholesterol Increased; Blood Thyroid Stimulating Hormone Increased; Drug Interaction; Drug Withdrawal Syndrome; High Density Lipoprotein Increased; Nitrite Urine Present; Overdose; Total Cholesterol/Hdl Ratio Decreased; Urine Analysis Abnormal | Escitalopram Oxalate    |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral, 25 Mg (25 Mg, 1 In 1 D), Oral                                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                              | Abilify                 |              |            | S           | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                              |                         |              |            |             | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                                                                                                                                                                                              |                         |              |            |             | Oral         | 7.5 Mg (7.5 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral, 2.5 Mg (2.5 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                                                                                                                                                                                                                              | Methadone Hydrochloride |              |            | S           | Oral         | See Image                                                                                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                              |                         |              |            |             | Oral         | See Image                                                                                     |                 |              |
|                                                                                                                                                                                                                                                                                              |                         |              |            |             | Oral         | See Image                                                                                     |                 |              |
|                                                                                                                                                                                                                                                                                              |                         |              |            |             | Oral         | See Image                                                                                     |                 |              |
|                                                                                                                                                                                                                                                                                              | Seroquel                |              |            | S           | Oral         | 25-200 Mg, Oral                                                                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|-----------------------------------------------------------------|-----------------|------------------------------|----------------|
| 29-Jul-2011                                                                          | 7960701                                                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000020649                     |                                                                 | 50 YR           | Male                         | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Parasomnia; Screaming                                                                | Escitalopram Oxalate                                                      |                    |                    | S               | Oral                           | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 20 Mg (10 Mg, 2 In 1 D), Oral |                 | Not Reported                 |                |
|                                                                                      |                                                                           |                    |                    |                 | Oral                           | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 20 Mg (10 Mg, 2 In 1 D), Oral |                 |                              |                |
|                                                                                      | Codiovan (Valsartan Hydrochlorothiazide) (Valsartan, Hydrochlorothiazide) |                    |                    | C               |                                |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Bisoprolol Fumarate Ass (Acetylsalicylic Acid) (Acetylsalicylic Acid)     |                    |                    | C<br>C          |                                |                                                                 |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-Jul-2011                                                                          | 8060639                                                                   | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022126                     |                                                                 | 88 YR           | Female                       | DNK            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Nail Injury; Product Friable; Product Quality Issue; Restlessness                    | Escitalopram Oxalate                                                      |                    |                    | S               | Oral                           | 10 Mg (10 Mg, 1 In 1 D), Oral                                   |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>                                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 29-Jul-2011                                                                          | 8060844                                                                   | EXPEDITED (15-DAY) | N                  | HO, OT          | BR-SANOFI-AVENTIS-2011SA047666 |                                                                 |                 | Male                         | BRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>                                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                   |                |
| Blood Thyroid Stimulating Hormone Increased; Hypercholesterolaemia; Ischaemic Stroke | Lantus                                                                    |                    |                    | S               | Subcutaneous                   |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Acetylsalicylic Acid                                                      |                    |                    | S               |                                |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Metformin Hydrochloride                                                   |                    |                    | S               |                                |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Lexapro                                                                   |                    |                    | S               |                                |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Thiamine Hydrochloride                                                    |                    |                    | S               |                                |                                                                 |                 | Not Reported                 |                |
|                                                                                      | Losartan Potassium                                                        |                    |                    | C               |                                |                                                                 |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                            |                                      |                    |                    |                              |                            |                                 |                 |              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|------------------------------|----------------------------|---------------------------------|-----------------|--------------|----------------|
| Selozok<br>Humalog                                                                                                                                                         |                                      | C<br>C             |                    | Not Reported<br>Not Reported |                            |                                 |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Jul-2011                                                                                                                                                                | 8061497                              | EXPEDITED (15-DAY) | N                  | DS                           | AU-PURDUE-USA-2011-0072359 |                                 | 49 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Apathy; Decreased<br>Appetite; Disturbance In<br>Attention; Fatigue; Feeling<br>Of Body Temperature<br>Change; Insomnia;<br>Myalgia; Somnolence;<br>Urine Output Decreased | Oxynorm                              |                    |                    | S                            | Oral                       |                                 |                 | Purdue       |                |
|                                                                                                                                                                            | Venlafaxine                          |                    |                    | S                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Escitalopram Oxalate                 |                    |                    | S                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Dothiepin /00160401/                 |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Lithium                              |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Aug-2011                                                                                                                                                                | 8085805                              | EXPEDITED (15-DAY) | Y                  | DS                           | 1000022499                 |                                 | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Contractions<br>Involuntary; Muscle<br>Spasticity                                                                                                                   | Escitalopram Oxalate                 |                    |                    | S                            | Oral                       | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                                                                                                                                            | Xanax                                |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Atarax                               |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Baclofene (Baclofene)<br>(Baclofene) |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                   | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>              | <u>Mfr Control #</u>       | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Aug-2011                                                                                                                                                                | 7826813                              | EXPEDITED (15-DAY) | N                  | DS, HO, OT                   | 2010SP040550               |                                 | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                  | <u>Route</u>               | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Amblyopia; Amenorrhoea;<br>Arteriovenous<br>Malformation; Back Pain;<br>Blood Follicle Stimulating<br>Hormone Increased; Blood<br>Iron Decreased; Brain                    | Nuvaring                             |                    |                    | S                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Lexapro                              |                    |                    | S                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Dilantin                             |                    |                    | S                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Advil                                |                    |                    | C                            |                            |                                 |                 | Not Reported |                |
|                                                                                                                                                                            | Marijuana                            |                    |                    | C                            |                            |                                 |                 | Not Reported |                |

Midline Shift; Brain  
Oedema; Cerebral  
Haemorrhage; Cerebral  
Infarction;  
Cerebrovascular Accident;  
Cholecystitis;  
Cholelithiasis; Cyst;  
Depression; Diarrhoea;  
Disorientation; Dizziness;  
Drug Eruption;  
Encephalomalacia;  
Epilepsy; Eye Laser  
Surgery; Fatigue;  
Gallbladder Disorder;  
Heterophoria; Hormone  
Level Abnormal; Hot  
Flush; Hypercoagulation;  
Hyperhidrosis;  
Hyperlipidaemia;  
Hypoaesthesia;  
Hypobarism;  
Hypovitaminosis;  
Insomnia; Intracranial  
Venous Sinus  
Thrombosis; Jaw Disorder;  
Libido Decreased;  
Meniere'S Disease;  
Menstruation Irregular;  
Muscle Spasms; Muscle  
Tightness; Nausea;  
Nervousness; Night  
Sweats; Obstruction;  
Oligomenorrhoea; Panic  
Reaction; Parosmia; Post-  
Traumatic Stress Disorder;  
Pregnancy Test Positive;  
Seizure; Sinus  
Congestion; Stress;  
Temporomandibular Joint  
Syndrome; Therapy Non-  
Responder; Tinnitus;  
Toxicity To Various

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Agents; Transaminases  
Increased; Transient  
Ischaemic Attack;  
Transverse Sinus  
Thrombosis; Urticaria;  
Vertigo; Visual Field  
Defect; Visual Field  
Defect; Vitamin D  
Decreased

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2011              | 7991688       | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000021030           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                | <u>Product</u>                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Angioedema;<br>Hyponatraemia; Toxic<br>Skin Eruption | Escitalopram Oxalate                                       |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
|                                                      | Tegretol                                                   |              |            | S           | Oral         | 400 Mg (200 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                      | Theralene (Alimemazine<br>Tartrate) (Alimemazine Tartrate) |              |            | C           |              |                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Aug-2011              | 8056110       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000022004           |                      | 26 YR      | Male       | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Sopor; Suicide Attempt | Escitalopram Oxalate |              |            | S           |              | Overdose : 14 Tablets At<br>Once (14 Dosage Forms,<br>Once) |                 | Not Reported |
|                        | Risperidone          |              |            | S           |              | Overdose: 30 Tablets At<br>Once (30 Dosage Forms,<br>Once)  |                 | Not Reported |
|                        | Bromazepam           |              |            | S           |              | Overdose: 15 Tablets At<br>Once (15 Dosage Forms,<br>Once)  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 02-Aug-2011                                                                                                                                                                                                                                   | 8735273              | DIRECT             | N                  | OT              |                      |                                                                                | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Visual                                                                                                                                                                                                                         | Lexapro              |                    |                    | S               |                      |                                                                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2011                                                                                                                                                                                                                                   | 7744473              | EXPEDITED (15-DAY) | Y                  | DE              | 1000017486           |                                                                                | 16 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Completed Suicide; Dizziness Postural; Ear Infection; Insomnia; Intentional Overdose; Multiple Injuries; Off Label Use; Product Dose Omission; Road Traffic Accident; Skin Laceration; Treatment Noncompliance                    | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg, At Night) (80 Mg, Once)<br>10 Mg (10 Mg, At Night) (80 Mg, Once) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Aug-2011                                                                                                                                                                                                                                   | 8044830              | EXPEDITED (15-DAY) | Y                  | CA, HO, RI, OT  | 1000021901           |                                                                                | < 1 DAY         | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                         | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Bradycardia Neonatal; Caesarean Section; Cardiac Murmur; Congenital Choroid Plexus Cyst; Foetal Acidosis; Foetal Distress Syndrome; Foetal Heart Rate Deceleration Abnormality; Hypotonia Neonatal; Maternal Drugs Affecting Foetus; Neonatal | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 40 Mg (40 Mg, 1 In 1 D) , Transplacental                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                               | Methyldopa           |                    |                    | S               | Transplacental       |                                                                                | 18 DAY          | Not Reported |                |
|                                                                                                                                                                                                                                               | Folic Acid           |                    |                    | C               |                      |                                                                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Complications Of  
Substance Abuse;  
Neonatal Hypotension;  
Neonatal Respiratory  
Depression; Neonatal  
Tachycardia; Overdose;  
Pelvic Kidney; Premature  
Baby; Serotonin  
Syndrome; Small For  
Dates Baby

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2011              | 8063988       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000022192           |                      | 90 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Aphasia; Cerebral<br>Haemorrhage; Fall;<br>Hemianopia; Injury;<br>Intraventricular<br>Haemorrhage | Escitalopram Oxalate                            |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                   | Aspirin                                         |              |            | S           |              | 100 Mg (100 Mg,1 In 1 D)       |                 | Not Reported |
|                                                                                                   | Seroquel (Quetiapine)<br>(Quetiapine)           |              |            | C           |              |                                |                 | Not Reported |
|                                                                                                   | Distraneurin (Clomethiazole)<br>(Clomethiazole) |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Aug-2011              | 8730903       | DIRECT           | N                  | DS              |                      |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Akathisia; Bone Disorder;<br>Cerebrovascular Accident;<br>Emotional Disorder;<br>Feeling Abnormal;<br>Homicidal Ideation;<br>Influenza Like Illness;<br>Mania; Panic Attack;<br>Paraesthesia; Serotonin<br>Syndrome; Suicidal<br>Ideation; Tinnitus;<br>Unevaluable Event; Visual | Lexapro        |              |            | S           | Oral         | 10mg Once Daily    |                 | Forest     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Acuity Reduced

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 04-Aug-2011              | 8068677       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2011SA046528 |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypokalaemia;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Stilnox                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                    | Escitalopram Oxalate   |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                    | Bisoprolol Fumarate    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                    | Aspirin                |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                    | Galantamine            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                    | Calcium Carbonate      |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Acetaminophen          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                    | Aerius (Desloratadine) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Aug-2011              | 8068961       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ROCHE-793994      |                      | 81 YR      | Female     | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxic Epidermal<br>Necrolysis | Rivotril                                    |              |            | S           | Oral         | Dose: 2.5 Mg/MI    |                 | Roche        |
|                               | Bactrim Forte                               |              |            | S           | Oral         |                    |                 | Roche        |
|                               | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Escitalopram Oxalate                        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Aug-2011              | 8045149       | EXPEDITED (15-DAY) | Y                  | DE              | PHFR2011GB04264      |                      | 61 YR      | Male       | GBR            |

| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Lung Neoplasm Malignant;<br>Organ Failure; Respiratory<br>Failure | Clozaril       |              |            | S           | Oral         | 450 Mg Daily       |                 | Novartis     |
|                                                                   | Sulpiride      |              |            | S           | Oral         | 600 Mg, Unk        |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                 |                           |                    |                    |                 |                      |                              |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                                                                                                            |                           |                    | S                  | Oral            | 20 Mg, Unk           |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2011                                                                                                                                     | 8091309                   | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022560           |                              | 17 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Platelet Count Decreased                                                                                                                        | Lexapro                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Aug-2011                                                                                                                                     | 8096110                   | EXPEDITED (15-DAY) | Y                  | DE              | DSA_47315_2011       |                              | 69 YR           | Female       | POL            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Deep Vein Thrombosis;<br>Depression; Pulmonary Embolism                                                                | Venlafaxine Hydrochloride |                    |                    | S               |                      | (225 Mg)                     |                 | Not Reported |                |
|                                                                                                                                                 | Quetiapine Fumarate       |                    |                    | S               |                      | (100 Mg) ; (300 Mg)          |                 | Not Reported |                |
|                                                                                                                                                 | Paroxetine Hydrochloride  |                    |                    | S               |                      | (20 Mg)                      |                 | Not Reported |                |
|                                                                                                                                                 | Sertraline Hydrochloride  |                    |                    | S               |                      | (100 Mg)                     |                 | Not Reported |                |
|                                                                                                                                                 | Mirtazapine (Mirtazapine) |                    |                    | S               |                      | (30 Mg) ; (45 Mg)            |                 | Not Reported |                |
|                                                                                                                                                 | Reboxetine Mesylate       |                    |                    | S               |                      | (4 Mg)                       |                 | Not Reported |                |
|                                                                                                                                                 | Escitalopram Oxalate      |                    |                    | S               |                      | (20 Mg)                      |                 | Not Reported |                |
|                                                                                                                                                 | Olanzapine (Olanzapine)   |                    |                    | S               |                      | (5 Mg)                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Aug-2011                                                                                                                                     | 7750052                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000017594           |                              | 60 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Confusional State; Drug Dependence; Ear Pain; Feeling Jittery; Gastrointestinal Disorder; Insomnia; Malaise; Nausea; Nightmare; Poor | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1in 1 D),Oral  |                 | Not Reported |                |
|                                                                                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | See Image                    |                 | Not Reported |                |
|                                                                                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | See Image                    |                 | Not Reported |                |
|                                                                                                                                                 | Escitalopram Oxalate      |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                      |                                     |                           |                                              |                          |                               |                               |                          |                     |                         |  |  |              |  |  |
|--------------------------------------|-------------------------------------|---------------------------|----------------------------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|--|--|--------------|--|--|
| Quality Sleep; Withdrawal Syndrome   |                                     |                           | Temesta (Lorazepam) (Tablets)<br>(Lorazepam) |                          |                               | C                             |                          |                     | Oral                    |  |  | Not Reported |  |  |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a>                  | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |  |              |  |  |
| 08-Aug-2011                          | 8079432                             | NON-EXPEDITED             | N                                            |                          | US-PFIZER INC-2011179842      |                               | 33 YR                    | Female              | USA                     |  |  |              |  |  |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>                          | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |  |              |  |  |
| Anxiety; Headache; Malaise; Nausea   | Advil                               |                           |                                              | S                        | Oral                          | 200 Mg Three To Four Tablets  |                          | Pfizer              |                         |  |  |              |  |  |
|                                      | Advil                               |                           |                                              | S                        | Oral                          | Unk                           |                          | Pfizer              |                         |  |  |              |  |  |
|                                      | Lexapro                             |                           |                                              | S                        |                               | Unk                           |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Alprazolam                          |                           |                                              | C                        |                               | 2 Mg, 2x/Day                  |                          | Not Reported        |                         |  |  |              |  |  |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a>                  | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |  |              |  |  |
| 08-Aug-2011                          | 8090086                             | EXPEDITED (15-DAY)        | Y                                            | DE                       | 1000022583                    |                               | 96 YR                    | Female              | DNK                     |  |  |              |  |  |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>                          | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |  |              |  |  |
| Confusional State; Dehydration; Fall | Escitalopram Oxalate                |                           |                                              | S                        | Oral                          | Oral                          |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Bromazepam                          |                           |                                              | S                        | Oral                          | Oral                          |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Isoptine (Verapamiil Hydrochloride) |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Levothyroxine Sodium                |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Tareg                               |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Aspirin                             |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Symbicort                           |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Singulair                           |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
|                                      | Desloratadine                       |                           |                                              | C                        |                               |                               |                          | Not Reported        |                         |  |  |              |  |  |
| <a href="#">FDA Received Date</a>    | <a href="#">Case #</a>              | <a href="#">Case Type</a> | <a href="#">Health Prof</a>                  | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |  |              |  |  |
| 09-Aug-2011                          | 8081725                             | EXPEDITED (15-DAY)        | Y                                            | DE                       | US-JNJFOC-20110802114         |                               |                          | Female              | USA                     |  |  |              |  |  |
| <a href="#">Preferred Term</a>       | <a href="#">Product</a>             | <a href="#">Comp.</a>     | <a href="#">OTC</a>                          | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |  |              |  |  |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                      |   |   |         |                  |  |              |
|----------------------|----------------------|---|---|---------|------------------|--|--------------|
| Intentional Overdose | Tylenol              | Y | S | Unknown |                  |  | Not Reported |
|                      | Tylenol              |   | S | Unknown | 1 Bottle         |  | Not Reported |
|                      | Depakote Er          |   | S |         | 500mg, 1-6 Hours |  | Not Reported |
|                      | Zolpidem Tartrate    |   | S |         | 10, Qh8ym        |  | Not Reported |
|                      | Carisoprodol         |   | S |         |                  |  | Not Reported |
|                      | Escitalopram Oxalate |   | S |         | 20, Qam          |  | Not Reported |
|                      | Lamotrigine          |   | S |         | 200, Qms         |  | Not Reported |
|                      | Sonata               |   | S |         |                  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2011              | 8080135       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022328           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aortic Valve Incompetence;<br>Arteriosclerosis; Mitral Valve Incompetence | Escitalopram Oxalate |              |            | S           |              |                    | 2 YR            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Aug-2011              | 8094682       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022669           |                      | 25 YR      | Male       | CHN            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                           | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------|-----------------|--------------|
| Constipation;<br>Haematochezia | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral |                 |              |
|                                |                |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral |                 |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------------------|-----------------|--------------|----------------|
| 10-Aug-2011                                                           | 8095670                                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000020204                     |                                  | 17 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;<br>Maternal Exposure During<br>Pregnancy; Pregnancy | Escitalopram Oxalate                             |                    |                    | S               |                                | 10 Mg (10 Mg,1 In 1 D)           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2011                                                           | 8097496                                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022709                     |                                  | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematochezia                                                         | Escitalopram Oxalate                             |                    |                    | S               | Oral                           | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Aug-2011                                                           | 8111198                                          | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022630                     |                                  |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Nephrolithiasis                                                       | Lexapro                                          |                    |                    | S               | Oral                           | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Aug-2011                                                           | 8046277                                          | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-<br>2011SE41855 |                                  | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haematoma;<br>Confusional State;<br>Hyponatraemia            | Candesartan Cilexetil And<br>Hydrochlorothiazide |                    |                    | S               | Oral                           | 8 + 12.5 Mg Daily                |                 | Astrazeneca  |                |
|                                                                       | Escitalopram Oxalate                             |                    |                    | S               | Oral                           |                                  |                 | Not Reported |                |
|                                                                       | Aspirin                                          |                    |                    | S               | Oral                           |                                  |                 | Not Reported |                |
|                                                                       | Atenolo\Nifedipine                               |                    |                    | C               | Oral                           |                                  |                 | Not Reported |                |
|                                                                       | Oxazepam                                         |                    |                    | C               | Oral                           |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                             |                                                                                                                                                  |                    |                    |                                      |                              |                                               |                 |                                                                                                                              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------------------------|------------------------------|-----------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------|----------------|
| Potassium Chloride                                                                                                                                                                                                                                          |                                                                                                                                                  |                    | C                  | Oral                                 |                              |                                               | Not Reported    |                                                                                                                              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                                                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 11-Aug-2011                                                                                                                                                                                                                                                 | 8083498                                                                                                                                          | EXPEDITED (15-DAY) | Y                  | HO, OT                               | 2011AP001528                 |                                               | 67 YR           | Female                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                                                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Anhedonia; Bradykinesia;<br>Condition Aggravated;<br>Decreased Appetite;<br>Depressed Mood; Drug<br>Ineffective; Family Stress;<br>Flat Affect; Gait<br>Disturbance; Insomnia;<br>Major Depression;<br>Parkinsonism; Somatic<br>Delusion; Suicidal Ideation | Risperidone<br>Paroxetine Hydrochloride<br>Escitalopram Oxalate<br>Rosuvastatin<br>Hydrochlorothiazide<br>Lisinopril<br>Duloxetine<br>Clonazepam |                    |                    | S<br>S<br>S<br>C<br>C<br>C<br>C<br>C |                              | 0.5 Mg;Qd; 0.5 Mg;Bid                         |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                                                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 11-Aug-2011                                                                                                                                                                                                                                                 | 8742829                                                                                                                                          | DIRECT             | Y                  |                                      |                              |                                               | 65 YR           | Female                                                                                                                       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                                                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Dizziness; Nausea                                                                                                                                                                                                                                           | Lexapro                                                                                                                                          |                    |                    | S                                    |                              | One Per Day                                   |                 | Not Reported                                                                                                                 |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                    | <u>Case #</u>                                                                                                                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>         | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>                                                                                                                   | <u>Country</u> |
| 12-Aug-2011                                                                                                                                                                                                                                                 | 8088605                                                                                                                                          | EXPEDITED (15-DAY) | N                  | OT                                   | US-PFIZER INC-<br>2011181339 |                                               | 45 YR           | Male                                                                                                                         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                       | <u>Product</u>                                                                                                                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>                 | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>                                                                                                                   |                |
| Agitation; Amnesia; Anger;<br>Drug Level Above<br>Therapeutic; Homicide                                                                                                                                                                                     | Xanax<br>Citalopram<br>Zolpidem Tartrate<br>Diphenhydramine<br>Acetone<br>Caffeine                                                               |                    |                    | S<br>S<br>S<br>S<br>S<br>S           | Oral                         | Unk<br>Unk<br>10 Mg, Unk<br>Unk<br>Unk<br>Unk |                 | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported                                       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Lexapro                                                                                                                                         |                                                                             |                    | S                  |                 | Unk                                                 |                                                 |                 | Not Reported |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|-------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Aug-2011                                                                                                                                     | 8088895                                                                     | EXPEDITED (15-DAY) | Y                  | HO, LT          | US-ROXANE<br>LABORATORIES, INC.-<br>2011-RO-01129RO |                                                 | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Respiratory Distress;<br>Staphylococcal Infection;<br>Urosepsis                                                                                 | Lorazepam                                                                   |                    |                    | S               |                                                     |                                                 |                 | Roxane       |                |
|                                                                                                                                                 | Escitalopram Oxalate                                                        |                    |                    | S               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Benzodiazepine                                                              |                    |                    | S               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Methylphenidate                                                             |                    |                    | S               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Linezolid                                                                   |                    |                    | S               | Intravenous (not<br>otherwise specified)            |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Piperacillin And Tazobactam                                                 |                    |                    | S               | Intravenous (not<br>otherwise specified)            |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Vancomycin                                                                  |                    |                    | S               | Intravenous (not<br>otherwise specified)            |                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                        | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Aug-2011                                                                                                                                     | 7249213                                                                     | EXPEDITED (15-DAY) | Y                  | HO              | 21323                                               |                                                 | 84 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bronchoalveolar Lavage<br>Abnormal; Cyanosis;<br>Haemoptysis; International<br>Normalised Ratio<br>Increased; Overdose;<br>Respiratory Distress | Escitalopram Oxalate                                                        |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                |                 | Not Reported |                |
|                                                                                                                                                 | Sintrom                                                                     |                    |                    | S               | Oral                                                | 2 To 4 Mg Daily According<br>To Inr Value, Oral |                 | Not Reported |                |
|                                                                                                                                                 | Lasilix (Furosemide) (Tablets)                                              |                    |                    | C               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Daonil (Glibenclamide)                                                      |                    |                    | C               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | (Glibenclamide)                                                             |                    |                    |                 |                                                     |                                                 |                 |              |                |
|                                                                                                                                                 | Imovane (Zopiclone) (Zopiclone)                                             |                    |                    | C               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | Levothyrox (Levothyroxine<br>Sodium) (Tablets)                              |                    |                    | C               |                                                     |                                                 |                 | Not Reported |                |
|                                                                                                                                                 | (Levothyroxine Sodium)<br>Glucophage (Metformin<br>Hydrochloride) (Tablets) |                    |                    | C               |                                                     |                                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

(Metformin Hydrochloride)

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|------------------------------|-------------------------|
| 15-Aug-2011                       | 8048669                 | EXPEDITED (15-DAY)        | N                           | HO                       | 1000021874                    |                               |                          | Female                       | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Dyspnoea; Panic Attack            | Viibryd<br>Lexapro      |                           |                             | S<br>S                   |                               |                               |                          | Not Reported<br>Not Reported |                         |

| <a href="#">FDA Received Date</a>                                                                                                       | <a href="#">Case #</a>                               | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>    | <a href="#">Age</a>      | <a href="#">Sex</a>          | <a href="#">Country</a> |
|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------|--------------------------|------------------------------|-------------------------|
| 15-Aug-2011                                                                                                                             | 8068631                                              | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000022290                    |                                  | 88 YR                    | Female                       | DNK                     |
| <a href="#">Preferred Term</a>                                                                                                          | <a href="#">Product</a>                              | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>      | <a href="#">Duration</a> | <a href="#">Mfr</a>          |                         |
| Abnormal Behaviour;<br>Cerebellar Haematoma;<br>Confusional State;<br>Headache;<br>Hypercoagulation;<br>Hyponatraemia; Lung<br>Disorder | Escitalopram Oxalate                                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                          | Not Reported                 |                         |
|                                                                                                                                         | Candesartan Cilexetil And<br>Hydrochlorothiazide     |                           |                             | S                        |                               | 8 Mg/ 12.5 Mg (1 In 1 D)         |                          | Not Reported                 |                         |
|                                                                                                                                         | Aspirin                                              |                           |                             | S                        | Oral                          | 75 Mg (75 Mg, 1 In 1 D),<br>Oral |                          | Not Reported                 |                         |
|                                                                                                                                         | Diffu K (Potassium Chloride)<br>(Potassium Chloride) |                           |                             | C                        |                               |                                  |                          | Not Reported                 |                         |
|                                                                                                                                         | Tenordate (Nif-Ten) (Nif-Ten)<br>Oxazepam            |                           |                             | C<br>C                   |                               |                                  |                          | Not Reported<br>Not Reported |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 15-Aug-2011                       | 8096990                 | DIRECT                    | N                           | OT                       |                               |                               | 38 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Constipation; Muscle<br>Spasms    | Lexapro                 |                           |                             | S                        |                               | 1 Daily                       |                          | Not Reported        |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>  | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|--------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Aug-2011                       | 7136909                | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | CH-ASTRAZENECA-<br>2009SE15253 |                               | 30 YR               | Male                | CHE                     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Electrocardiogram Qt Prolonged; Endocarditis; Syncope; Ventricular Tachycardia; Weight Decreased | Seroquel                       |                    |                    | S               | Oral                 |                                  | 2 YR            | Not Reported |                |
|                                                                                                  | Seroquel                       |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                  | Ritalin                        |                    |                    | S               | Oral                 |                                  | 2 YR            | Not Reported |                |
|                                                                                                  | Ritalin                        |                    |                    | S               | Oral                 |                                  | 3 DAY           | Not Reported |                |
|                                                                                                  | Methadone Hydrochloride        |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                  | Valium                         |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                  | Cipralelex                     |                    |                    | S               | Oral                 |                                  |                 | Not Reported |                |
|                                                                                                  | Zopiclone                      |                    |                    | C               | Oral                 |                                  | 4 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2011                                                                                      | 8108005                        | EXPEDITED (15-DAY) | N                  | OT              | 1000022824           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                                          | Lexapro                        |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2011                                                                                      | 8118144                        | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022248           |                                  | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia; Anger; Homicide; Imprisonment; Loss Of Consciousness                         | Lexapro                        |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                  | Ambien                         |                    |                    | S               | Oral                 | 10 Mg Prn (10 Mg,As Needed),Oral |                 | Not Reported |                |
|                                                                                                  | Xanax                          |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                  | Diphenhydramine Hydrochloride  |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                  | Acetone (Acetone) (Acetone)    |                    |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                                  | Caffeine (Caffeine) (Caffeine) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Aug-2011                                                                                      | 8748927                        | DIRECT             | N                  | OT              |                      |                                  | 68 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                 |         |   |      |                            |              |
|-------------------------------------------------------------------------------------------------|---------|---|------|----------------------------|--------------|
| Anhedonia; Depressed Mood; Depression; Feeling Abnormal; Feelings Of Worthlessness; Hypersomnia | Lexapro | S | Oral | 1 & 1/2 Tablets, Daily, Po | Not Reported |
|-------------------------------------------------------------------------------------------------|---------|---|------|----------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2011              | 8014704       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021540           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>                                                                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anal Haemorrhage; Ecchymosis | Lexapro                                                                                                                          |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                              | Lexapro                                                                                                                          |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                              | Spiriva                                                                                                                          |              |            | C           |              |                               |                 | Not Reported |
|                              | Simvastatine (Simvastatin) (Tablets) (Simvastatin) Symbicort (Budesonide, Formoterol Fumarate) (Budesonide, Formoterol Fumarate) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Aug-2011              | 8039382       | EXPEDITED (15-DAY) | Y                  | DE              | 1000021787           |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aspiration; Poisoning; Unresponsive To Stimuli | Escitalopram Oxalate  |              |            | S           |              |                    |                 | Not Reported |
|                                                | Oxycodone (Oxycodone) |              |            | S           |              |                    |                 | Not Reported |
|                                                | Diazepam (Diazepam)   |              |            | S           |              |                    |                 | Not Reported |
|                                                | Nordazepam            |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Aug-2011              | 8093759       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2011SE47636 |                      | 80 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                                             |             |                      |                         |  |       |                                              |
|----------------------------------------------------------------------------------------|---------------------------------------------|-------------|----------------------|-------------------------|--|-------|----------------------------------------------|
| Drug Interaction;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Atacand<br>Urapidil<br>Escitalopram Oxalate | S<br>C<br>S | Oral<br>Oral<br>Oral | Daily<br>Daily<br>Daily |  | 4 DAY | Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------|---------------------------------------------|-------------|----------------------|-------------------------|--|-------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-Aug-2011              | 8096137       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-<br>2011SE48064 |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                 | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Partial<br>Seizures | Zolmitriptan                                        |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                       | Transilane (Potassium<br>Bicarbonate\Psyllium Husk) |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Oxazepam                                            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Lescol                                              |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Zopiclone                                           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Bisoprolol Fumarate                                 |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Actonel                                             |              |            | C           | Oral         |                    |                 | Not Reported |
|                                       | Valacyclovir Hydrochloride                          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                       | Escitalopram Oxalate                                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                       | Sanmigran                                           |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Aug-2011              | 8111792       | EXPEDITED (15-DAY) | Y                  | HO              | 2011MA010840         |                      | 52 YR      | Female     | TWN            |

| <u>Preferred Term</u>                                                                                                                                                                                        | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Cerebral Atrophy;<br>Extrapyramidal Disorder;<br>Gait Disturbance; Muscle<br>Rigidity; Orthostatic<br>Hypotension;<br>Psychomotor<br>Hyperactivity; Treatment<br>Noncompliance; Tremor; | Fluoxetine               |              |            | S           |              |                    |                 | Alphapharm   |
|                                                                                                                                                                                                              | Sertraline Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                              | Escitalopram Oxalate     |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urinary Incontinence

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Aug-2011                                                                                    | 8112142                       | EXPEDITED (15-DAY) | N                  | OT              | AUR-APL-2011-04656   |                      | 45 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Amnesia; Anger; Antidepressant Drug Level Above Therapeutic; Homicide; Imprisonment | Citalopram Hydrobromide       |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                | Zolpidem                      |                    |                    | S               | Oral                 | (10 Mg), Oral        |                 | Not Reported |                |
|                                                                                                | Xanax                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                | Diphenhydramine Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                | Acetone                       |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                | Caffeine                      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                | Lexapro                       |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                             | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 19-Aug-2011                                                                                          | 8053744                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021963           |                                                                                            | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemoglobin Decreased; Neutropenia; Red Blood Cell Count Decreased; White Blood Cell Count Decreased | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                      |                            |                    |                    |                 | Oral                 | 10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                      |                            |                    |                    |                 | Oral                 | 10 Mg (10 Mg 1 In 1 D), Oral; 15 Mg (15 Mg, 1 In 1 D), Oral; 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                      | Promethazine Hydrochloride |                    |                    | S               | Oral                 | 25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral                               |                 | Not Reported |                |
|                                                                                                      |                            |                    |                    |                 | Oral                 | 25 Mg (25 Mg, 1 In 1 D), Oral; 50 Mg (50 Mg, 1 In 1 D), Oral                               |                 |              |                |
|                                                                                                      |                            |                    |                    |                 |                      |                                                                                            |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                |   |      |                                                                |              |
|--------------------------------|---|------|----------------------------------------------------------------|--------------|
| Agomelatine                    | S | Oral | 25 Mg (25 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1 D),Oral | Not Reported |
|                                |   | Oral | 25 Mg (25 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1 D),Oral |              |
| Ximova (Zopiclone) (Zopiclone) | C |      |                                                                | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 19-Aug-2011              | 8098343       | EXPEDITED (15-DAY) | Y                  | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0738119A |                      | 78 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Drug Interaction;<br>Dyspnoea; Loss Of<br>Consciousness; Malaise;<br>Partial Seizures | Valacyclovir Hydrochloride     |              |            | S           | Oral         | 500mg Per Day      |                 | Glaxosmithkline |
|                                                                                       | Escitalopram Oxalate           |              |            | S           | Oral         | 15mg Per Day       |                 | Unknown         |
|                                                                                       | Zolmitriptan                   |              |            | S           | Oral         | 2.5mg Per Day      |                 | Unknown         |
|                                                                                       | Sanmigran                      |              |            | S           | Oral         | 1mg Per Day        |                 | Unknown         |
|                                                                                       | Potassium Bicarbonate\Psyllium |              |            | C           | Oral         |                    |                 | Unknown         |
|                                                                                       | Hemicellulose                  |              |            |             |              |                    |                 |                 |
|                                                                                       | Oxazepam                       |              |            | C           | Oral         | 10mg Unknown       |                 | Unknown         |
|                                                                                       | Lescol                         |              |            | C           | Oral         | 20mg Per Day       |                 | Unknown         |
|                                                                                       | Zopiclone                      |              |            | C           | Oral         | 7.5mg Per Day      |                 | Unknown         |
|                                                                                       | Bisoprolol Fumarate            |              |            | C           | Oral         | 3.75mg Per Day     |                 | Unknown         |
|                                                                                       | Actonel                        |              |            | C           | Oral         | 35mg Weekly        |                 | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Aug-2011              | 8113431       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022865           |                      | 64 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Haematuria            | Escitalopram Oxalate                                                         |              |            | S           | Oral         | 5mg - 10mg (1 In 1 D),<br>Oral |                 | Not Reported |
|                       | Corsodyl (Chlorhexidine<br>Gluconate, Chlorhexidine<br>Digluconate Solution) |              |            | C           |              |                                |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                           |                          |                    |                    |                 |                              |                                  |                 |                |                |
|---------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|----------------|----------------|
| Fybogel<br>Imipramine                                                     |                          |                    | C<br>C             |                 | Not Reported<br>Not Reported |                                  |                 |                |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Aug-2011                                                               | 8099518                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2011190779 |                                  | 42 YR           | Male           | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>     |                |
| Feeling Abnormal; Product<br>Dose Omission;<br>Strabismus; Vision Blurred | Pristiq Extended Release |                    |                    | S               | Oral                         | 50 Mg, Daily                     |                 | Pfizer         |                |
|                                                                           | Lexapro                  |                    |                    | S               | Oral                         | 20 Mg, Daily                     |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Aug-2011                                                               | 8116421                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022928                   |                                  | 45 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>     |                |
| Diarrhoea; Lymphocytic<br>Infiltration                                    | Lexapro                  |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Aug-2011                                                               | 8118195                  | EXPEDITED (15-DAY) | Y                  | HO              | 2011MA011405                 |                                  | 67 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>     |                |
| Depression; Drug<br>Ineffective; Parkinsonism;<br>Somatic Delusion        | Risperidone              |                    |                    | S               |                              | 0.5 Mg;Bid;                      |                 | Actavis Totowa |                |
|                                                                           | Clonazepam               |                    |                    | S               |                              |                                  |                 | Not Reported   |                |
|                                                                           | Escitalopram Oxalate     |                    |                    | S               |                              |                                  |                 | Not Reported   |                |
|                                                                           | Paroxetine Hydrochloride |                    |                    | C               |                              |                                  |                 | Not Reported   |                |
|                                                                           | Hydrochlorothiazide      |                    |                    | C               |                              |                                  |                 | Not Reported   |                |
|                                                                           | Lisinopril               |                    |                    | C               |                              |                                  |                 | Not Reported   |                |
|                                                                           | Rosuvastatin             |                    |                    | C               |                              |                                  |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 22-Aug-2011                                                               | 8128373                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000022869                   |                                  | 80 YR           | Female         | DNK            |
| <u>Preferred Term</u>                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                        |                                             |             |                  |                  |                                              |
|----------------------------------------------------------------------------------------|---------------------------------------------|-------------|------------------|------------------|----------------------------------------------|
| Gait Disturbance;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Escitalopram Oxalate<br>Atacand<br>Urapidil | S<br>S<br>S | Oral<br><br>Oral | Oral<br><br>Oral | Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------|---------------------------------------------|-------------|------------------|------------------|----------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Aug-2011              | 8142733       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000022847           |                      | 72 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>                                                                                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>                    | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                                                                                       |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------------------|--------------|-----------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------|
| Coronary Artery Disease;<br>Ventricular Arrhythmia;<br>Ventricular Extrasystoles;<br>Ventricular Tachycardia | Lexapro<br><br>Nadolol<br>Crestor<br>Aspirin (Acetylsalicylic Acid)<br>Micardis<br>Janumet(Sitagliptin, Metformin) |              |            | S<br><br>C<br>C<br>C<br>C<br>C | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 5 Mg (5 Mg, 1 In 1 D),<br>Oral |                 | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2011              | 7960789       | EXPEDITED (15-DAY) | Y                  | HO              | 1000020671           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                            | <u>Product</u>                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|--------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Abdominal Pain;<br>Abdominal Pain Upper;<br>Blood Cholesterol<br>Increased; Fatigue;<br>Insomnia | Escitalopram Oxalate<br>Atrovent<br>Berodual (Fenoterol) |              |            | S<br>C<br>C |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2011              | 8088959       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHHY2011FR69793      |                      | 89 YR      | Female     | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>               |
|-----------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------------------|
| Dizziness; Fall; Glare;<br>Joint Injury | Tramadol Hydrochloride<br>Nitroderm |              |            | S<br>S      | Oral         | 100 Mg, Bid<br>Unk Unkn, Qd |                 | Novartis<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |              |              |
|----------------------|---|------|--------------|--------------|
| Furosemide           | S | Oral | Unk Ukn, Qd  | Not Reported |
| Isosorbide Dinitrate | S | Oral | 20 Mg, Bid   | Not Reported |
| Vastarel             | S | Oral | Unk Ukn, Bid | Not Reported |
| Escitalopram Oxalate | S |      | 0.25 Df, Unk | Not Reported |
| Dafalgan             | C |      | 6 Df, Unk    | Not Reported |
| Bromazepam           | C |      | 0.5 Df, Unk  | Not Reported |
| Seretide Diskus      | C |      | Unk Ukn, Bid | Not Reported |
| Trimebutine          | C |      | 100 Mg, Bid  | Not Reported |
| Ipratropium Bromide  | C |      | Unk Ukn, Tid | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Aug-2011              | 8121017       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022976           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Constipation;     | Escitalopram Oxalate |              |            | S           |              | (5 Mg)             |                 | Not Reported |
| Decreased Appetite;        | Escitalopram Oxalate |              |            | S           |              | See Image          |                 | Not Reported |
| Depression; Drug           | Escitalopram Oxalate |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Ineffective; Drug          | Escitalopram Oxalate |              |            | S           |              | 5 Mg               |                 | Not Reported |
| Withdrawal Syndrome;       | Escitalopram Oxalate |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Faecal Volume              | Escitalopram Oxalate |              |            | S           |              | 5 Mg               |                 | Not Reported |
| Decreased;                 | Escitalopram Oxalate |              |            | S           |              | 10 Mg              |                 | Not Reported |
| Gastrointestinal Disorder; | Escitalopram Oxalate |              |            | S           |              | 5 Mg               |                 | Not Reported |
| Gastrointestinal Oedema;   | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
| Micturition Disorder;      | Cymbalta             |              |            | S           | Oral         | 60 Mg, Oral        |                 | Not Reported |
| Suicidal Ideation; Urine   | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
| Output Decreased;          | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
| Vaginal Abscess; Wrong     | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
| Technique In Product       | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |
| Usage Process              | Cymbalta             |              |            | S           | Oral         | 30 Mg, Oral        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2011              | 8100660       | EXPEDITED (15-DAY) | Y                  | HO              | IT-BAYER-2011-071714 |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |                                |   |              |           |              |
|-----------|--------------------------------|---|--------------|-----------|--------------|
| Myoclonus | Acetylsalicylic Acid(<=100 Mg) | S | Oral         |           | Bayer        |
|           | Nitroglycerin                  | S | Transdermal  |           | Not Reported |
|           | Escitalopram Oxalate           | S | Oral         | 10 Mg, Qd | Not Reported |
|           | Escitalopram Oxalate           | S |              |           | Not Reported |
|           | Dipyridamole                   | S |              |           | Not Reported |
|           | Metoprolol                     | S | Oral         |           | Not Reported |
|           | Pantoprazole                   | S | Oral         |           | Not Reported |
|           | Insulin Nos                    | S | Subcutaneous |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2011              | 8104588       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR73076      |                      |            | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Hyponatraemia         | Hydrochlorothiazide/Valsartan |              |            | S           |              | 160 Mg Valsartan/ 25 Mg Hydrochlorothiazide |                 | Novartis     |
|                       | Escitalopram Oxalate          |              |            | S           |              | Unk Unk, Unk                                |                 | Not Reported |
|                       | Methotrexate                  |              |            | C           |              | Unk Unk, Unk                                |                 | Not Reported |
|                       | Metformin Hydrochloride       |              |            | C           |              | Unk Unk, Unk                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2011              | 8118554       | EXPEDITED (15-DAY) | N                  | CA              | 1000022942           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital Anomaly;<br>Hydrocephalus; Maternal<br>Drugs Affecting Foetus;<br>Spina Bifida | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Aug-2011              | 8120325       | EXPEDITED (15-DAY) | Y                  | HO              | 1000023020           |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                      |   |         |              |
|-------------------------------------------|----------------------|---|---------|--------------|
| Dissociative Disorder;<br>Nausea; Seizure | Escitalopram Oxalate | S | (10 Mg) | Not Reported |
|-------------------------------------------|----------------------|---|---------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2011              | 8120845       | EXPEDITED (15-DAY) | N                  | CA              | 1000022949           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Aug-2011              | 8123832       | EXPEDITED (15-DAY) | Y                  | HO              | 1000023038           |                      | 81 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                 | <u>Product</u>                                                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Atrial Flutter; Diverticulum; Haematochezia; Haematuria; Haemoglobin Decreased; Haemorrhage; International Normalised Ratio Increased | Escitalopram Oxalate                                                                                 |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                       | Sintrom                                                                                              |              |            | S           | Oral         | Oral                        |                 | Not Reported |
|                                                                                                                                       | Prozac                                                                                               |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                       | Omeprazol (Omeprazole)                                                                               |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                       | Cardyl Comprimido Recubiertos Con Pelicula (Atorvastatin Calcium Trihydrate) (Atorvastatin Calcium T |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                       | Trangorex Comprimidos (Amiodarone Hydrochloride) (Amiodarone Hydrochloride)                          |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Aug-2011              | 7898780       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000019325           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Amnesia; Disorientation; | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D) Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |                      |                    |                    |                                     |                          |                      |                 |              |                |
|-----------------------------------------------------------|----------------------|--------------------|--------------------|-------------------------------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Fatigue; Platelet Count Increased; Seizure; Tongue Biting | Escitalopram Oxalate | S                  | Oral               | 10, 5 Mg (10, 5 Mg, 1 In 1 D), Oral |                          |                      |                 | Not Reported |                |
|                                                           |                      |                    | Oral               | 10, 5 Mg (10, 5 Mg, 1 In 1 D), Oral |                          |                      |                 |              |                |
|                                                           | Viani                | C                  |                    |                                     |                          |                      | Not Reported    |              |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2011                                               | 8006385              | EXPEDITED (15-DAY) | Y                  | HO                                  | 1000021413               |                      | 39 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                   | Escitalopram Oxalate |                    |                    | S                                   | Oral                     | Oral                 |                 | Not Reported |                |
|                                                           | Viani                |                    |                    | C                                   |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2011                                               | 8108082              | EXPEDITED (15-DAY) | Y                  | HO                                  | FR-JNJFOC-20110810240    |                      | 55 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis Acute; Jaundice                                 | Haldol               |                    |                    | S                                   | Oral                     |                      |                 | Not Reported |                |
|                                                           | Escitalopram Oxalate |                    |                    | S                                   | Oral                     |                      |                 | Not Reported |                |
|                                                           | Cyamemazine          |                    |                    | S                                   | Oral                     |                      |                 | Not Reported |                |
|                                                           | Zyprexa              |                    |                    | S                                   | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                     | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2011                                               | 8108748              | EXPEDITED (15-DAY) | Y                  | DS, OT                              | FR-PFIZER INC-2011198814 |                      | 72 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                         | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Myalgia; Syncope; Vision Blurred              | Atarax               |                    |                    | S                                   | Oral                     | 25 Mg, Unk           | 28 DAY          | Pfizer       |                |
|                                                           | Escitalopram Oxalate |                    |                    | S                                   | Oral                     | 10 Mg, Unk           | 28 DAY          | Not Reported |                |
|                                                           | Tavanic              |                    |                    | C                                   | Oral                     | 500 Mg, 2x/Day       |                 | Not Reported |                |
|                                                           | Alendronate Sodium   |                    |                    | C                                   | Oral                     | 1 Df, Weekly         |                 | Not Reported |                |
|                                                           | Domperidone          |                    |                    | C                                   | Oral                     | 1 Df, 2x/Day         |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                  | Inipomp                                              |                    | C                  | Oral            | 40 Mg, Daily         |                             | Not Reported    |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                  | Dafalgan                                             |                    | C                  | Oral            | 2 To 4 Df Daily      |                             | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Aug-2011                                                                                                                                                                                      | 8126339                                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000023057           |                             | 73 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Cerebral Atrophy; Cerebral Small Vessel Ischaemic Disease; Culture Urine Positive; Delirium; Electroencephalogram Abnormal; Escherichia Infection; Hyponatraemia | Escitalopram Oxalate                                 |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D)      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Escitalopram Oxalate                                 |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D)      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2011                                                                                                                                                                                      | 8091586                                              | EXPEDITED (15-DAY) | Y                  | DS              | 1000022621           |                             | 49 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Chromaturia; Renal Pain                                                                                                                                                                          | Escitalopram Oxalate                                 |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lisinopril                                           |                    |                    | C               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Aug-2011                                                                                                                                                                                      | 8096345                                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000022646           |                             | 71 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Interstitial Lung Disease; Pulmonary Hypertension                                                                                                                                      | Lexapro                                              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, In 1 D) Oral  |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lexapro                                              |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                  | Promocard Durette (Isosorbide Mononitrate) (Tablets) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                  | Albuterol                                            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                  | Acetylsalicylic Acid                                 |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                      |   |              |
|--------------------------------------|---|--------------|
| Esomeprazole Magnesium               | C | Not Reported |
| Oxazepam                             | C | Not Reported |
| Risedronic Acid (Risedronate Sodium) | C | Not Reported |
| Metoprolol                           | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2011              | 8126415       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023028           |                      | 50 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Seizure               | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                       | Lamictal       |              |            | C           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Aug-2011              | 8126425       | EXPEDITED (15-DAY) | N                  | HO              | 1000023030           |                      | 39 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Abdominal Pain Upper; Back Pain; Bruxism; Chest Pain; Dizziness; Dry Mouth; Dyspnoea; Fatigue; Flatulence; Insomnia; Muscle Spasms; Myelodysplastic Syndrome; Night Sweats | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                            | Oxycodone Hydrochloride |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Aug-2011              | 8112698       | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2011194543 |                      | 83 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                          |                                                                                                |                                      |                                                              |                                                                                                         |                                                                                                                        |
|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Agranulocytosis; Anaemia;<br>Febrile Neutropenia;<br>Waldenstrom'S<br>Macroglobulinaemia | Xanax<br>Escitalopram Oxalate<br>Tahor<br>Plavix<br>Selokeen<br>Ramipril<br>Aspirin<br>Inexium | S<br>S<br>C<br>C<br>C<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral<br>Oral | Unk<br>Unk<br>10 Mg, 1x/Day<br>75 Mg, Unk<br>100 Mg, Unk<br>1.25 Mg, 1x/Day<br>75 Mg, Unk<br>20 Mg, Unk | Pfizer<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Aug-2011              | 8129490       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023103           |                      | 47 YR      | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Lung Disorder; Sinusitis | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                          | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2011              | 8137453       | EXPEDITED (15-DAY) | Y                  | DE              | 100023111            |                      | 61 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Lung Adenocarcinoma;<br>Neoplasm Progression;<br>Organ Failure; Respiratory<br>Failure | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                        | Clozaril             |              |            | S           | Oral         | 450 Mg (450 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                        | Sulpiride            |              |            | S           | Oral         | 600 Mg (600 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Aug-2011              | 8137533       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000023135           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                           |                      |   |      |                                     |              |
|-------------------------------------------------------------------------------------------|----------------------|---|------|-------------------------------------|--------------|
| Diplopia; Eye Pain; Halo Vision; Migraine; Photophobia; Pupils Unequal; Vitreous Floaters | Escitalopram Oxalate | S | Oral | Dose, Oral, (10 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                           |                      |   | Oral | Dose, Oral, (10 Mg, 1 In 1 D), Oral |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Sep-2011              | 7987485       | EXPEDITED (15-DAY) | Y                  | CA              | 1000020997           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|---------------------------------------|-----------------|--------------|
| Congenital Musculoskeletal Anomaly; Maternal Drugs Affecting Foetus | Lexapro        |              |            | S           | Transplacental | 20 Mg (20 Mg,1 In 1 D),Transplacental |                 | Not Reported |
|                                                                     | Oxazepam       |              |            | S           | Transplacental | 60 Mg (60 Mg,1 In 1 D),Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2011              | 8117578       | EXPEDITED (15-DAY) | Y                  | HO, LT          | BR-PFIZER INC-2011203332 |                      | 86 YR      | Female     | BRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Fibrillation   | Lyrica               |              |            | S           | Oral         | 75 Mg Daily        |                 | Pfizer       |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Sep-2011              | 8117702       | EXPEDITED (15-DAY) | Y                  | OT              | PL-MYLANLABS-2011S1017697 |                      | 69 YR      | Female     | POL            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Embolism Venous       | Sertraline Hydrochloride  |              |            | S           | Unknown      | Maximum Daily Dose Of 100mg |                 | Not Reported |
|                       | Paroxetine Hydrochloride  |              |            | S           | Unknown      | Maximum Daily Dose Of 20mg  |                 | Not Reported |
|                       | Venlafaxine Hydrochloride |              |            | S           | Unknown      | Maximum Daily Dose Of 225mg |                 | Not Reported |
|                       | Mirtazapine               |              |            | S           | Unknown      | Maximum Daily Dose Of 30mg  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |                             |              |
|----------------------|---|---------|-----------------------------|--------------|
| Mirtazapine          | S | Unknown | Maximum Daily Dose Of 45mg  | Not Reported |
| Reboxetine           | S | Unknown | Maximum Daily Dose Of 4mg   | Not Reported |
| Quetiapine           | S | Unknown | Maximum Daily Dose Of 100mg | Not Reported |
| Escitalopram Oxalate | S | Unknown | Maximum Daily Dose Of 20mg  | Not Reported |
| Olanzapine           | S | Unknown | Maximum Daily Dose Of 5mg   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8062577       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022227           |                      | 35 YR      | Male       | DNK            |

| <u>Preferred Term</u>           | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Alcoholism; Labile Hypertension | Escitalopram Oxalate                             |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                 |                                                  |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 |              |
|                                 | Escitalopram Oxalate                             |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |
|                                 | Doliprane (Paracetamol) (Paracetamol)            |              |            | C           |              |                                                              |                 | Not Reported |
|                                 | Moxydar (Moxydar) (Moxydar)                      |              |            | C           |              |                                                              |                 | Not Reported |
|                                 | Gaviscon (Gaviscon) Gaviscon)                    |              |            | C           |              |                                                              |                 | Not Reported |
|                                 | Inexium (Esomeprazole Magnesium)                 |              |            | C           |              |                                                              |                 | Not Reported |
|                                 | Pariet (Rabeprazole Sodium) (Rabeprazole Sodium) |              |            | C           |              |                                                              |                 | Not Reported |
|                                 | Lexomil (Bromazepam) (Bromazepam)                |              |            | C           |              |                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8080606       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022411           |                      | 39 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Eosinophil Count Increased; Leukopenia; Lymphocyte Percentage Increased; Neutropenia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral   |                 | Not Reported |
|                                                                                      | Seroquel Xr          |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8082775       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022350           |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cutaneous Lupus Erythematosus | Lexapro                                                     |              |            | S           | Oral         | 10 Mg,Oral         |                 | Not Reported |
|                               | Lexapro                                                     |              |            | S           | Oral         | 15 Mg,Oral         |                 | Not Reported |
|                               | Lexapro                                                     |              |            | S           | Oral         | 10 Mg,Oral         |                 | Not Reported |
|                               | Lexapro                                                     |              |            | S           | Oral         | 5 Mg,Oral          |                 | Not Reported |
|                               | Exelon (Rivastigmine) (Transdermal) (Rivastigmine)          |              |            | C           |              |                    |                 | Not Reported |
|                               | Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium) |              |            | C           |              |                    |                 | Not Reported |
|                               | Namenda                                                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8111532       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000022848           |                      | 83 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                   | <u>Product</u>                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Asthenia; Fatigue; Fluid Intake Reduced; Hypophagia; Hypotension; Nausea; Pneumonia; Restlessness; Somnolence; Vomiting | Escitalopram Oxalate                              |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                                                         | Prothipendyl Hydrochloride                        |              |            | S           | Oral         | 80 Mg (80 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                         | Mirtazapine                                       |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                         | Pantozol                                          |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                         | Torsemide                                         |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                                         | Ass (Acetylsalicylic Acid) (Acetylsalicylic Acid) |              |            | C           |              |                               |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |   |              |
|-------------------------------------------------------------|---|--------------|
| Enalapril Maleate                                           | C | Not Reported |
| Allopurinol                                                 | C | Not Reported |
| Bisoprolol Fumarate                                         | C | Not Reported |
| Limptar N (Quinine Sulfate)<br>(Quinine Sulfate)            | C | Not Reported |
| Magnetran (Magnesium<br>Aspartate) (Magnesium<br>Aspartate) | C | Not Reported |
| Actraphane (Human Insulin)<br>(Human Insulin)               | C | Not Reported |
| Exelon (Rivastigmine)<br>(Rivastigmine)                     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8119272       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-<br>2011201348 |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma Scale Abnormal;<br>Miosis; Somnolence | Xanax                |              |            | S           | Oral         | 0.25 Mg, 3x/Day    | 4 DAY           | Pfizer       |
|                                            | Morphine Sulfate     |              |            | S           | Oral         | 30 Mg, 2x/Day      | 4 DAY           | Not Reported |
|                                            | Morphine Sulfate     |              |            | S           | Oral         | 10 Mg, 6x/Day      | 4 DAY           | Not Reported |
|                                            | Durogesic            |              |            | S           | Transdermal  | 50ug/Hour          | 4 DAY           | Not Reported |
|                                            | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 1x/Day      | 4 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8135263       | EXPEDITED (15-DAY) | Y                  | HO              | 1000023195           |                      | 55 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase<br>Increased; Bilirubin<br>Conjugated Increased;<br>Blood Alkaline<br>Phosphatase Increased;<br>Blood Bilirubin Increased;<br>Blood Creatine | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 -In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                                   | Haldol               |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                   | Cyamemazine          |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |         |   |      |                                 |  |  |  |              |  |
|----------------------------------------------------------------------------------------------|---------|---|------|---------------------------------|--|--|--|--------------|--|
| Phosphokinase Increased;<br>Depression; Gamma-<br>Glutamyltransferase<br>Increased; Jaundice | Zyprexa | S | Oral | 50 Mg (50 Mg, 1 In 1<br>D),Oral |  |  |  |              |  |
|                                                                                              |         |   | Oral | 20 Mg (20 Mg, 1in 1<br>D),Oral  |  |  |  | Not Reported |  |
|                                                                                              |         |   | Oral | 20 Mg (20 Mg, 1in 1<br>D),Oral  |  |  |  |              |  |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8135283       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000023186           |                      | 64 YR      | Female     | DNK            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Asthenia;                        | Lexapro        |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D),Oral      |                 | Not Reported |
| Thrombocytopenia; Yellow<br>Skin | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Sep-2011              | 8135408       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023314           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Maternal Drugs Affecting<br>Foetus; Small For Dates<br>Baby | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8006639       | EXPEDITED (15-DAY) | Y                  | HO              | CH-PFIZER INC-<br>2011132053 |                      | 36 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>     | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|------------------|---------------------------------------|-----------------|------------|
| Coagulopathy; Cytarabine<br>Syndrome; Hepatocellular<br>Injury; Myalgia; Rash; | Cytosar-U                |              |            | S           | Intravenous drip | 1000 Mg/M2, 2x/Day (Day 7 DAY<br>1-6) |                 | Pfizer     |
| Rhabdomyolysis;                                                                | Cytosar-U                |              |            | S           | Intravenous drip | 1000 Mg/M2, 2x/Day (Day 6 DAY<br>1-6) |                 | Pfizer     |
| Serotonin Syndrome                                                             | Idarubicin Hydrochloride |              |            | S           | Intravenous drip | 12 Mg/M2, 1x/Day (Day 1- 3 DAY<br>3)  |                 | Pfizer     |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |   |                   |                             |        |              |
|------------------------------|---|-------------------|-----------------------------|--------|--------------|
| Cipraxel                     | S | Oral              | 10 Mg, 1x/Day               | 45 DAY | Not Reported |
| Amsidyl                      | S | Intravenous drip  | 120 Mg/M2, 1x/Day (Day 4-6) | 3 DAY  | Not Reported |
| Famvir                       | S | Oral              | 500 Mg, 2x/Day              | 8 DAY  | Not Reported |
| Candidas                     | S | Oral              | 70 Mg, 1x/Day               | 6 DAY  | Not Reported |
| Meropenem                    | S | Intravenous drip  | 1 G, 3x/Day                 | 8 DAY  | Not Reported |
| Motilium                     | C | Sublingual        | 10 Mg, As Needed            | 10 DAY | Not Reported |
| Motilium                     | C |                   |                             |        | Not Reported |
| Piperacillin And Tazobactam  | C |                   | 2.25 Mg, 3x/Day             | 12 DAY | Not Reported |
| Piperacillin And Tazobactam  | C |                   | 2.25 Mg, Once Per 3 Days    | 12 DAY | Not Reported |
| Metoclopramide Hydrochloride | C | Oral              | 10 Mg, 3x/Day               | 35 DAY | Not Reported |
| Metoclopramide Hydrochloride | C |                   |                             |        | Not Reported |
| Nexium                       | C | Oral              | 40 Mg, 1x/Day               |        | Not Reported |
| Nexium                       | C |                   |                             |        | Not Reported |
| Perfalgan                    | C | Intravenous bolus | 500 Mg, As Needed           | 50 DAY | Not Reported |
| Stilnox                      | C | Oral              | 10 Mg, As Needed            | 50 DAY | Not Reported |
| Buscopan                     | C | Oral              | 10 Mg, As Needed            | 50 DAY | Not Reported |
| Primolut-N                   | C | Oral              | 5 Mg, 4x/Day                |        | Not Reported |
| Dexamethasone                | C | Oral              | 8 Mg, 3x/Day                |        | Not Reported |
| Vfend                        | C | Oral              | 1 G, 2x/Day                 | 9 DAY  | Not Reported |
| Flagyl                       | C |                   | 500 Mg, 3x/Day              | 24 DAY | Not Reported |

| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 06-Sep-2011                 | 8096518              | EXPEDITED (15-DAY) | Y                  | HO              | FR-GLAXOSMITHKLINE-B0738591A |                      | 38 YR           | Male            | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cheilitis; Dermatitis       | Lamictal             |                    |                    | S               | Oral                         | 100mg Twice Per Day  | 68 DAY          | Glaxosmithkline |                |
| Bullous; Genital            | Escitalopram Oxalate |                    |                    | S               | Oral                         |                      | 68 DAY          | Unknown         |                |
| Ulceration; Mucosal         | Symbicort            |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
| Erosion; Nikolsky'S Sign;   |                      |                    |                    |                 |                              |                      |                 |                 |                |
| Prurigo; Rash Morbilliform; |                      |                    |                    |                 |                              |                      |                 |                 |                |
| Skin Lesion; Stevens-       |                      |                    |                    |                 |                              |                      |                 |                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Johnson Syndrome

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8120619       | EXPEDITED (15-DAY) | Y                  | DE, OT          | PL-TEVA-298803ISR    |                      | 69 YR      | Female     | POL            |

| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death; Embolism Venous | Sertraline Hydrochloride  |              |            | S           |              | 100 Milligram;     |                 | Not Reported |
|                        | Venlafaxine Hydrochloride |              |            | S           |              | 225 Milligram;     |                 | Not Reported |
|                        | Mirtazapine               |              |            | S           |              | 30 Milligram;      |                 | Not Reported |
|                        | Mirtazapine               |              |            | S           |              | 45 Milligram;      |                 | Not Reported |
|                        | Quetiapine                |              |            | S           |              | 100 Milligram;     |                 | Not Reported |
|                        | Quetiapine                |              |            | S           |              | 300 Milligram;     |                 | Not Reported |
|                        | Paroxetine Hydrochloride  |              |            | S           |              | 20 Milligram;      |                 | Not Reported |
|                        | Reboxetine                |              |            | S           |              | 4 Milligram;       |                 | Not Reported |
|                        | Escitalopram Oxalate      |              |            | S           |              | 20 Milligram;      |                 | Not Reported |
|                        | Olanzapine                |              |            | S           |              | 5 Milligram;       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8120916       | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-20110812827 |                      | 49 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Intentional Self-Injury;<br>Sluggishness | Topamax              |              |            | S           | Oral         | 6 Tablets          |                 | Not Reported |
|                                                                   | Escitalopram Oxalate |              |            | S           | Oral         | 8 Tablets          |                 | Not Reported |
|                                                                   | Seroquel             |              |            | S           | Oral         | 12 Tablets         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8121533       | EXPEDITED (15-DAY) | Y                  | HO, OT          | BE-JNJFOC-20110900932 |                      | 74 YR      | Female     | BEL            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Toxicity<br>To Various Agents | Risperidone    |              |            | S           | Oral         |                    |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |   |         |              |
|-------------------------|---|---------|--------------|
| Furosemide              | S | Unknown | Not Reported |
| Spironolactone          | S | Unknown | Not Reported |
| Escitalopram Oxalate    | S | Unknown | Not Reported |
| Levomepromazine         | S | Unknown | Not Reported |
| Lormetazepam            | C | Unknown | Not Reported |
| Metformin Hydrochloride | C | Unknown | Not Reported |
| Repaglinide             | C | Unknown | Not Reported |
| Dexetimide              | C | Unknown | Not Reported |
| Lisinopril              | S | Unknown | Not Reported |
| Lisinopril              | S | Unknown | Not Reported |
| Irbesartan              | S | Unknown | Not Reported |
| Lithium                 | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8122171       | EXPEDITED (15-DAY) | N                  | OT              | US-WATSON-2011-13519 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Depression; Tremor    | Fioricet                 |              |            | S           | Oral         | Unk                   |                 | Watson       |
|                       | Pristiq Extended Release |              |            | S           | Unknown      | Unk                   |                 | Not Reported |
|                       | Lexapro                  |              |            | S           | Unknown      | Unk                   |                 | Not Reported |
|                       | Cymbalta                 |              |            | S           | Unknown      | 4 Tabs In The Morning |                 | Not Reported |
|                       | Klonopin                 |              |            | S           | Unknown      | Unk                   |                 | Not Reported |
|                       | Reglan                   |              |            | S           | Unknown      | Unk                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Sep-2011              | 8122430       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR77439      |                      | 33 YR      | Male       | FRA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Spinal Cord Haematoma; Vomiting | Voltaren       |              |            | S           | Oral         | 1 Df, Qd           | 8 DAY           | Novartis     |
|                                 | Klipal         |              |            | S           |              | 1 Df, Tid          | 5 DAY           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |              |        |              |
|----------------------|---|------|--------------|--------|--------------|
| Thiocolchicoside     | S | Oral | Unk Unk, Unk | 8 DAY  | Not Reported |
| Dafalgan             | S |      | 1 Df, Tid    | 8 DAY  | Not Reported |
| Escitalopram Oxalate | S | Oral | 5 Mg, Unk    |        | Not Reported |
| Escitalopram Oxalate | S | Oral | 20 Mg, Daily | 35 DAY | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2011              | 8010787       | EXPEDITED (15-DAY) | Y                  | HO              | CH-MERCK-1106USA02371 |                      | 36 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                       | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|---------------------------------------|-------------------------------|-----------------|--------------|
| Coagulopathy; Cytarabine Syndrome; Hepatocellular Injury; Myalgia; Rash; Rhabdomyolysis; Serotonin Syndrome | Cancidas                     |              |            | S           | Unknown                               | Optimal Immunomodulating Dose | 6 DAY           | Merck        |
|                                                                                                             | Cipraxel                     |              |            | S           | Oral                                  | Optimal Immunomodulating Dose | 45 DAY          | Not Reported |
|                                                                                                             | Cipraxel                     |              |            | S           | Oral                                  | Optimal Immunomodulating Dose | 45 DAY          | Not Reported |
|                                                                                                             | Cytosar-U                    |              |            | S           | Intravenous (not otherwise specified) |                               | 6 DAY           | Not Reported |
|                                                                                                             | Idarubicin Hydrochloride     |              |            | S           | Intravenous (not otherwise specified) | Optimal Immunomodulating Dose | 3 DAY           | Not Reported |
|                                                                                                             | Famvir                       |              |            | S           | Unknown                               |                               | 8 DAY           | Not Reported |
|                                                                                                             | Meropenem                    |              |            | S           | Unknown                               |                               | 8 DAY           | Not Reported |
|                                                                                                             | Amsidyl                      |              |            | S           | Unknown                               |                               | 3 DAY           | Not Reported |
|                                                                                                             | Motilium                     |              |            | C           | Sublingual                            |                               | 10 DAY          | Not Reported |
|                                                                                                             | Motilium                     |              |            | C           | Sublingual                            |                               | 10 DAY          | Not Reported |
|                                                                                                             | Piperacillin And Tazobactam  |              |            | C           | Unknown                               |                               | 12 DAY          | Not Reported |
|                                                                                                             | Metoclopramide Hydrochloride |              |            | C           | Oral                                  |                               | 35 DAY          | Not Reported |
|                                                                                                             | Metoclopramide Hydrochloride |              |            | C           | Oral                                  |                               | 35 DAY          | Not Reported |
|                                                                                                             | Nexium                       |              |            | C           | Oral                                  | Optimal Immunomodulating Dose |                 | Not Reported |
|                                                                                                             | Nexium                       |              |            | C           | Oral                                  | Optimal Immunomodulating Dose |                 | Not Reported |

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|                       |   |         |                                         |              |
|-----------------------|---|---------|-----------------------------------------|--------------|
| Perfalgan             | C | Unknown | 50 DAY                                  | Not Reported |
| Buscopan              | C | Unknown | Optimal Immunomodulating Dose<br>50 DAY | Not Reported |
| Stilnox               | C | Unknown | Optimal Immunomodulating Dose<br>50 DAY | Not Reported |
| Norethindrone Acetate | C | Unknown |                                         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2011              | 8124279       | EXPEDITED (15-DAY) | Y                  | HO              | 1000022955           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Gastroduodenal Ulcer; Melaena; Oesophageal Ulcer | Escitalopram Oxalate                |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                  | Aspirin                             |              |            | S           | Oral         | 75 Mg (75 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                  | Voltaren                            |              |            | S           |              |                               | 2 WEEK          | Not Reported |
|                                                  | Dalacin (Clindamycin) (Clindamycin) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Sep-2011              | 8125058       | EXPEDITED (15-DAY) |                    | HO, LT          | FR-PFIZER INC-2011203843 |                      | 21 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress Syndrome; Dyspnoea; Eosinophilic Pneumonia | Xanax          |              |            | S           | Oral         |                    |                 | Pfizer       |
|                                                                       | Trinordiol     |              |            | S           | Oral         |                    |                 | Pfizer       |
|                                                                       | Escitalopram   |              |            | S           | Oral         | 10 Mg, 2x/Day      |                 | Not Reported |
|                                                                       | Depakote       |              |            | S           | Oral         | 750 Mg, 1x/Day     |                 | Not Reported |
|                                                                       | Stilnox        |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                       | Tardyferon     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Sep-2011              | 8145127       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023390           |                      | 49 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Deafness; Tinnitus                                                                                                                                                                                                                              | Escitalopram Oxalate     |                  |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Sep-2011                                                                                                                                                                                                                                     | 8749726                  | DIRECT           | Y                  |                 |                              |                                  | 16 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Dizziness; Emotional<br>Disorder; Erythema; Fall;<br>Flushing; Hyperhidrosis;<br>Insomnia; Nausea;<br>Overdose; Pyrexia;<br>Serotonin Syndrome;<br>Tremor                                                                 | Lexapro                  |                  |                    | S               | Oral                         | Qday Am                          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                        | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Sep-2011                                                                                                                                                                                                                                     | 8080087                  | NON-EXPEDITED    | N                  | OT              | US-PFIZER INC-<br>2011177274 |                                  | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                           | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Circumstance<br>Or Information Capable Of<br>Leading To Medication<br>Error; Diarrhoea;<br>Disturbance In Attention;<br>Faeces Discoloured;<br>Micturition Disorder;<br>Nervousness; Pain;<br>Personality Change;<br>Weight Decreased | Pristiq Extended Release |                  |                    | S               |                              | 50 Mg, 1x/Day                    | 15 DAY          | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Pristiq Extended Release |                  |                    | S               |                              |                                  |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                 | Fioricet                 |                  |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                                                                                                                                                                                                 | Cymbalta                 |                  |                    | S               |                              | 4 Tablets In The Morning         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                 | Cymbalta                 |                  |                    | S               |                              |                                  |                 | Not Reported |                |
| Cymbalta                                                                                                                                                                                                                                        |                          |                  | S                  |                 |                              |                                  | Not Reported    |              |                |
| Lexapro                                                                                                                                                                                                                                         |                          |                  | S                  |                 | Unk                          |                                  | Not Reported    |              |                |
| Lexapro                                                                                                                                                                                                                                         |                          |                  | S                  |                 |                              |                                  | Not Reported    |              |                |
| Klonopin                                                                                                                                                                                                                                        |                          |                  | C                  |                 | 0.5 Mg, As Needed            |                                  | Not Reported    |              |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                               |                                             |                    |                    |                 |                      |                               |                 |              |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| Estradiol                                                                                                                                                                                                                                                                                                     |                                             |                    | C                  |                 | 0.5 Mg               |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                      | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Sep-2011                                                                                                                                                                                                                                                                                                   | 8126842                                     | EXPEDITED (15-DAY) |                    | OT              | PHHY2011BR77449      |                               | 81 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                         | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Faeces Discoloured; Haematemesis; Haemorrhage; Pruritus; Ulcer                                                                                                                                                                                                                                   | Losartan Potassium                          |                    |                    | S               | Oral                 | 50 Mg, Unk                    |                 | Novartis     |                |
|                                                                                                                                                                                                                                                                                                               | Exelon                                      |                    |                    | S               |                      | 2 Mg, Unk                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Metformin Hydrochloride                     |                    |                    | S               |                      | 500 Mg, Unk                   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Memantine Hydrochloride                     |                    |                    | S               |                      | 10 Mg, Unk                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Lexapro                                     |                    |                    | S               |                      | 10 Mg, Unk                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Lipidil                                     |                    |                    | S               |                      | 200 Mg, Unk                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                      | <u>Case #</u>                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Sep-2011                                                                                                                                                                                                                                                                                                   | 8144919                                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000023429           |                               | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                         | <u>Product</u>                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain; Affective Disorder; Agitation; Anxiety; Asthenia; Blood Potassium Decreased; Blood Sodium Decreased; Cognitive Disorder; Crying; Haemoglobin Decreased; Hepatitis; Hepatitis Acute; Hypokalaemia; Logorrhoea; Memory Impairment; Mental Disorder; Microalbuminuria; Muscle Spasms; Tachypnoea | Escitalopram Oxalate                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Zolpidem Tartrate                           |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Bipreterax (Indapamide)                     |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Erbumine, Perindopril Erbumine)             |                    |                    |                 |                      |                               |                 |              |                |
|                                                                                                                                                                                                                                                                                                               | Inegy (Ezetimibe, Simvastatin)              |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Aspirin                                     |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Pantoprazole                                |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                               | Meteospasmyl (Alverine Citrate, Methionine) |                    |                    | C               |                      |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 09-Sep-2011                                                                                                 | 8008823                      | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-2011SE36772 |                      | 36 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coagulopathy; Cytarabine Syndrome; Hepatocellular Injury; Myalgia; Rash; Rhabdomyolysis; Serotonin Syndrome | Meropenem                    |                    |                    | S               | Intravenous drip           |                      |                 | Not Reported |                |
|                                                                                                             | Cipraxel                     |                    |                    | S               | Oral                       |                      | 45 DAY          | Not Reported |                |
|                                                                                                             | Cipraxel                     |                    |                    | S               | Oral                       |                      | 45 DAY          | Not Reported |                |
|                                                                                                             | Cytosar-U                    |                    |                    | S               | Intravenous drip           |                      | 6 DAY           | Not Reported |                |
|                                                                                                             | Idarubicin Hydrochloride     |                    |                    | S               | Intravenous drip           |                      | 3 DAY           | Not Reported |                |
|                                                                                                             | Amsidyl                      |                    |                    | S               | Intravenous drip           |                      |                 | Not Reported |                |
|                                                                                                             | Famvir                       |                    |                    | S               | Oral                       |                      | 8 DAY           | Not Reported |                |
|                                                                                                             | Cancidas                     |                    |                    | S               | Oral                       |                      | 6 DAY           | Not Reported |                |
|                                                                                                             | Motilium                     |                    |                    | C               | Sublingual                 |                      | 10 DAY          | Not Reported |                |
|                                                                                                             | Motilium                     |                    |                    | C               | Sublingual                 |                      | 10 DAY          | Not Reported |                |
|                                                                                                             | Piperacillin And Tazobactam  |                    |                    | C               |                            |                      | 12 DAY          | Not Reported |                |
|                                                                                                             | Metoclopramide Hydrochloride |                    |                    | C               | Oral                       |                      | 35 DAY          | Not Reported |                |
|                                                                                                             | Metoclopramide Hydrochloride |                    |                    | C               | Oral                       |                      | 35 DAY          | Not Reported |                |
|                                                                                                             | Nexium                       |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                             | Nexium                       |                    |                    | C               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                             | Perfalgan                    |                    |                    | C               | Intravenous bolus          |                      | 50 DAY          | Not Reported |                |
|                                                                                                             | Stilnox                      |                    |                    | C               | Oral                       |                      | 50 DAY          | Not Reported |                |
|                                                                                                             | Buscopan                     |                    |                    | C               | Oral                       |                      | 50 DAY          | Not Reported |                |
|                                                                                                             | Primolut N                   |                    |                    | C               | Oral                       | One Per Four Days    |                 | Not Reported |                |
|                                                                                                             | Dexamethasone                |                    |                    | C               | Oral                       |                      | 0 MTH           | Not Reported |                |
|                                                                                                             | Vfend                        |                    |                    | C               | Oral                       | One Per Two Days     | 9 DAY           | Not Reported |                |
|                                                                                                             | Flagyl                       |                    |                    | C               |                            |                      | 24 DAY          | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2011                                                                                                 | 8087096                      | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022484                 |                      | 33 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>               | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------------|-----------------------------------------------------------------------|-----------------|--------------|----------------|
| No Adverse Event                    | Lexapro                                                              |                    |                    | S               | Oral                               | 10 Mg (10 M, 1 In 1 D),<br>Oral; 10 Mg Bid (10 Mg, 2<br>In 1 D), Oral |                 | Not Reported |                |
|                                     | Loratadine (Loratadine)                                              |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
|                                     | Acetaminophen\Hydrocodone<br>Bitartrate                              |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
|                                     | Zanaflex (Tizanidine<br>Hydrochloride) (Tizanidine<br>Hydrochloride) |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
|                                     | Motrin                                                               |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
|                                     | Methocarbamol<br>(Methocarbamol)                                     |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
|                                     | (Methacarbamol)                                                      |                    |                    |                 |                                    |                                                                       |                 |              |                |
|                                     |                                                                      |                    |                    |                 |                                    |                                                                       |                 |              |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2011                         | 8087811                                                              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022540                         |                                                                       | 43 YR           | Female       | DNK            |
| <u>Preferred Term</u>               | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Vertigo;<br>Vomiting | Escitalopram Oxalate                                                 |                    |                    | S               | Oral                               | 1 Df (1 Dosage Forms, 1in<br>1 D), Oral                               |                 | Not Reported |                |
|                                     | Tegretol<br>(Carbamazepine)(Tablets)(Carb<br>amazepine)              |                    |                    | C               |                                    |                                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u>                                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Sep-2011                         | 8088804                                                              | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-<br>2011SA048936 |                                                                       | 89 YR           | Female       | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Vertigo                       | Furosemide                                                           |                    |                    | S               | Oral                               |                                                                       |                 | Not Reported |                |
|                                     | Isosorbide Dinitrate                                                 |                    |                    | S               | Oral                               |                                                                       |                 | Not Reported |                |
|                                     | Escitalopram Oxalate                                                 |                    |                    | S               | Oral                               |                                                                       |                 | Not Reported |                |
|                                     | Trimetazidine Dihydrochloride                                        |                    |                    | S               | Oral                               |                                                                       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                             |   |             |              |
|---------------------------------------------|---|-------------|--------------|
| Tramadol Hydrochloride                      | S | Oral        | Not Reported |
| Nitroderm                                   | S | Transdermal | Not Reported |
| Fenoterol Hydrobromide\Ipratropium Bromide  | C | Unknown     | Not Reported |
| Dafalgan                                    | C | Unknown     | Not Reported |
| Bromazepam                                  | C | Unknown     | Not Reported |
| Fluticasone Propionate\Salmeterol Xinafoate | C | Unknown     | Not Reported |
| Trimebutine                                 | C | Unknown     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Sep-2011              | 8144787       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000023211           |                      | 34 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Adverse Event; Akathisia; Anxiety; Balance Disorder; Brain Injury; Burning Sensation; Depression; Derealisation; Dizziness; Emotional Disorder; Fear; Feeling Abnormal; Food Intolerance; Hallucination; Hallucination, Visual; Headache; Hypersensitivity; Influenza; Influenza Like Illness; Insomnia; Mania; Memory Impairment; Nausea; Night Blindness; Nightmare; Panic Attack; Paraesthesia; Screaming; Serotonin Syndrome; Tachyphrenia; Tinnitus; Tremor; Unevaluable Event; Violence-Related Symptom; Visual Impairment; Vitamin A | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------|--------------------------|-----------------|--------------|----------------|
| 09-Sep-2011                                 | 8145503              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023474                    |                          | 21 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Menstrual Disorder;<br>Metrorrhagia; Nausea | Escitalopram Oxalate |                    |                    | S               |                               | 10 Mg (10 Mg, 1 In 1 D)  |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Sep-2011                                 | 8130123              | EXPEDITED (15-DAY) | Y                  | OT              | FR-JNJFOC-<br>20110901262     |                          | 87 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Miosis; Overdose;<br>Somnolence             | Durogesic            |                    |                    | S               | Transdermal                   |                          | 4 DAY           | Not Reported |                |
|                                             | Morphine Sulfate     |                    |                    | S               | Oral                          |                          | 4 DAY           | Not Reported |                |
|                                             | Morphine Sulfate     |                    |                    | S               | Oral                          |                          | 4 DAY           | Not Reported |                |
|                                             | Xanax                |                    |                    | S               | Oral                          |                          | 4 DAY           | Not Reported |                |
|                                             | Escitalopram Oxalate |                    |                    | S               | Oral                          |                          | 4 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2011                                 | 8134551              | EXPEDITED (15-DAY) | Y                  | HO              | FR-MYLANLABS-<br>2011S1018633 |                          | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                               | Amitriptyline        |                    |                    | S               | Unknown                       |                          |                 | Not Reported |                |
|                                             | Altizide             |                    |                    | S               | Unknown                       | Long Term                |                 | Not Reported |                |
|                                             | Escitalopram Oxalate |                    |                    | S               | Unknown                       |                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Sep-2011                                 | 8151999              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023637                    |                          | 25 YR           | Female       | DNK            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcohol Use; Loss Of                        | Lexapro              |                    |                    | S               | Oral                          | 10 Mg (10 Mg, 1 In 1 D), |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Consciousness

Oral

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------|-----------------|--------------|----------------|
| 13-Sep-2011                                                                                           | 8154138              | EXPEDITED (15-DAY) | Y                  | LT              | 1000023645           |                                                | 87 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Drug Interaction;<br>Miosis; Respiratory<br>Distress; Somnolence;<br>Toxicity To Various Agents | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral               |                 | Not Reported |                |
|                                                                                                       | Morphine Sulfate     |                    |                    | S               | Oral                 | 6 Df (1 Dosage Forms, 6<br>In 1 D), Oral       |                 | Not Reported |                |
|                                                                                                       | Durogesic            |                    |                    | S               |                      | 0.3333 Df (1 Dosage<br>Forms, 1 In 3 D), Other |                 | Not Reported |                |
|                                                                                                       | Xanax                |                    |                    | S               |                      | (1 Dosage Forms, 3 D)                          |                 | Not Reported |                |

| <u>FDA Received Date</u>                                          | <u>Case #</u>                                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------|----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| 13-Sep-2011                                                       | 8162872                                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000023640           |                                          | 99 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                             | <u>Product</u>                                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Creatine<br>Phosphokinase Increased;<br>Fall; Skin Abrasion | Escitalopram Oxalate                                     |                    |                    | S               |                      | 1 In 1 D                                 |                 | Not Reported |                |
|                                                                   | Aceprometazine\Meprobamate                               |                    |                    | S               | Oral                 | 1 Df (1 Dosage Forms, 1<br>In 1 D), Oral |                 | Not Reported |                |
|                                                                   | Cyamemazine                                              |                    |                    | S               | Oral                 | 6 Mg (6 Mg, 1 In 1 D), Oral              |                 | Not Reported |                |
|                                                                   | Doliprane (Paracetamol)<br>(Tablets) (Paracetamol)       |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                   | Ceris (Tropium Chloride)<br>(Tablets) (Tropium Chloride) |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                   | Lipanthyl (Fenofibrate)<br>(Fenofibrate)                 |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                                                   |                                                          |                    |                    |                 |                      |                                          |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 14-Sep-2011              | 8155434        | EXPEDITED (15-DAY) | Y                  | HO              | 1000023730           |                      |                 | Male       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Night Sweats; Pyrexia; Rash; Tremor      Lexapro      S      Oral      Oral      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Sep-2011              | 8046573       | EXPEDITED (15-DAY) | Y                  | HO              | 1000021902           |                      | 36 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                     | <u>Product</u>                                                                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                                                       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------|------------|-------------|---------------------------------------|--------------------------------------------------------------------------|-----------------|--------------|
| Aphasia; Apraxia; Coagulopathy; Confusional State; Coordination Abnormal; Cytarabine Syndrome; Dizziness; Febrile Neutropenia; Hepatic Enzyme Increased; Hepatocellular Injury; Hyperreflexia; International Normalised Ratio Decreased; Myalgia; Nausea; Nervous System Disorder; Rash; Rhabdomyolysis; Serotonin Syndrome; Sleep Disorder; Toxicity To Various Agents; Tremor; Vomiting | Escitalopram Oxalate                                                              |              |            | S           | Oral                                  | 10 Mg (10 Mg, 1 In 1 D), Oral                                            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Cytosar-U                                                                         |              |            | S           | Intravenous (not otherwise specified) | 2000 Mg/M2 (1000 Mg/M2, 2 In 1 D), Intravenous (Not Otherwise Specified) |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Idarubicin Hydrochloride                                                          |              |            | S           | Intravenous (not otherwise specified) | 2000 Mg/M2 (1000 Mg/M2, 2 In 1 D), Intravenous (Not Otherwise Specified) |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Amsidyl                                                                           |              |            | S           |                                       | 12 M/M2 (12 Mg/M2, 1 In 1 D), Intravenous (Not Otherwise Specified)      |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Famvir                                                                            |              |            | S           | Oral                                  | 120 Mg/M2 (120 Mg/M2, 1 In 1 D)                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Cancidas                                                                          |              |            | S           | Oral                                  | 1000 Mg (500 Mg, 2 In 1 D), Oral                                         |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Meropenem                                                                         |              |            | S           | Oral                                  | 70 Mg (70 Mg, 1 In 1 D), Oral                                            |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                   |              |            | S           | Intravenous (not otherwise specified) | 3 Gm (1 Gm, 3 In 1 D), Intravenous                                       |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Motilium (Domperidone) (Tablets) (Domperidone)                                    |              |            | C           |                                       |                                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Tazobac (Pip/Tazo)-(Pip/Tazo)                                                     |              |            | C           |                                       |                                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Paspertin (Metoclopramide Hydrochloride) (Tablets) (Metoclopramide Hydrochloride) |              |            | C           |                                       |                                                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                           | Nexium (Esomeprazole Magnesium) (Tablets) (Esomeprazole Magnesium)                |              |            | C           |                                       |                                                                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |   |              |
|----------------------------------------------------------|---|--------------|
| Perfalgan                                                | C | Not Reported |
| Stilnox (Zolpidem Tartrate)                              | C | Not Reported |
| (Zolpidem Tartrate)                                      |   |              |
| Buscopan (Hyoscine Butylbromide) (Hyoscine Butylbromide) | C | Not Reported |
| Primolut N (Norethisterone) (Norethisterone)             | C | Not Reported |
| Dexamethason (Dexamethasone) (Dexamethasone)             | C | Not Reported |
| Vfend                                                    | C | Not Reported |
| Flagyl (Metronidazole) (Metronidazole)                   | C | Not Reported |

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 15-Sep-2011                                                                                                      | 8056540                                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022065           |                               | 61 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                                                                        | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | Oral                          |                 | Not Reported |                |
|                                                                                                                  | Escitalopram Oxalate                   |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                  | Detensiel (Bisoprolol) (Bisoprolol)    |                    |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                  | Exforge (Diovan Amlol) (Diovain Amlol) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Sep-2011                                                                                                      | 8159960                                | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000023731           |                               |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anorgasmia; Decreased Appetite; Drug Withdrawal Syndrome; Nausea; Nocturnal Fear; Suicidal Ideation; Tachycardia | Escitalopram Oxalate                   |                    |                    | S               |                      |                               |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2011              | 8128866       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-JNJFOC-20110812898 |                      | 75 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                   | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Suicide Attempt; Toxicity<br>To Various Agents | Tramadol Hydrochloride            |              |            | S           | Oral         | 10 X 100 Mg                       |                 | Not Reported |
|                                                                         | Motilium                          |              |            | S           | Unknown      | 6 X 10 Mg                         |                 | Not Reported |
|                                                                         | Motilium                          |              |            | S           | Unknown      | 10 Mg Three Times A Day (1-1-1-0) |                 | Not Reported |
|                                                                         | Dafalgan                          |              |            | S           | Oral         | 1 G 4 Times A Day (1-1-1-1)       |                 | Not Reported |
|                                                                         | Dafalgan                          |              |            | S           | Oral         | 32 G                              |                 | Not Reported |
|                                                                         | Atenolol\Nifedipine               |              |            | S           | Unknown      | 50/25 Once A Day (1-0-0-0)        |                 | Not Reported |
|                                                                         | Atenolol\Nifedipine               |              |            | S           | Unknown      | 2 X 50/25                         |                 | Not Reported |
|                                                                         | Atorvastatin                      |              |            | S           | Unknown      | 2 X 20 Mg                         |                 | Not Reported |
|                                                                         | Atorvastatin                      |              |            | S           | Unknown      | 20 Mg Once A Day (0-0-1-0)        |                 | Not Reported |
|                                                                         | Levothyroxine Sodium              |              |            | S           | Unknown      | 0.1 Mg Once A Day (1-0-0-0)       |                 | Not Reported |
|                                                                         | Levothyroxine Sodium              |              |            | S           | Unknown      | 2 X 0.1 Mg                        |                 | Not Reported |
|                                                                         | Hydrochlorothiazide W/Irbesartan  |              |            | S           | Unknown      | 2 X 150/12.5                      |                 | Not Reported |
|                                                                         | Hydrochlorothiazide W/Irbesartan  |              |            | S           | Unknown      | 150/12.5 1/2 Per Day (1/2-0-0-0)  |                 | Not Reported |
|                                                                         | Calcium Carbonate\Cholecalciferol |              |            | S           | Unknown      | 4 Doses At A Time                 |                 | Not Reported |
|                                                                         | Calcium Carbonate\Cholecalciferol |              |            | S           | Unknown      | Twice A Day (1-1-0-0)             |                 | Not Reported |
|                                                                         | Remeron                           |              |            | S           | Unknown      | 15 Mg Once A Day (0-0-0-1)        |                 | Not Reported |
|                                                                         | Remeron                           |              |            | S           | Unknown      | 2 X 15 Mg                         |                 | Not Reported |
|                                                                         | Cipralex                          |              |            | S           | Unknown      | 2 X 20 Mg                         |                 | Not Reported |
|                                                                         | Cipralex                          |              |            | S           | Unknown      | 20 Mg (1-0-0-0)                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |         |                            |              |
|-----------|---|---------|----------------------------|--------------|
| Oxycontin | S | Unknown | 10 Mg (1-0-0-2)            | Not Reported |
| Oxycontin | S | Unknown | 2 * 30 Mg                  | Not Reported |
| Xarelto   | C | Oral    | 10 X 10 Mg                 | Not Reported |
| Xarelto   | C | Oral    | 10 Mg Once A Day (0-0-1-0) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2011              | 8133985       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000023159           |                      | 21 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                     | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Eosinophilic Pneumonia;<br>Rhinitis; Severe Acute<br>Respiratory Syndrome | Escitalopram Oxalate                    |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                           | Depakote                                |              |            | S           | Oral         | (750 Mg), Oral                   |                 | Not Reported |
|                                                                           | Zolpidem Tartrate                       |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)          |                 | Not Reported |
|                                                                           | Ferrous Sulfate                         |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                                                                           | Xanax                                   |              |            | S           | Oral         | Oral                             |                 | Not Reported |
|                                                                           | Levonorgestrel And Ethinyl<br>Estradiol |              |            | S           | Oral         | Oral                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Sep-2011              | 8144849       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000023431           |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                  | <u>Product</u>                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Aggression; Alcoholism;<br>Apathy; Condition<br>Aggravated; Depression;<br>Hallucination; Insomnia;<br>Mania; Nausea; Paranoia;<br>Sexually Inappropriate<br>Behaviour; Suicidal<br>Ideation; Vomiting | Escitalopram Oxalate                                    |              |            | S           | Oral         | Daily Dose Not Reported<br>(20 Mg), Oral |                 | Not Reported |
|                                                                                                                                                                                                        | Clonazepam (Clonazepam)<br>(Tablets) (Clonazepam)       |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                        | Cymbalta                                                |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                        | Topamax (Topiramate)<br>(Topiramate)                    |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                        | Lithium                                                 |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                        | Risperdal                                               |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                        | Pantoprazole (Pantoprazole)<br>(Tablets) (Pantoprazole) |              |            | C           |              |                                          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                    |                                                  |                    |                    |                 |                             |                                                                                     |                 |              |                |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|-----------------------------|-------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| Pms-Procyclidine (Procyclidine)                                                                                                    |                                                  |                    |                    | C               |                             |                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2011                                                                                                                        | 7201902                                          | EXPEDITED (15-DAY) | Y                  | HO              | 1000010156                  |                                                                                     | 85 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Anxiety; Confusional<br>State; Partial Seizures;<br>Seizure; Status<br>Epilepticus; Suicidal<br>Ideation | Escitalopram Oxalate                             |                    |                    | S               | Oral                        | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                                    |                 | Not Reported |                |
|                                                                                                                                    | Escitalopram Oxalate                             |                    |                    | S               | Oral                        | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                                    |                 | Not Reported |                |
|                                                                                                                                    | Exelon                                           |                    |                    | S               | Transdermal                 | 9.5 Mg (9.5 Mg, 1 In 24<br>Hr), Transdermal                                         |                 | Not Reported |                |
|                                                                                                                                    | Exelon                                           |                    |                    | S               | Transdermal                 | 4.5 Mg (4.5 Mg, 1 In 1 D),<br>Transdermal 4.6 Mg (4.6<br>Mg, 1 In 1 D), Transdermal |                 | Not Reported |                |
|                                                                                                                                    | Spironolactone                                   |                    |                    | C               |                             |                                                                                     |                 | Not Reported |                |
|                                                                                                                                    | Ginkor( Ginko Biloba, Troxirutin,<br>Heptaminol) |                    |                    | C               |                             |                                                                                     |                 | Not Reported |                |
|                                                                                                                                    | Meteospasmyl ( Alverine Citrate,<br>Simeticone)  |                    |                    | C               |                             |                                                                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2011                                                                                                                        | 8141289                                          | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-<br>47698 |                                                                                     | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                                                    | Hydrocodone Bitartrate And<br>Acetaminophen      |                    |                    | S               | Oral                        | Unk, Unk                                                                            |                 | Ranbaxy      |                |
|                                                                                                                                    | Escitalopram Oxalate                             |                    |                    | S               | Oral                        | Unk,Unk                                                                             |                 | Not Reported |                |
|                                                                                                                                    | Clonazepam                                       |                    |                    | S               | Oral                        | Unk, Unk                                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                           | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Sep-2011                                                                                                                        | 8141875                                          | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-<br>47816 |                                                                                     | 55 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                              | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                                          |   |      |          |  |              |
|-------------------|------------------------------------------|---|------|----------|--|--------------|
| Completed Suicide | Acetaminophen\Codeine Phosphate          | S | Oral | Unk, Unk |  | Ranbaxy      |
|                   | Hydrocodone Bitartrate And Acetaminophen | S | Oral | Unk      |  | Ranbaxy      |
|                   | Escitalopram Oxalate                     | S | Oral | Unk      |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 19-Sep-2011              | 8142240       | EXPEDITED (15-DAY) | Y                  | HO              | CH-JNJFOC-20110903406 |                      | 46 YR      | Female     | CHE            |

| <u>Preferred Term</u>                              | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Infarction;<br>Hypertensive Heart Disease | Invega                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                    | Pipamperone            |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                    | Antabuse               |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                    | Unspecified Ingredient |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                    | Cipraxel               |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Sep-2011              | 8144062       | DIRECT           | N                  | OT              |                      |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Blood Glucose Increased; Depression; Hypertension | Lexapro        |              |            | S           | Oral         | 10mg Or 5mg        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 21-Sep-2011              | 7969782       | EXPEDITED (15-DAY) | Y                  | HO              | CH-MERCK-1105USA03810 |                      | 20 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Metabolic Acidosis;<br>Suicide Attempt | Janumet        |              |            | S           | Oral         |                    | 1 DAY           | Merck        |
|                                                                 | Cipraxel       |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                                 | Amisulpride    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                 | Lorazepam      |              |            | C           | Unknown      |                    |                 | Not Reported |

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| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------|-----------------|--------------|----------------|
| 21-Sep-2011                                                                       | 8024804              | EXPEDITED (15-DAY) | Y                  | HO              | 1000021650                   |                                     | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Papilloedema; Visual Acuity Reduced                                               | Escitalopram Oxalate |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2011                                                                       | 8136179              | EXPEDITED (15-DAY) | Y                  | DE              | IT-ABBOTT-11P-083-0852392-00 |                                     | 64 YR           | Female       | ITA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Overdose                                                       | Depakene             |                    |                    | S               |                              | Overdose: Unknown                   |                 | Not Reported |                |
|                                                                                   | Ciprallex            |                    |                    | S               |                              | Overdose: Unknown                   |                 | Not Reported |                |
|                                                                                   | Mirtazapine          |                    |                    | S               |                              | Overdose: Unknown                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Sep-2011                                                                       | 8145608              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-47852      |                                     | 58 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                 | Lorazepam            |                    |                    | S               | Oral                         | Unk, Unk                            |                 | Ranbaxy      |                |
|                                                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                         | Unk, Unk                            |                 | Not Reported |                |
|                                                                                   | Valproic Acid        |                    |                    | S               | Oral                         | Unk, Unk                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2011                                                                       | 6766901              | NON-EXPEDITED      | Y                  | OT              | US-ASTRAZENECA-2006UW27731   |                                     | 55 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Diabetes Mellitus; Erectile Dysfunction; Haemoglobin | Seroquel             |                    |                    | S               | Oral                         | 25 Mg-200 Mg, 200 Mg 3 Pills A Day. |                 | Not Reported |                |
|                                                                                   | Seroquel             |                    |                    | S               | Oral                         | 25 Mg-200 Mg, 200 Mg 3              |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                              |                         |   |         |                                                        |         |              |
|----------------------------------------------------------------------------------------------|-------------------------|---|---------|--------------------------------------------------------|---------|--------------|
| Decreased;<br>Hypertriglyceridaemia;<br>Liver Function Test<br>Abnormal; Weight<br>Increased | Seroquel                | S | Oral    | Pills A Day.<br>25 Mg-200 Mg, 200 Mg 3<br>Pills A Day. |         | Not Reported |
|                                                                                              | Seroquel                | S | Oral    | 100 Mg-400 Mg                                          | 774 DAY | Not Reported |
|                                                                                              | Seroquel                | S | Oral    | 100 Mg-400 Mg                                          | 774 DAY | Not Reported |
|                                                                                              | Seroquel                | S | Oral    | 100 Mg-400 Mg                                          | 774 DAY | Not Reported |
|                                                                                              | Lexapro                 | S | Unknown |                                                        |         | Not Reported |
|                                                                                              | Geodon                  | C | Oral    |                                                        | 256 DAY | Not Reported |
|                                                                                              | Imipramine              | C | Oral    |                                                        | 4 MTH   | Not Reported |
|                                                                                              | Invega                  | C |         |                                                        | 9 MTH   | Not Reported |
|                                                                                              | Abilify                 | C |         |                                                        | 32 DAY  | Not Reported |
|                                                                                              | Neurontin               | C |         | 300 Mg- 1800 Mg                                        |         | Not Reported |
|                                                                                              | Vitamin E               | C |         |                                                        |         | Not Reported |
|                                                                                              | Clonazepam              | C |         |                                                        |         | Not Reported |
|                                                                                              | Nexium                  | C |         |                                                        |         | Not Reported |
|                                                                                              | Trazodone Hydrochloride | C |         |                                                        |         | Not Reported |
|                                                                                              | Paxil                   | C |         | 20 Mg-40 Mg                                            |         | Not Reported |
|                                                                                              | Remeron                 | C |         |                                                        |         | Not Reported |
|                                                                                              | Viagra                  | C |         |                                                        |         | Not Reported |
|                                                                                              | Niaspan                 | C |         |                                                        |         | Not Reported |
|                                                                                              | Ranitidine              | C |         |                                                        |         | Not Reported |
|                                                                                              | Lipitor                 | C |         |                                                        |         | Not Reported |
|                                                                                              | Androgel                | C |         |                                                        |         | Not Reported |
|                                                                                              | Ciprofloxacin           | C |         |                                                        |         | Not Reported |
|                                                                                              | Diovan                  | C |         |                                                        |         | Not Reported |
|                                                                                              | Avandamet               | C |         |                                                        |         | Not Reported |
|                                                                                              | Topamax                 | C |         |                                                        |         | Not Reported |
|                                                                                              | Protonix                | C | Oral    |                                                        |         | Not Reported |
|                                                                                              | Risperdal               | C | Oral    | 1 Mg - 3 Mg                                            |         | Not Reported |
|                                                                                              | Klonopin                | C |         | 2 Mg 1 Bid 1 And 1/2 Hs                                |         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8147310       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-48168 |                      | 30 YR      | Unknown    | USA            |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide                                                                   | Oxcarbazepine        |                  |                    | S               | Oral                       | Unk, Unk             |                 | Ranbaxy      |                |
|                                                                                     | Escitalopram Oxalate |                  |                    | S               | Oral                       | Unk, Unk             |                 | Not Reported |                |
|                                                                                     | Bupropion            |                  |                    | S               | Oral                       | Unk, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2011                                                                         | 8148323              | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2011SE09048 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Screen Positive                                                                | Seroquel             |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Lexapro              |                  |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2011                                                                         | 8149084              | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2011SE35740 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Decreased Appetite; Depression; Panic Attack; Phobia | Seroquel             |                  |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                     | Lexapro              |                  |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Sep-2011                                                                         | 8150101              | NON-EXPEDITED    | Y                  |                 | US-ASTRAZENECA-2011SE12408 |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Disorientation; Fatigue; Somnolence                              | Seroquel Xr          |                  |                    | S               | Oral                       |                      | 1 DAY           | Astrazeneca  |                |
|                                                                                     | Seroquel Xr          |                  |                    | S               | Oral                       |                      | 1 DAY           | Astrazeneca  |                |
|                                                                                     | Seroquel Xr          |                  |                    | S               | Oral                       |                      | 3 DAY           | Astrazeneca  |                |
|                                                                                     | Seroquel Xr          |                  |                    | S               | Oral                       |                      | 3 DAY           | Astrazeneca  |                |
|                                                                                     | Seroquel Xr          |                  |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                     | Seroquel Xr          |                  |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |

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|                         |   |               |                      |              |
|-------------------------|---|---------------|----------------------|--------------|
| Lexapro                 | S | Oral          | 1 DAY                | Not Reported |
| Lexapro                 | S | Oral          | 1 DAY                | Not Reported |
| Lexapro                 | S | Oral          |                      | Not Reported |
| Lexapro                 | S | Oral          |                      | Not Reported |
| Xanax                   | C | Oral          | Three Tablets A Day  | Not Reported |
| Adderall                | C | Oral          | Two Tablets A Day    | Not Reported |
| Vicodin Hp              | C | Oral          | 10/660mg As Required | Not Reported |
| Depo-Provera            | C | Intramuscular | One In Three Months  | Not Reported |
| Methadone Hydrochloride | C | Oral          |                      | Not Reported |
| Motrin                  | C | Oral          |                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8150707       | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2010SE57629 |                      | 79 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Dry Mouth; Dysuria; Vision Blurred | Seroquel             |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                  | Toviaz               |              |            | S           | Oral         |                    | 5 DAY           | Not Reported |
|                                                  | Xanax                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Zocor                |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Lexapro              |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Fish Oil             |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Acetylsalicylic Acid |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                                  | Vitamin D2           |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8150825       | NON-EXPEDITED    | N                  | OT              | US-ASTRAZENECA-2011SE41665 |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca     |
|                       | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca     |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |         |              |
|---------|---|---------|--------------|
| Ativan  | S | Unknown | Not Reported |
| Lexapro | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8150967       | NON-EXPEDITED    | N                  | OT              | US-ASTRAZENECA-2011SE06856 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Oedema Peripheral;<br>Overdose; Swelling Face | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                               | Miralax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Lexapro        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Topamax        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                               | Neurontin      |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8151387       | NON-EXPEDITED    |                    | HO              | US-ASTRAZENECA-2010SE59766 |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fatigue; Suicide Attempt | Seroquel Xr    |              |            | S           | Oral         |                    | 31 DAY          | Not Reported |
|                          | Lexapro        |              |            | S           | Unknown      |                    |                 | Not Reported |
|                          | Xanax          |              |            | S           | Unknown      |                    |                 | Not Reported |
|                          | Lisinopril     |              |            | C           | Oral         |                    |                 | Not Reported |
|                          | Cymbalta       |              |            | C           | Oral         |                    |                 | Not Reported |
|                          | Oxycodone      |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8151740       | NON-EXPEDITED    | N                  |                 | US-ASTRAZENECA-2010SE38417 |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Drug Interaction | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                           | Doxepin        |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |       |              |
|-------------|---|---------|-------|--------------|
| Vitamin B12 | C |         |       | Not Reported |
| Colace      | C |         |       | Not Reported |
| Simethicone | C |         |       | Not Reported |
| Lamictal    | C |         |       | Not Reported |
| Risperdal   | C |         |       | Not Reported |
| Gemfibrozil | C |         |       | Not Reported |
| Aciphex     | C |         |       | Not Reported |
| Lexapro     | S | Oral    | 4 DAY | Not Reported |
| Lexapro     | S | Oral    |       | Not Reported |
| Ativan      | S | Unknown |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Sep-2011              | 8157992       | DIRECT           | Y                  | CA, DS, HO      |                      |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bicuspid Aortic Valve;<br>Craniosynostosis;<br>Dilatation Ventricular;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |              |            | S           | Oral         | 10mg 1 Po Daily    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2011              | 7899008       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019311           |                      | 36 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Infertility Male; Miscarriage<br>Of Partner; Sperm<br>Concentration Decreased;<br>Spermatozoa Morphology<br>Abnormal; Spermatozoa<br>Progressive Motility<br>Decreased | Escitalopram Oxalate        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                        | Alprazolam (Alprazolam)     |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                        | Zopiclone (Zopiclone)       |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                        | Pravastatine (Pravastatine) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2011              | 8084511       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000022513           |                      | 70 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------|--------------------|-----------------|-------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| Pulmonary Hypertension                                                                           | Lexapro                                           |                    |                    | S               | Oral                    | 10 Mg (10 Mg, 1 In 1 D), Oral                              |                 | Not Reported |                |
|                                                                                                  | Simvastatin (Simvastatin) (Tablets) (Simvastatin) |                    |                    | C               |                         |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2011                                                                                      | 8153371                                           | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-48009 |                                                            | 41 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide                                                     | Zolpidem Tartrate                                 |                    |                    | S               | Oral                    | Unk,Unk                                                    |                 | Ranbaxy      |                |
|                                                                                                  | Atenolol                                          |                    |                    | S               | Oral                    | Unk,Unk                                                    |                 | Ipca         |                |
|                                                                                                  | Escitalopram Oxalate                              |                    |                    | S               | Oral                    | Unk, Unk                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2011                                                                                      | 8153434                                           | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-47954 |                                                            | 39 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                | Topiramate                                        |                    |                    | S               | Oral                    | Unk, Unk                                                   |                 | Ranbaxy      |                |
|                                                                                                  | Escitalopram Oxalate                              |                    |                    | S               | Oral                    | Unk, Unk                                                   |                 | Not Reported |                |
|                                                                                                  | Bupropion                                         |                    |                    | S               | Oral                    | Unk, Unk                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Sep-2011                                                                                      | 8170165                                           | EXPEDITED (15-DAY) | N                  | HO              | 1000024018              |                                                            | 90 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Diverticulitis; Fatigue; Gastrointestinal Haemorrhage; Haemoglobin Decreased; Poor Quality Sleep | Lexapro                                           |                    |                    | S               | Oral                    | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                  |                                                   |                    |                    |                 | Oral                    | 5 Mg (5 Mg, 1 In 1 D), Oral; 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                  |   |              |
|----------------------------------|---|--------------|
| Proscar                          | C | Not Reported |
| Ferrous Sulfate                  | C | Not Reported |
| Nexium (Esomeprazole)            | C | Not Reported |
| Stool Softener (Docusate Sodium) | C | Not Reported |
| Centrum Silver Multivitamin      | C | Not Reported |
| Lisinopril                       | C | Not Reported |
| Simvastatin                      | C | Not Reported |
| Norvasc                          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Sep-2011              | 8171029       | EXPEDITED (15-DAY) | Y                  | HO              | 1000023881           |                      | 48 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Coma; Intentional Overdose | Escitalopram Oxalate |              |            | S           | Oral         | Oral; 30 Dosage Forms, Once, Oral |                 | Not Reported |
|                            | Lorazepam            |              |            | S           | Oral         | Oral; Oral                        |                 | Not Reported |
|                            | Lorazepam            |              |            | S           | Oral         | Oral; Oral                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2011              | 8119449       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000023023           |                      | 42 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Alopecia; Arthropathy; Articular Calcification; Cholelithiasis; Decreased Appetite; Fatigue; Nephrolithiasis; Photosensitivity Reaction; Polymyalgia Rheumatica; Weight Increased | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2011              | 8155412       | EXPEDITED (15-DAY) | Y                  | HO              | DK-MYLANLABS-2011S1019438 |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                     |                      |   |              |              |
|-----------------------------------------------------------------------------------------------------|----------------------|---|--------------|--------------|
| Coma; Intentional Overdose; Respiratory Rate Decreased; Seizure; Sinus Bradycardia; Suicide Attempt | Escitalopram Oxalate | S | 160 Mg       | Not Reported |
|                                                                                                     | Baclofen             | S | 1850mg       | Not Reported |
|                                                                                                     | Baclofen             | S | 1850mg       | Not Reported |
|                                                                                                     | Baclofen             | S | Up To 2500mg | Not Reported |
|                                                                                                     | Baclofen             | S | Up To 2500mg | Not Reported |
|                                                                                                     | Mirtazapine          | S | 230 Mg       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2011              | 8155622       | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-AUR-APL-2009-00008 |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiogenic Shock;                                          | Citalopram           |              |            | S           |              |                    |                 | Not Reported |
| Cardiotoxicity; Coma;                                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Hypotension; Overdose;                                      | Quinapril Hcl        |              |            | S           |              |                    |                 | Pfizer       |
| Pulseless Electrical Activity; Respiratory Arrest; Seizure; | Venlafaxine Hcl      |              |            | S           |              |                    |                 | Pfizer       |
| Ventricular Arrhythmia;                                     | Atenolol             |              |            | S           |              |                    |                 | Not Reported |
| Ventricular Tachycardia                                     | Enalapril            |              |            | S           |              |                    |                 | Not Reported |
|                                                             | Amitriptyline        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Sep-2011              | 8171229       | EXPEDITED (15-DAY) | Y                  | HO              | IMP_05435_2011       |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------------------|-----------------|--------------|
| Coma Scale Abnormal; Continuous Haemodiafiltration; Hypotonia; Loss Of Consciousness; Miosis; Overdose; Respiratory Acidosis; Respiratory Depression; Seizure; Sinus Bradycardia; Snoring; Toxicity To Various Agents | Baclofen                  |              |            | S           |              | (1850 Mg, Once) ; (2500 Mg, Once)<br>(1850 Mg, Once) ; (2500 Mg, Once) |                 | Not Reported |
|                                                                                                                                                                                                                       | Mirtazapine (Mirtazapine) |              |            | S           |              | (230 Mg, Once)                                                         |                 | Not Reported |
|                                                                                                                                                                                                                       | Escitalopram Oxalate      |              |            | S           |              | (160 Mg, Once)                                                         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 26-Sep-2011                                                                                                 | 8171488                                            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023962           |                                 |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Dependent Personality Disorder; Depressed Mood; Hyperventilation; Listless; Panic Attack; Suicidal Ideation | Lexapro                                            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                             | Mirtazapine                                        |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Sep-2011                                                                                                 | 8171491                                            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023900           |                                 | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Ecchymosis; Haemorrhage                                                                   | Escitalopram Oxalate                               |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                             | Escitalopram Oxalate                               |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral     |                 | Not Reported |                |
|                                                                                                             | Aspirin                                            |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                             | Rivotril (Clonazepam) (Clonazepam)                 |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                             | Losartan (Losartan Potassium) (Losartan Potassium) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                             | Levothyroxine Sodium                               |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                             | Lacipil (Lacidipine) (Lacidipine)                  |                    |                    | C               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Sep-2011                                                                                                 | 8008831                                            | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000021418           |                                 | 20 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Lactic Acid Increased; Continuous Haemodiafiltration; Intentional Overdose; Metabolic Acidosis;       | Escitalopram Oxalate                               |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                             | Janumet                                            |                    |                    | S               | Oral                 | Overdose: 180 Tabs Once, Oral   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                            |   |              |
|---------------------------|----------------------------|---|--------------|
| Suicide Attempt; Vomiting | Solian                     | C | Not Reported |
|                           | (Amisulpride)(Amisulpride) |   |              |
|                           | Temesta                    | C | Not Reported |
|                           | (Lorazepam)(Lorazepam)     |   |              |

| <u>FDA Received Date</u>                             | <u>Case #</u>                                                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 27-Sep-2011                                          | 8137119                                                                      | EXPEDITED (15-DAY) | Y                  | HO              | 1000023270           |                             | 91 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>                                                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| General Physical Health Deterioration; Hyponatraemia | Escitalopram Oxalate                                                         |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                      | Coaprovel (Irbesartan, Hydrochlorothiazide)(Irbesartan, Hydrochlorothiazide) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                      | Lercan (Lercanidipine Hydrochloride) (Lercanidipine Hydrochloride)           |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                      | Xanax                                                                        |                    |                    | C               |                      |                             |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|-----------------------------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 27-Sep-2011              | 8158152                                       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2011224017 |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Penicillin G Benzathine/Penicillin G Procaine |                  |                    | S               |                          | Unk                  |                 | Unknown      |                |
|                          | Dilantin                                      |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Ibuprofen                                     |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Lidocaine Hcl                                 |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Baclofen                                      |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Acetylsalicylic Acid                          |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro                                       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Toradol                                       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Sep-2011              | 8161270       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2011-05010   |                      | 64 YR      | Female     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide; Drug Level Increased; Intentional Overdose; Toxicologic Test Abnormal | Mirtazapine (Mirtazapine) |                    |                    | S               |                                | (30 Mg)              |                 | Not Reported |                |
|                                                                                          | Escitalopram Oxalate      |                    |                    | S               |                                | (10 Mg)              |                 | Not Reported |                |
|                                                                                          | Valproic Acid             |                    |                    | S               |                                | (300 Mg)             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                 | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Sep-2011                                                                              | 8160542                   | EXPEDITED (15-DAY) | Y                  | DE, OT          | FR-SANOFI-AVENTIS-2011SA058947 |                      |                 | Unknown      | FRA            |
| <u>Preferred Term</u>                                                                    | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                            | Irbesartan                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Citalopram                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Amitriptyline             |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Pantoprazole              |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Telmisartan               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Mirtazapine               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Hydrochlorothiazide       |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Tramadol Hydrochloride    |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Gliclazide                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Risperidone               |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Paclitaxel                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Amlodipine                |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Nitrendipine              |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Etoposide                 |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Chlorpromazine            |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Metopimazine              |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Spironolactone            |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Glyceril Trinitrate       |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Acebutolol Hydrochloride  |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |
|                                                                                          | Losartan Potassium        |                    |                    | S               | Unknown                        |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                          |   |         |              |
|--------------------------|---|---------|--------------|
| Carbamazepine            | S | Unknown | Not Reported |
| Furosemide               | S | Unknown | Not Reported |
| Sertraline Hydrochloride | S | Unknown | Not Reported |
| Paroxetine Hydrochloride | S | Unknown | Not Reported |
| Escitalopram Oxalate     | S | Unknown | Not Reported |
| Fluoxetine               | S | Unknown | Not Reported |
| Omeprazole               | S | Unknown | Not Reported |
| Oxcarbazepine            | S | Unknown | Not Reported |
| Indapamide               | S | Unknown | Not Reported |
| Rabeprazole Sodium       | S | Unknown | Not Reported |
| Desmopressin Acetate     | S | Unknown | Not Reported |
| Ramipril                 | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Sep-2011              | 8170879       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024146           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2011              | 8162343       | EXPEDITED (15-DAY) | N                  | OT              | GXBR2011US04775      |                      | 90 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthritis; Intervertebral Disc Compression;                                 | Loratadine     |              |            | S           | Oral         | 10 Mg, Qd          |                 | Novartis     |
| Intervertebral Disc Disorder; Transient Ischaemic Attack; Vitreous Floaters | Lexapro        |              |            | S           |              | 5 Mg, Unk          |                 | Not Reported |
|                                                                             | Lexapro        |              |            | S           |              | 10 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Sep-2011              | 8176244       | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2009-00008   |                      | 65 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Anoxia; Balance Disorder;<br>Bradycardia; Cardiac<br>Arrest; Cardiogenic Shock;<br>Cardiotoxicity; Coma;<br>Confusional State;<br>General Physical Health<br>Deterioration;<br>Hypotension; Ischaemia;<br>Left Ventricular<br>Hypertrophy; Overdose;<br>Poor Peripheral<br>Circulation; Pulmonary<br>Embolism; Pulseless<br>Electrical Activity;<br>Respiratory Arrest;<br>Rhythm Idioventricular;<br>Seizure; Urine Output<br>Decreased; Ventricular<br>Tachycardia | Atenolol (Atenolol)         |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Citalopram Hydrobromide     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Venlafaxine                 |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Enalapril                   |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Amitriptyline Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Quinapril Hydrochloride     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Escitalopram Oxalate        |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                             |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                             |                    |                    |                 |                      |                      |                 |              |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                             |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                                                                                                                                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Sep-2011                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 8176590                     | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2009-00147   |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Bradycardia; Cardiac<br>Arrest; Cardiogenic Shock;<br>Coma; Confusional State;<br>Hypotension; Hypoxic-<br>Ischaemic<br>Encephalopathy;<br>Mydriasis; Overdose;<br>Pulseless Electrical<br>Activity; Respiratory<br>Arrest; Rhythm<br>Idioventricular; Seizure;<br>Toxicity To Various<br>Agents; Unresponsive To                                                                                                                               | Atenolol (Atenolol)         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Citalopram Hydrobromide     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Venlafaxine                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Enalapril                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Amitriptyline Hydrochloride |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Quinapril Hydrochloride     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Escitalopram Oxalate        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Stimuli; Ventricular  
Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2011              | 8170974       | DIRECT           | Y                  | CA, DS, HO      |                      |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Bicuspid Aortic Valve;<br>Craniosynostosis; Left<br>Ventricular Hypertrophy;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |              |            | S           | Oral         | Lexapro 10mg 1 Po Daily<br>2004 Or 5 - 2009 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Sep-2011              | 8748963       | DIRECT           | N                  | DE, OT          |                      |                      | 35 DAY     | Female     | USA            |

| <u>Preferred Term</u>                                               | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|---------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------------------|
| Maternal Drugs Affecting<br>Foetus; Sudden Infant<br>Death Syndrome | Lexapro<br>Lamictal |              |            | S<br>C      |              |                    |                 | Forest<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2011              | 8166053       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-<br>2011SE57655 |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Fall;<br>Hyponatraemia | Inexium                                     |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                        | Inexium                                     |              |            | S           | Oral         |                    |                 | Astrazeneca  |
|                                        | Escitalopram Oxalate                        |              |            | S           | Oral         |                    | 12 DAY          | Not Reported |
|                                        | Zolpidem                                    |              |            | S           | Oral         |                    | 12 DAY          | Not Reported |
|                                        | Prazepam                                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Prazepam                                    |              |            | S           | Oral         |                    | 12 DAY          | Not Reported |
|                                        | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |      |  |  |  |  |              |
|--|----------|---|------|--|--|--|--|--------------|
|  | Gaviscon | S | Oral |  |  |  |  | Not Reported |
|  | Debridat | C |      |  |  |  |  | Not Reported |
|  | Spiriva  | C |      |  |  |  |  | Not Reported |
|  | Becotide | C |      |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Oct-2011              | 8749569       | DIRECT           | Y                  | HO, LT          |                      |                      | 71 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Hyponatraemia; Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Every Morning Po |                 | Not Reported |
|                        | Valproate Sodium     |              |            | S           | Oral         | 500 Mg Tid Po          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2011              | 8060637       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000022127           |                      | 34 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abnormal Dreams;<br>Aggression; Anxiety;<br>Dyspnoea; Epilepsy;<br>Muscle Rigidity; Mydriasis;<br>Trismus | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg(10 Mg, 1 In 1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Oct-2011              | 8166466       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023779           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                  | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------|-----------------|--------------|
| Drug Ineffective;<br>Overdose; Panic Attack | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D);<br>30 Mg (30 Mg, 1 In 1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2011              | 8182639       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024244           |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                              |                                                      |   |      |                                                           |              |
|------------------------------------------------------------------------------|------------------------------------------------------|---|------|-----------------------------------------------------------|--------------|
| Depression; Drug Interaction; Fatigue; Fungal Infection; Mania; Palpitations | Lexapro                                              | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral                               | Not Reported |
|                                                                              | Lexapro                                              | S | Oral | 20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral | Not Reported |
|                                                                              |                                                      |   | Oral | 20 Mg (20 Mg,1 In 1 D),Oral ; 10 Mg (10 Mg,1 In 1 D),Oral |              |
|                                                                              | Fluconazole                                          | S | Oral | Daily (1 In 1 D),Oral                                     | Not Reported |
|                                                                              | Deplin (Calcium Levomefolate) (Calcium Levomefolate) | C |      |                                                           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2011              | 8184248       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024313           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                             | <u>Product</u>                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|-------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Hypokalaemia; Hypomagnesaemia; Torsade De Pointes | Escitalopram Oxalate                                                                |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                   | Methadone Hydrochloride                                                             |              |            | S           |              | 180 Mg                        |                 | Not Reported |
|                                                   | Quetiapine Fumarate                                                                 |              |            | S           | Oral         | 50 Mg, Oral                   |                 | Not Reported |
|                                                   | Creon                                                                               |              |            | C           |              |                               |                 | Not Reported |
|                                                   | Esomeprazole Magnesium Trihydrate (Esomeprazole Magnesium) (Esomeprazole Magnesium) |              |            | C           |              |                               |                 | Not Reported |
|                                                   | Vitaminorum B.P.C. (Kapsovit) (Kapsovit)                                            |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Oct-2011              | 8184283       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024341           |                      | 74 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                 | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Circulatory Collapse; Contusion; Electrocardiogram Qt Prolonged; Fall | Lexapro             |              |            | S           |              | 10 Mg (1 Time)      |                 | Not Reported |
|                                                                       | Atenolol (Atenolol) |              |            | S           | Oral         | 50 Mg (1 Time),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Aspirin                                                                                                                     |                         | S                  |                    | 150 Mg (1 Time) |                              | Not Reported                                                       |                 |              |                |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------------------------------|-----------------|--------------|----------------|
| Atorvastatin Calcium                                                                                                        |                         | S                  |                    |                 |                              | Not Reported                                                       |                 |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2011                                                                                                                 | 6994733                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000005980                   |                                                                    | 7 YR            | Male         | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Aggression; Completed<br>Suicide; Impulsive<br>Behaviour                                             | Lexapro                 |                    |                    | S               | Oral                         | 5 Mg (5 Mg, 1 In 1 D), Oral                                        |                 | Not Reported |                |
|                                                                                                                             | Symbyax                 |                    |                    | S               |                              | 3mg/25mg (1 In 1 D),                                               |                 | Not Reported |                |
|                                                                                                                             | Vyvanse                 |                    |                    | S               | Oral                         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1<br>D), Oral |                 | Not Reported |                |
|                                                                                                                             |                         |                    |                    |                 | Oral                         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral; 50 Mg (50 Mg, 1 In 1<br>D), Oral |                 |              |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2011                                                                                                                 | 8170476                 | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | AT-PFIZER INC-<br>2011234765 |                                                                    | 30 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Triglycerides<br>Increased; Depression;<br>Gambling Disorder; Post-<br>Traumatic Stress Disorder;<br>Weight Increased | Effexor Xr              |                    |                    | S               | Oral                         | 225 Mg, 1x/Day                                                     |                 | Pfizer       |                |
|                                                                                                                             | Ciprallex               |                    |                    | S               | Oral                         | 20 Mg, 1x/Day                                                      |                 | Not Reported |                |
|                                                                                                                             | Seroquel                |                    |                    | S               | Oral                         | 50 Mg, 1x/Day                                                      |                 | Not Reported |                |
|                                                                                                                             | Prothipendyl            |                    |                    | S               | Oral                         | 80 Mg, 1x/Day                                                      |                 | Not Reported |                |
|                                                                                                                             | Abilify                 |                    |                    | C               | Oral                         | 5 Mg, 1x/Day                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                                               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Oct-2011                                                                                                                 | 8170659                 | EXPEDITED (15-DAY) | Y                  | OT              | GXKR2011DE02966              |                                                                    |                 | Unknown      | DEU            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Missed; Maternal<br>Exposure During<br>Pregnancy                                                                   | Trazodone Hydrochloride |                    |                    | S               | Oral                         | 12.5 Mg/Day                                                        |                 | Novartis     |                |
|                                                                                                                             | Ciprallex               |                    |                    | S               | Oral                         | 5 Mg/Day                                                           |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |              |              |
|----------------------|---|------|--------------|--------------|
| Folic Acid           | C | Oral | 0.8 Mg/Day   | Not Reported |
| Levothyroxine Sodium | C | Oral | 137.5 Mg/Day | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2011              | 8184729       | EXPEDITED (15-DAY) | Y                  | DE              | 1000024359           |                      | 81 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                     | <u>Product</u>                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                 | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------------------------|-----------------|--------------|
| Cerebellar Haematoma;<br>Depressed Level Of<br>Consciousness;<br>Hemiplegia; Hypertension | Escitalopram Oxalate                                                  |              |            | S           |              |                                                    |                 | Not Reported |
|                                                                                           | Coumadin                                                              |              |            | S           | Oral         | 0.5 Df In Morning And 0.25<br>Df Alternately, Oral |                 | Not Reported |
|                                                                                           | Ciprofibrate                                                          |              |            | S           |              |                                                    |                 | Not Reported |
|                                                                                           | Digoxin                                                               |              |            | S           |              |                                                    |                 | Not Reported |
|                                                                                           | Cardensiel (Bisoprolol<br>Fumarate) (Bisoprolol Fumarate)             |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Stablon (Tianeptine Sodium)<br>(Tianeptine Sodium)                    |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Monotildiem (Diltiazem<br>Hydrochloride) (Diltiazem<br>Hydrochloride) |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Modopar (Madopar) (Madopar)                                           |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Diffu K (Potassium Chloride)<br>(Potassium Chloride)                  |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Exelon (Rivastigmine)<br>(Rivastigmine)                               |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Lioresal                                                              |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Mepronizine (Clindorm)<br>(Clindorm)                                  |              |            | C           |              |                                                    |                 | Not Reported |
|                                                                                           | Mianserine (Mianserin<br>Hydrochloride) (Mianserin<br>Hydrochloride)  |              |            | C           |              |                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Oct-2011              | 8184866       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024338           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Hepatitis; Hepatitis  | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|----------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 06-Oct-2011                                                                | 8187484                 | EXPEDITED (15-DAY) | Y                  | OT              | 2011AP002179                             |                      | 55 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Cough;                                                                     | Citalopram Hydrobromide |                    |                    | S               |                                          | 10 Mg;Am;            |                 | Not Reported         |                |
| Gastroesophageal Reflux Disease; Headache;                                 | Escitalopram Oxalate    |                    |                    | S               |                                          | 10 Mg;Am             |                 | Not Reported         |                |
| Nausea; Salivary Hypersecretion                                            | Vitamins With Minerals  |                    |                    | C               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Oct-2011                                                                | 7596043                 | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000016080                               |                      |                 | Female               | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction; Feeling Abnormal; Joint Lock;                            | Lexapro                 |                    |                    | S               | Oral                                     | Oral                 |                 | Not Reported         |                |
| Serotonin Syndrome                                                         | Zoloft                  |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                            | Wellbutrin              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Oct-2011                                                                | 8160545                 | EXPEDITED (15-DAY) | Y                  |                 | US-PURDUE-USA-2010-0048602               |                      | 49 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Anxiety; Energy Increased; Inadequate Analgesia; Product Formulation Issue | Oxycontin               |                    |                    | S               |                                          | 80 Mg, Q8h           |                 | Purdue               |                |
|                                                                            | Lexapro                 |                    |                    | S               | Oral                                     | 10 Mg, Unk           | 11 DAY          | Not Reported         |                |
|                                                                            | Zoloft                  |                    |                    | S               | Oral                                     | 100 Mg, Unk          | 38 DAY          | Not Reported         |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 07-Oct-2011                                                                | 8172266                 | EXPEDITED (15-DAY) | N                  | DE, HO          | FR-BRISTOL-MYERS SQUIBB COMPANY-16099350 |                      | 81 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Altered State Of Consciousness; Blood                                      | Coumadin                |                    |                    | S               |                                          | Coumadine 2 Mg, 0.5  |                 | Bristol Myers Squibb |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pressure Increased;  
Cerebellar Haematoma;  
Hemiplegia

Tablet Alternating With  
0.25 Tablet Each Morning  
For Several Months

|                      |   |      |              |
|----------------------|---|------|--------------|
| Escitalopram Oxalate | S | Oral | Not Reported |
| Ciprofibrate         | S | Oral | Not Reported |
| Digoxin              | S | Oral | Not Reported |
| Mono-Tildiem         | C |      | Not Reported |
| Bisoprolol Fumarate  | C |      | Not Reported |
| Tianeptine           | C |      | Not Reported |
| Modopar              | C |      | Not Reported |
| Potassium Chloride   | C |      | Not Reported |
| Exelon               | C |      | Not Reported |
| Lioresal             | C |      | Not Reported |
| Meprobamate          | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Oct-2011              | 8186287       | EXPEDITED (15-DAY) | N                  | CA              | 1000024402           |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Cardiac Murmur; Maternal<br>Drugs Affecting Foetus;<br>Patent Ductus Arteriosus;<br>Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Oct-2011              | 8173663       | EXPEDITED (15-DAY) | Y                  | HO, OT          | AT-PFIZER INC-<br>2011235925 |                      | 69 YR      | Female     | AUT            |

| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Delirium; Depression; Fall;<br>Generalised Anxiety<br>Disorder | Lyrica                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                | Cipralext               |              |            | S           |              | 10-20 Mg Daily     | 36 DAY          | Not Reported |
|                                                                | Trazodone Hydrochloride |              |            | S           |              | 100-150 Mg Daily   | 34 DAY          | Not Reported |
|                                                                | Oxazepam                |              |            | S           |              | 45-75 Mg Daily     |                 | Not Reported |
|                                                                | Mirtazapine             |              |            | S           |              | 15mg Daily         | 2 DAY           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |             |       |              |
|-------------|---|-------------|-------|--------------|
| Mirtazapine | S | 30 Mg, Unk  | 7 DAY | Not Reported |
| Tenormin    | C | 50 Mg Daily |       | Not Reported |
| Pantoloc    | C | 40 Mg, Unk  |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 7583384       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000015970           |                      | 39 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Depressed Mood;<br>Disturbance In Attention;<br>Drooling; Fatigue; Feeling<br>Of Despair; Feelings Of<br>Worthlessness;<br>Headache; Ischaemic<br>Stroke; Speech Disorder;<br>Supranuclear Palsy | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                  | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                                                                                                                                                                                  | Clonazepam           |              |            | C           |              |                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 7877888       | EXPEDITED (15-DAY) | Y                  | DE              | 1000019122           |                      | < 1 DAY    | Female     | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------------------------|-----------------|--------------|
| Foetal Death; Maternal<br>Drugs Affecting Foetus | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D)<br>Transplacental |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8168839       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20111000795 |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                  | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Fall;<br>Hyponatraemia | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Escitalopram Oxalate                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Zolpidem                                    |              |            | S           | Oral         |                    |                 | Not Reported |
|                                        | Prazepam                                    |              |            | S           | Oral         |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |   |         |              |
|----------|---|---------|--------------|
| Prazepam | S | Oral    | Not Reported |
| Inexium  | S | Oral    | Not Reported |
| Inexium  | S | Oral    | Not Reported |
| Gaviscon | S | Oral    | Not Reported |
| Gaviscon | S | Oral    | Not Reported |
| Debridat | C | Unknown | Not Reported |
| Spiriva  | C | Unknown | Not Reported |
| Becotide | C | Unknown | Not Reported |

| <u>FDA Received Date</u>                                                                                           | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                           | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|-----------------------|-------------------------------------------------|----------------------|-----------------|--------------------------------------------------------------------------------------|----------------|
| 11-Oct-2011                                                                                                        | 8175876                                                        | EXPEDITED (15-DAY) | N                  | HO                    | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16114514 |                      | 63 YR           | Female                                                                               | USA            |
| <u>Preferred Term</u>                                                                                              | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                           |                |
| Abdominal Pain Upper;<br>Blood Glucose Increased;<br>Fall; Hallucination;<br>Musculoskeletal Chest<br>Pain; Nausea | Glucophage<br>Lexapro<br>Wellbutrin<br>Xanax<br>Fentanyl Patch |                    |                    | S<br>S<br>C<br>C<br>C |                                                 |                      | 4 YR            | Bristol Myers Squibb<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |                |
|                                                                                                                    |                                                                |                    |                    |                       |                                                 | Started 5yrs Ago     |                 |                                                                                      |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>                                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|------------------------------------------------------------------|------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------|-----------------|----------------------------------------|----------------|
| 11-Oct-2011                                                      | 8176229                                                    | EXPEDITED (15-DAY) |                    | HO, OT          | TR-PFIZER INC-<br>2011235597 |                              | 53 YR           | Male                                   | TUR            |
| <u>Preferred Term</u>                                            | <u>Product</u>                                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>                             |                |
| Deep Vein Thrombosis;<br>Major Depression; Suicidal<br>Behaviour | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Alprazolam |                    |                    | S<br>S<br>S     |                              | 10 Mg, A Day<br>20 Mg, A Day |                 | Not Reported<br>Not Reported<br>Pfizer |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|------------|----------------|
| 11-Oct-2011              | 8176399        | EXPEDITED (15-DAY) | Y                  | DE              | TR-ASTRAZENECA-<br>2011SE60399 |                      | 50 YR           | Female     | TUR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                 |           |   |         |              |
|-----------------|-----------|---|---------|--------------|
| Hepatic Failure | Arimidex  | S | Oral    | Zeneca       |
|                 | Nexium    | S | Oral    | Not Reported |
|                 | Ciprallex | S | Unknown | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8189188       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024478           |                      | 45 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                              | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Confusional State;<br>Hepatitis; Incorrect Dose<br>Administered; Pneumonia<br>Aspiration; Prothrombin<br>Time Prolonged;<br>Psychomotor Retardation;<br>Somnolence | Escitalopram Oxalate                     |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D)<br>Oral                                    |                 | Not Reported |
|                                                                                                                                                                    | Cyamemazine                              |              |            | S           | Oral         | 100 Mg (25 Mg, 4 In 1 D),<br>One Intake Of 105 Df, Oral            |                 | Not Reported |
|                                                                                                                                                                    | Bromazepam                               |              |            | S           | Oral         | 2 Df (0.5 Dosage Forms, 4<br>In 1 D), One Intake Of 30<br>Df, Oral |                 | Not Reported |
|                                                                                                                                                                    | Subutex (Buprenorphine<br>Hydrochloride) |              |            | C           |              |                                                                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8189238       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024472           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Condition Aggravated;<br>Memory Impairment | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8190109       | EXPEDITED (15-DAY) | Y                  | OT              | DSA_47766_2011       |                      | 32 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Abdominal Discomfort;<br>Fear; Impaired Work<br>Ability; Loss Of Personal<br>Independence In Daily | Venlafaxine    |              |            | S           |              | (75 Mg Daily),(150 Mg<br>Daily), (75 Mg Daily), (150<br>Mg Daily) | 1 MTH           | Not Reported |
|                                                                                                    |                |              |            |             |              | (75 Mg Daily),(150 Mg                                             | 6 WEEK          |              |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Activities; Nausea;  
Persecutory Delusion

Escitalopram Oxalate  
Clonazepam  
Olanzapine

S  
C  
C

Daily), (75 Mg Daily), (150  
Mg Daily)  
(10 Mg Qd, (10 Mg Qd)

Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8192663       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024439           |                      | 49 YR      | Female     | DNK            |

| <u>Preferred Term</u>          | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|-------------------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|--------------|
| Aphasia; Cerebral<br>Haematoma | Escitalopram Oxalate          |              |            | S           | Oral         | 1 Df (1 Dosage Forms,1 In<br>1 D),Oral |                 | Not Reported |
|                                | Abilify                       |              |            | S           | Oral         | 1 Df (1 Dosage Forms,1 In<br>1 D),Oral |                 | Not Reported |
|                                | Trihexyphenidyl Hydrochloride |              |            | S           | Oral         | 1 Df (1 Dosage Forms,1 In<br>1 D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Oct-2011              | 8192869       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024407           |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Speech Disorder       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |
|                       | Xanax                |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Oct-2011              | 8176671       | EXPEDITED (15-DAY) | Y                  | HO              | US-JNJFOC-<br>20111003969 |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                         | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Drug<br>Screen False Positive;<br>Intentional Overdose;<br>Partial Seizures;<br>Tachycardia | Tramadol Hydrochloride |              |            | S           | Oral         | 600-800 Mg Daily   |                 | Not Reported |
|                                                                                                               | Naproxen               |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                               | Omeprazole             |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                    |                           |                    |                    |                 |                                                 |                                        |                 |              |                |
|--------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                               |                           |                    |                    | S               | Unknown                                         |                                        |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Oct-2011                                                        | 8177036                   | EXPEDITED (15-DAY) | N                  | HO, OT          | AT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16151151 |                                        | 30 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Eating Disorder; Weight Increased                                  | Abilify                   |                    |                    | S               |                                                 | Also 10mg On Feb2011(Dose Not Changed) |                 | Not Reported |                |
|                                                                    | Venlafaxine Hydrochloride |                    |                    | S               |                                                 |                                        |                 | Not Reported |                |
|                                                                    | Seroquel                  |                    |                    | S               |                                                 |                                        |                 | Not Reported |                |
|                                                                    | Cipralex                  |                    |                    | S               |                                                 |                                        |                 | Not Reported |                |
|                                                                    | Prothipendyl              |                    |                    | S               |                                                 |                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2011                                                        | 7987062                   | EXPEDITED (15-DAY) | Y                  |                 | 1000020959                                      |                                        | 46 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Bladder Sensation; Urinary Retention; Urine Flow Decreased | Escitalopram Oxalate      |                    |                    | S               | Oral                                            | 10 Mg (10 Mg, 1 In 1 D), Oral          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Oct-2011                                                        | 8194913                   | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024459                                      |                                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Nephrolithiasis                                                    | Lexapro                   |                    |                    | S               |                                                 | 20 Mg (20 Mg, 1 In 1 D)                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                           | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                        | 7701166                   | NON-EXPEDITED      | N                  | OT              | 1000014928                                      |                                        | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                              | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |         |   |      |           |              |
|------------------------------------------------------------|---------|---|------|-----------|--------------|
| Blood Thyroid Stimulating<br>Hormone Decreased;<br>Syncope | Lexapro | S | Oral | See Image | Not Reported |
|                                                            |         |   | Oral | See Image |              |
|                                                            |         |   | Oral | See Image |              |
|                                                            |         |   | Oral | See Image |              |
|                                                            | Lexapro | S | Oral | See Image | Not Reported |
|                                                            |         |   | Oral | See Image |              |
|                                                            |         |   | Oral | See Image |              |
|                                                            |         |   | Oral | See Image |              |
|                                                            | Nexium  | C |      |           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 7701205       | NON-EXPEDITED    | Y                  | DE              | 1000014986           |                      | 19 YR      | Female     | USA            |

| <u>Preferred Term</u>         | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|-------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------|-----------------|--------------|
| Accidental Overdose;<br>Mania | Lexapro                 |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                  |                 | Not Reported |
|                               | Lexapro                 |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D),Oral |                 | Not Reported |
|                               |                         |              |            |             | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; 15 Mg (15 Mg, 1 In 1<br>D),Oral |                 |              |
|                               | Xanax                   |              |            | S           | Oral         | 0.5 Mg Tid Prn, Oral                                              |                 | Not Reported |
|                               | Vicodin                 |              |            | S           | Oral         | Oral                                                              |                 | Not Reported |
|                               | Alcohol                 |              |            | S           | Oral         | Oral                                                              |                 | Not Reported |
|                               | Seroquel Xr             |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |
|                               | Trazodone Hydrochloride |              |            | C           |              |                                                                   |                 | Not Reported |
|                               | Ultram                  |              |            | C           |              |                                                                   |                 | Not Reported |
|                               | Imitrex                 |              |            | C           |              |                                                                   |                 | Not Reported |
|                               | Skelaxin                |              |            | C           |              |                                                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8181841       | EXPEDITED (15-DAY) | N                  | OT              | US-TEVA-304301USA    |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                              |                               |   |      |               |  |              |
|------------------------------------------------------------------------------|-------------------------------|---|------|---------------|--|--------------|
| Depression; Drug Interaction; Fatigue; Fungal Infection; Mania; Palpitations | Fluconazole                   | S | Oral |               |  | Not Reported |
|                                                                              | Deplin (Calcium Levomefolate) | C |      |               |  | Not Reported |
|                                                                              | (Calcium Levomefolate)        |   |      |               |  |              |
|                                                                              | Escitalopram Oxalate          | S | Oral | 10 Milligram; |  | Not Reported |
|                                                                              | Escitalopram Oxalate          | S | Oral | 20 Milligram; |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225598       | NON-EXPEDITED    | Y                  | RI              | 1000018065           |                      | 40 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Bipolar Disorder; Crying; Drug Ineffective; Suicidal Ideation | Lexapro                                     |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                               | Wellbutrin                                  |              |            | S           |              |                             |                 | Not Reported |
|                                                               | Trazodone (Trazodone) (Tablets) (Trazodone) |              |            | C           |              |                             |                 | Not Reported |
|                                                               | Topamax (Topiramate) (Topiramate)           |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225618       | NON-EXPEDITED    | N                  | RI, OT          | 1000018159           |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Crying; Depression; Mood Swings; Paranoia; Suicidal Ideation | Lexapro                                                     |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                              | Alprazolam (Alprazolam) (1 Milligram, Tablets) (Alprazolam) |              |            | C           |              |                             |                 | Not Reported |
|                                                              | Tramadol (Tramadol) (50 Milligram, Tablets) (Tramadol)      |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225622       | NON-EXPEDITED    | Y                  | RI, OT          | 1000018260           |                      | 25 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Stomatitis; Suicidal  | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                                                                                                                                                                                                  |                  |                    |                 |                      |                                                                                          |                 |              |                |  |  |              |  |  |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|------------------------------------------------------------------------------------------|-----------------|--------------|----------------|--|--|--------------|--|--|
| Ideation                                           |                                                                                                                                                                                                  |                  | Xanax              |                 |                      | C                                                                                        |                 |              | D),Oral        |  |  | Not Reported |  |  |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                                                                                                                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |  |              |  |  |
| 14-Oct-2011                                        | 8225647                                                                                                                                                                                          | NON-EXPEDITED    | Y                  | RI, OT          | 1000018377           |                                                                                          | 57 YR           | Female       | USA            |  |  |              |  |  |
| <u>Preferred Term</u>                              | <u>Product</u>                                                                                                                                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |  |  |              |  |  |
| Hypersomnia; Myalgia;<br>Nephrolithiasis; Overdose | Lexapro                                                                                                                                                                                          |                  |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral                                |                 | Not Reported |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral                                |                 |              |                |  |  |              |  |  |
|                                                    | Lexapro                                                                                                                                                                                          |                  |                    | S               | Oral                 | 40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral |                 | Not Reported |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 | Oral                 | 40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral |                 |              |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 | Oral                 | 40 Mg (40 Mg,1 In 1 D),Oral ; 20 Mg (20 Mg,1 In 1 D),Oral ; 30 Mg, (30 Mg,1 In 1 D),Oral |                 |              |                |  |  |              |  |  |
|                                                    | Lipitor<br>Nadolol (Nadolol) (Nadolol)<br>Dexedrine (Dexamfetamine Sulfate) (Dexamfetamine Sulfate)<br>Adderall (Amphetamine, Dextroamphetamine) (Amphetamine, Dextroamphetamine)<br>Pravastatin |                  |                    | S               |                      |                                                                                          |                 | Not Reported |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    | C               |                      |                                                                                          |                 |              |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    | C               |                      |                                                                                          |                 |              |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    | C               |                      |                                                                                          |                 |              |                |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 |                      |                                                                                          |                 |              | Not Reported   |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 |                      |                                                                                          |                 |              | Not Reported   |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 |                      |                                                                                          |                 |              | Not Reported   |  |  |              |  |  |
|                                                    |                                                                                                                                                                                                  |                  |                    |                 |                      |                                                                                          |                 |              | Not Reported   |  |  |              |  |  |
| <u>FDA Received Date</u>                           | <u>Case #</u>                                                                                                                                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |  |  |              |  |  |
| 14-Oct-2011                                        | 8225668                                                                                                                                                                                          | NON-EXPEDITED    | Y                  | RI, OT          | 1000018695           |                                                                                          | 11 YR           | Male         | USA            |  |  |              |  |  |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>         | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|--------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Depression; Suicidal Ideation | Lexapro                                                      |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral |                 | Not Reported |
|                               |                                                              |              |            |             | Oral         | 10 Mg (10 Mg,1 In 1 D),Oral ; 15 Mg (15 Mg,1 In 1 D),Oral |                 |              |
|                               | Abilify (Aripiprazole) (5 Milligram, Tablets) (Aripiprazole) |              |            | C           |              |                                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225669       | NON-EXPEDITED    | N                  | RI, OT          | 1000018998           |                      | 63 YR      | Male       | USA            |

| <u>Preferred Term</u>         | <u>Product</u>                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Suicidal Ideation | Lexapro                                        |              |            | S           | Oral         | (1 In 1 D),Oral    |                 | Not Reported |
|                               | Vitamin B-12 (Cyanocobalamin) (Cyanocobalamin) |              |            | C           |              |                    |                 | Not Reported |
|                               | Vicodin (Hydrocodone) (Hydrocodone)            |              |            | C           |              |                    |                 | Not Reported |
|                               | Lisinopril                                     |              |            | C           |              |                    |                 | Not Reported |
|                               | Simvastatin                                    |              |            | C           |              |                    |                 | Not Reported |
|                               | Omeprazole                                     |              |            | C           |              |                    |                 | Not Reported |
|                               | Nifedipine                                     |              |            | C           |              |                    |                 | Not Reported |
|                               | Carvedilol                                     |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225678       | NON-EXPEDITED    | Y                  | HO              | 1000019254           |                      | 44 YR      | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Overdose; Suicide Attempt | Lexapro        |              |            | S           | Oral         | Oral ; Oral                      |                 | Not Reported |
|                           | Lunesta        |              |            | S           | Oral         | 2 Mg (2 Mg,1 In 1 D),Oral ; Oral |                 | Not Reported |
|                           |                |              |            |             | Oral         | 2 Mg (2 Mg,1 In 1 D),Oral ; Oral |                 |              |
|                           | Ambien Cr      |              |            | S           | Oral         | 12.5 Mg (12.5 Mg,1 In 1          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |       |  |  |   |      |                                                             |  |  |              |
|--|-------|--|--|---|------|-------------------------------------------------------------|--|--|--------------|
|  |       |  |  |   | Oral | D),Oral ; Oral<br>12.5 Mg (12.5 Mg,1 In 1<br>D),Oral ; Oral |  |  |              |
|  | Xanax |  |  | S | Oral | Oral ; Oral                                                 |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225707       | NON-EXPEDITED    | N                  | HO              | 1000019281           |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Intentional Overdose;<br>Suicide Attempt | Lexapro                |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |
|                                          | Oxycontin              |              |            | S           | Oral         | Oral                           |                 | Not Reported |
|                                          | Unspecified Ingredient |              |            | S           | Oral         | Oral                           |                 | Not Reported |
|                                          | Unspecified Ingredient |              |            | S           | Oral         | Oral                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225711       | NON-EXPEDITED    | N                  | RI, OT          | 1000019386           |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225715       | NON-EXPEDITED    | N                  | HO, OT          | 1000019477           |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Suicidal Ideation     | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225763       | NON-EXPEDITED    | N                  | OT              | 1000015749           |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                          |              |   |      |                                                                                                     |              |
|----------------------------------------------------------------------------------------------------------|--------------|---|------|-----------------------------------------------------------------------------------------------------|--------------|
| Crying; Dry Mouth; Feeling Abnormal; Pain; Productive Cough; Suicidal Ideation; Thirst; Weight Increased | Lexapro      | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 5 Mg (5 Mg, 1 In 1 D),<br>Oral 2.5 (2.5 Mg, Every Other Day), Oral | Not Reported |
|                                                                                                          |              |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 5 Mg (5 Mg, 1 In 1 D),<br>Oral 2.5 (2.5 Mg, Every Other Day), Oral |              |
|                                                                                                          |              |   | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral 5 Mg (5 Mg, 1 In 1 D),<br>Oral 2.5 (2.5 Mg, Every Other Day), Oral |              |
|                                                                                                          | Lexapro      | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                                                                    |              |
|                                                                                                          | Keppra       | S |      |                                                                                                     | Not Reported |
|                                                                                                          | Synthroid    | C |      |                                                                                                     | Not Reported |
|                                                                                                          | Baby Aspirin | C |      |                                                                                                     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225768       | NON-EXPEDITED    | Y                  | DE              | 1000015826           |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Completed Suicide     | Lexapro                                                     |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       | Klonopin (Clonazepam) (0.5 Milligram, Tablets) (Clonazepam) |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8225780       | NON-EXPEDITED    | N                  | OT              | 1000015921           |                      |            | Male       | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Suicidal Ideation | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                              | 8225830                                                                          | NON-EXPEDITED    | N                  | OT              | 1000015938           |                                                              | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Dizziness; Fatigue; Mania; Suicidal Ideation | Lexapro                                                                          |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                          | Baclofen                                                                         |                  |                    | C               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                          | Aspirin                                                                          |                  |                    | C               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                              | 8225879                                                                          | NON-EXPEDITED    | Y                  | OT              | 1000016476           |                                                              | 35 YR           | Male         | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Parkinsonism                                             | Lexapro                                                                          |                  |                    | S               |                      |                                                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                 | <u>Case #</u>                                                                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                              | 8226014                                                                          | NON-EXPEDITED    | N                  | OT              | 1000016592           |                                                              | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>                                                                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Dystonia                                                 | Lexapro                                                                          |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |                |
|                                                          | Trazodone (Trazodone) (Tablets) (Trazodone)                                      |                  |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                          | Geodon (Ziprasidone) (Ziprasidone)                                               |                  |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                          | Propranolol                                                                      |                  |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                          | Focalin Xr (Dexmethylphenidate Hydrochloride) (Dexmethylphenidate Hydrochloride) |                  |                    | C               |                      |                                                              |                 | Not Reported |                |
|                                                          | Topamax (Topiramate)                                                             |                  |                    | C               |                      |                                                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

(Topiramate)

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                                                   | 8226022                                                   | NON-EXPEDITED    | N                  | HO              | 1000016758           |                                  | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Chest Pain;<br>Electrocardiogram<br>Change; Hyperhidrosis;<br>Nausea; Paraesthesia;<br>Tremor | Lexapro                                                   |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                               | Azor (Amlodipine, Olmesartan)<br>(Amlodipine, Olmesartan) |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                               | Xyzal                                                     |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                                               | Prilosec (Omeprazole)<br>(Omeprazole)                     |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                   | 8226048                                                   | NON-EXPEDITED    | Y                  | OT              | 1000016800           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                            | Lexapro                                                   |                  |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                   | 8226073                                                   | NON-EXPEDITED    | Y                  | OT              | 1000016801           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                            | Lexapro                                                   |                  |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>                                             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                   | 8226088                                                   | NON-EXPEDITED    | Y                  | OT              | 1000016802           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>                                            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Serotonin Syndrome                                                                            | Lexapro                                                   |                  |                    | S               |                      |                                  |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                    | 8226108        | NON-EXPEDITED    | N                  | DE              | 1000022739           |                         | 44 YR           | Male         | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Anxiety;<br>Completed Suicide;<br>Suicidal Ideation | Lexapro        |                  |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>                        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|--------------------------------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                              | 8226110                              | NON-EXPEDITED    | Y                  | RI, OT          | 1000017219           |                                  | 43 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                    | <u>Product</u>                       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Fatigue;<br>Overdose; Somnolence;<br>Suicidal Ideation | Lexapro                              |                  |                    | S               | Oral                 | 30 Mg (30 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                          | Zoloft                               |                  |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                          | Cymbalta                             |                  |                    | S               | Oral                 | 60 Mg (60 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                          | Wellbutrin                           |                  |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
|                                                                          | Methadone (Methadone)<br>(Methadone) |                  |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                                                                            | 8226131                                                      | NON-EXPEDITED    | N                  | HO              | 1000017235           |                             | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                               | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Blood Pressure<br>Decreased; Panic Attack;<br>Suicidal Ideation;<br>Supraventricular<br>Tachycardia; Tremor | Lexapro                                                      |                  |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                        | Metoprolol (Metoprolol) (Tablets)<br>(Metoprolol)            |                  |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                        | Levothyroxine Sodium                                         |                  |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                        | Omeprazole                                                   |                  |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                        | Xanax (Alprazolam) (0.25<br>Milligram, Tablets) (Alprazolam) |                  |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                        | Decadron (Dexamethasone)<br>(Tablets) (Dexamethasone)        |                  |                    | C               |                      |                             |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                                                                                                       | 8226132                                                       | NON-EXPEDITED    | N                  | RI, OT          | 1000013431           |                               | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Glycosylated Haemoglobin Decreased; Glycosylated Haemoglobin Increased; Hypomania; Irritability; Somnolence; Type 2 Diabetes Mellitus | Lexapro                                                       |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                   | Birth Control (Nos) (Contraceptives Nos) (Contraceptives Nos) |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                                                                       | 8226197                                                       | NON-EXPEDITED    | Y                  | RI, OT          | 1000019506           |                               | 38 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                                                                                                 | Lexapro                                                       |                  |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                                                                       | 8226199                                                       | NON-EXPEDITED    | Y                  | HO              | 1000014465           |                               | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia                                                                                                                                     | Lexapro                                                       |                  |                    | S               | Oral                 | 10 Mg(10 Mg, 1 In 1 D), Oral  |                 | Not Reported |                |
|                                                                                                                                                   | Lisinopril                                                    |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                   | Atenolol                                                      |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                   | Simvastatin                                                   |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                                                                                   | Xanax                                                         |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                                                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                                                                                       | 8226202                                                       | NON-EXPEDITED    | Y                  | RI, OT          | 1000017296           |                               |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                                                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Tachycardia                                                                                                                           | Lexapro                                                       |                  |                    | S               |                      |                               |                 | Not Reported |                |



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| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|---------------------------------------------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 14-Oct-2011                                                                  | 8226215                                                 | NON-EXPEDITED    | Y                  | RI, OT          | 1000021173           |                               | 9 YR            | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Incorrect Route Of Product Administration                        | Lexapro                                                 |                  |                    | S               |                      |                               |                 | Not Reported |                |
|                                                                              | Nasonex                                                 |                  |                    | S               |                      | Nasal                         |                 | Not Reported |                |
|                                                                              | Asmanex                                                 |                  |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                  | 8226217                                                 | NON-EXPEDITED    | N                  | RI, OT          | 1000021426           |                               |                 | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation; Suicide Attempt                                           | Lexapro                                                 |                  |                    | S               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                  | 8226226                                                 | NON-EXPEDITED    | Y                  | HO              | 1000017394           |                               | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Missed; Maternal Exposure During Pregnancy; Urinary Tract Infection | Lexapro                                                 |                  |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                              | Prenatal Vitamins With Dha (Prenatal Vitamins With Dha) |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                              | Retin A Gel 0.1% (Tretinoin) (Tretinoin)                |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>                                           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                                  | 8226229                                                 | NON-EXPEDITED    | N                  | RI, OT          | 1000021610           |                               | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>                                          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                            | Lexapro                                                 |                  |                    | S               |                      |                               |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|-------------------------------------------------------------|-------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------------------------|----------------|
| 14-Oct-2011                                                 | 8226243           | NON-EXPEDITED    | N                  | OT              | 1000019507           |                               | 49 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Anxiety; Depression; Night Sweats; Suicidal Ideation        | Lexapro           |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2011                                                 | 8226244           | NON-EXPEDITED    | Y                  | HO              | 1000022068           |                               |                 | Female                       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hypomania                                                   | Lexapro<br>Zoloft |                  |                    | S<br>S          |                      |                               |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2011                                                 | 8226245           | NON-EXPEDITED    | Y                  | HO              | 1000017468           |                               | 55 YR           | Male                         | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion | Lexapro           |                  |                    | S               |                      |                               |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2011                                                 | 8226247           | NON-EXPEDITED    | Y                  | OT              | 1000022296           |                               |                 | Female                       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
| Suicidal Ideation                                           | Lexapro           |                  |                    | S               |                      |                               |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 14-Oct-2011                                                 | 8226252           | NON-EXPEDITED    | N                  | HO              | 1000019547           |                               | 53 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                   |                |
|                                                             |                   |                  |                    |                 |                      |                               |                 |                              |                |

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Abdominal Pain Upper; Disturbance In Attention; Feeling Abnormal      Lexapro      S      Oral      20 Mg (20 Mg), Oral      Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226256       | NON-EXPEDITED    | N                  | RI, OT          | 1000022437           |                      | 75 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u>                                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Aggression; Amnesia; Food Craving; Headache; Insomnia; Mental Impairment; Suicidal Ideation | Lexapro                                                     |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral                                |                 | Not Reported |
|                                                                                             | Lexapro                                                     |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                             |                                                             |              |            |             | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral | 1 DAY           |              |
|                                                                                             | Diovan                                                      |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Metformin Hydrochloride                                     |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Simvastatin                                                 |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Cilostazol (Cilostazol)                                     |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | (Cilostazol)                                                |              |            |             |              |                                                              |                 |              |
|                                                                                             | Hydrocodone                                                 |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Losartan Hydrochlorothiazide                                |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | (Losartan, Hydrochlorothiazide)                             |              |            |             |              |                                                              |                 |              |
|                                                                                             | (Losartan, Hydrochlorothiazide)                             |              |            |             |              |                                                              |                 |              |
|                                                                                             | Metoprolol Succinate                                        |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Levothyroxine (Levothyroxine Sodium) (Levothyroxine Sodium) |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | Prilosec (Omeprazole)                                       |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | (Omeprazole)                                                |              |            |             |              |                                                              |                 |              |
|                                                                                             | Alka Seltzer (Sodium Bicarbonate, Citric Acid, Aspirin)     |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                             | (Sodium Bicarbonate, Citric Acid, Aspirin)                  |              |            |             |              |                                                              |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226261       | NON-EXPEDITED    | Y                  | RI, OT          | 1000019668           |                      | 60 YR      | Male       | USA            |

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| <u>Preferred Term</u>          | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|-----------------------------|--------------|------------|-------------|---------------------------------------|------------------------------------------------------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged | Lexapro                     |              |            | S           | Oral                                  | Oral                                                             |                 | Not Reported |
|                                | Vibativ                     |              |            | S           | Intravenous (not otherwise specified) | 10 Mg/Kg Total Daily Dose, Intravenous (Not Otherwise Specified) |                 | Not Reported |
|                                | Trazodone Hydrochloride     |              |            | S           | Oral                                  | Oral                                                             |                 | Not Reported |
|                                | Reglan                      |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Warfarin Sodium             |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Novolin R                   |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Hydromorphone Hydrochloride |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Metoprolol                  |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Lisinopril                  |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Sitagliptin                 |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Imdur                       |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Lasix                       |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Cilostazol                  |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Vitamin D (Colecalciferol)  |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Calcium Citrate             |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Omeprazole                  |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Zolpidem                    |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Lipitor                     |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Fentanyl                    |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Lantus                      |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                | Oxycodone                   |              |            | C           |                                       |                                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226266       | NON-EXPEDITED    | N                  | LT              | 1000020040           |                      |            | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective; Suicidal Ideation | Lexapro        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                     | Abilify        |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226267       | NON-EXPEDITED    | N                  | RI, OT          | 1000017752           |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |                                                                                 |   |      |                                  |              |
|--------------|---------------------------------------------------------------------------------|---|------|----------------------------------|--------------|
| Hypertension | Lexapro                                                                         | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|              | Synthroid (Levothyroxine Sodium) (50 Microgram, Tablets) (Levothyroxine Sodium) | C |      |                                  | Not Reported |
|              | Alendronate (Alendronate Sodium) (Alendronate Sodium)                           | C |      |                                  | Not Reported |
|              | Ambien (Zolpidem Tartrate) (5 Milligram, Tablets) (Zolpidem Tartrate)           | C |      |                                  | Not Reported |
|              | Simvastatin (Simvastatin) (20 Milligram, Tablets) (Simvastatin)                 | C |      |                                  | Not Reported |
|              | Centrum Vitamins (Centrum Vitamins) (Centrum Vitamins)                          | C |      |                                  | Not Reported |
|              | Calcium (Calcium) (Calcium)                                                     | C |      |                                  | Not Reported |
|              | Vitamin D (Vitamin D) (Vitamin D)                                               | C |      |                                  | Not Reported |
|              | Viactiv (Calcium) (Calcium)                                                     | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226271       | NON-EXPEDITED    | N                  | RI, OT          | 1000020557           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose; Overdose; Suicide Attempt | Lexapro                |              |            | S           |              | Oral               |                 | Not Reported |
|                                                 | Unspecified Ingredient |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226272       | NON-EXPEDITED    | Y                  | HO              | 1000022690           |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pancreatitis          | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226273       | NON-EXPEDITED    | Y                  | OT              | 1000017836           |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                                                                      |   |      |      |              |
|----------|----------------------------------------------------------------------|---|------|------|--------------|
| Overdose | Lexapro                                                              | S | Oral | Oral | Not Reported |
|          | Neurontin                                                            | S | Oral | Oral | Not Reported |
|          | Oxycontin (Oxycodone Hydrochloride) (Oxycodone Hydrochloride)        | C |      |      | Not Reported |
|          | Morphine Sulfate                                                     | C |      |      | Not Reported |
|          | Diazepam                                                             | C |      |      | Not Reported |
|          | Vicodin Er (Hydrocodone, Acetaminophen) (Hydrocodone, Acetaminophen) | C |      |      | Not Reported |
|          | Soma (Carisoprodol) (Carisoprodol)                                   | C |      |      | Not Reported |
|          | Parafon Forte (Chlorzoxazone) (Chlorzoxazone)                        | C |      |      | Not Reported |
|          | Zanaflex (Tizanidine Hydrochloride) (Tizanidine Hydrochloride)       | C |      |      | Not Reported |
|          | Klonopin                                                             | C |      |      | Not Reported |
|          | Ativan                                                               | C |      |      | Not Reported |
|          | Phenergan (Promethazine) (Promethazine)                              | C |      |      | Not Reported |
|          | Relafen (Nabumetone) (Nabumetone)                                    | C |      |      | Not Reported |
|          | Lidoderm (Lidocaine) (Poultice Or Patch) (Lidocaine)                 | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8226301       | NON-EXPEDITED    | N                  | OT              | 1000020784           |                      | 67 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                                           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Feeling Jittery; Suicidal Ideation | Lexapro        |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every Other Day (10 Mg, 1 In 2 D), Oral<br>10 Mg (10 Mg, 1 In 1 D), Oral; 10 Mg Every Other Day (10 Mg, 1 In 2 D), Oral |                 | Not Reported |
|                                             | Seroquel       |              |            | C           |              |                                                                                                                                                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                   |                | Xanax            |                    | C               |                      |                                  |                 |              | Not Reported   |
|-------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                   |                | Synthroid        |                    | C               |                      |                                  |                 |              | Not Reported   |
|                                                                   |                | Coreg            |                    | C               |                      |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                       | 8226302        | NON-EXPEDITED    | Y                  | RI, OT          | 1000018027           |                                  |                 | Male         | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Somnolence;<br>Suicidal Ideation; Weight<br>Increased | Lexapro        |                  |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                   | Invenga        |                  |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                       | 8226314        | NON-EXPEDITED    | Y                  | HO              | 1000020983           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Confusional<br>State; Hyponatraemia                     | Lexapro        |                  |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                       | 8226330        | NON-EXPEDITED    | Y                  | HO              | 1000020984           |                                  | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Fatigue;<br>Hyponatraemia                               | Lexapro        |                  |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                   | Clonazepam     |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                   | Vytorin        |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                   | Aspirin        |                  |                    | C               |                      |                                  |                 | Not Reported |                |
|                                                                   | Carbamazepine  |                  |                    | C               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Oct-2011                                                       | 8228485        | NON-EXPEDITED    | N                  | RI, OT          | 1000017454           |                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                             |   |      |                                  |              |
|----------------------------------------------------------------------------------------------|-----------------------------|---|------|----------------------------------|--------------|
| Disturbance In Attention;<br>Headache; Insomnia;<br>Nervousness; Tremor;<br>Weight Decreased | Lexapro                     | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                              | Ambien                      | C |      |                                  | Not Reported |
|                                                                                              | Glyburide                   | C |      |                                  | Not Reported |
|                                                                                              | Vytorin (Inegy) (Inegy)     | C |      |                                  | Not Reported |
|                                                                                              | Calcium (Calcium) (Calcium) | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8228577       | NON-EXPEDITED    | N                  | RI, OT          | 1000021106           |                      | 47 YR      | Female     | USA            |

| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Dizziness; Intentional<br>Overdose; Suicide Attempt | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 250 Mg, Oral |                 | Not Reported |
|                                                     |                |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 250 Mg, Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8236433       | NON-EXPEDITED    | Y                  | RI, OT          | 10000015444          |                      | 61 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Angioedema; Urticaria | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                       | Vesicare       |              |            | C           |              |                              |                 | Not Reported |
|                       | Simvastatin    |              |            | C           |              |                              |                 | Not Reported |
|                       | Coumadin       |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Oct-2011              | 8239074       | NON-EXPEDITED    | Y                  | HO              | 10000820982          |                      |            | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asthenia; Confusional<br>State; Hyponatraemia | Lexapro        |              |            | S           |              |                    |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 15-Oct-2011                                                  | 8182389              | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2011SE60473 |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                                                    | Inexium              |                    |                    | S               | Oral                       |                      | 1 MTH           | Astrazeneca  |                |
|                                                              | Amoxicillin          |                    |                    | S               | Oral                       |                      | 1 MTH           | Not Reported |                |
|                                                              | Clarithromycin       |                    |                    | S               | Oral                       |                      | 1 MTH           | Not Reported |                |
|                                                              | Aricept              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                              | Flagyl               |                    |                    | S               | Oral                       |                      | 1 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2011                                                  | 7948744              | EXPEDITED (15-DAY) | Y                  | DE              | 2011SP018390               |                      | 34 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                            | Mirtazapine          |                    |                    | S               | Oral                       | 30 Mg;Qd;Po          |                 | Not Reported |                |
|                                                              | Ciprallex            |                    |                    | S               | Oral                       | 20 Mg;Qd;Po          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Oct-2011                                                  | 8183271              | DIRECT             | N                  | DE              |                            |                      | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asphyxia;<br>Completed Suicide;<br>Feeling Abnormal | Lexapro              |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Oct-2011                                                  | 8168441              | EXPEDITED (15-DAY) | Y                  | HO              | 1000024066                 |                      | 17 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                      |   |      |                             |              |
|-------------------------|----------------------|---|------|-----------------------------|--------------|
| Off Label Use; Priapism | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg,1 In 1 D),Oral | Not Reported |
|                         | Escitalopram Oxalate | S | Oral | Oral                        | Not Reported |
|                         | Invega               | C |      |                             | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Oct-2011              | 8174969       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024082           |                      | 41 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Agitation; Decreased Appetite; Dizziness; Fatigue; Headache; Hyperhidrosis; Nausea; Palpitations; Paraesthesia; Sinusitis; Suicidal Ideation; Tinnitus; Vomiting; Weight Decreased; Withdrawal Syndrome | Lexapro        |              |            | S           | Oral         | See Image                    |                 | Not Reported |
|                                                                                                                                                                                                         | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                                                                         | Alprazolam     |              |            | C           |              |                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2011              | 8185810       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2011248798 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alcohol Interaction; Loss Of Consciousness | Chantix        |              |            | S           | Oral         | 0.5 Mg, Daily      |                 | Pfizer       |
|                                            | Chantix        |              |            | S           | Oral         | 1 Mg, 2x/Day       |                 | Pfizer       |
|                                            | Lexapro        |              |            | S           | Oral         | 10 Mg, Daily       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 18-Oct-2011              | 8186416       | EXPEDITED (15-DAY) | N                  | HO, OT          | FR-GLAXOSMITHKLINE-B0727777A |                      | 45 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Conversion Disorder; Crying; Major Depression; Mental Disorder; Suicidal | Derogat        |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                                          | Enbrel         |              |            | S           | Unknown      | 50mg Weekly        |                 | Unknown         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                      |   |                                       |         |
|------------------|----------------------|---|---------------------------------------|---------|
| Ideation; Tremor | Escitalopram Oxalate | S | Unknown                               | Unknown |
|                  | Anafranil            | C | Intravenous (not otherwise specified) | Unknown |

| <u>FDA Received Date</u>                                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 18-Oct-2011                                                                  | 8202109              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000022156           |                             | 52 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Breast Discomfort; Breast Tenderness; Generalised Oedema; Nausea | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
|                                                                              | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 18-Oct-2011              | 8202173        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024535           |                      |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oesophageal Achalasia    | Lexapro        |                    |                    | S               |                      | 10 Mg (10 Mg)        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2011                                                      | 7995134              | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-AMGEN-FRASP2011030054 |                      | 46 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Conversion Disorder; Major Depression; Suicidal Ideation; Tremor | Enbrel               |                    |                    | S               |                          | 50 Mg, Weekly        |                 | Amgen        |                |
|                                                                  | Escitalopram Oxalate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                  | Deroxat              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2011                | 8120942        | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-SANOFI-AVENTIS-2011SA055863 |                      | 21 YR           | Female       | FRA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Respiratory Distress | Stilnox        |                    |                    | S               | Oral                           |                      | 13 DAY          | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                      |   |      |        |              |
|-----------------------------------------------|----------------------|---|------|--------|--------------|
| Syndrome; Dyspnoea;<br>Eosinophilic Pneumonia | Depakote             | S | Oral | 5 DAY  | Not Reported |
|                                               | Escitalopram Oxalate | S | Oral | 18 DAY | Not Reported |
|                                               | Ferrous Sulfate      | S | Oral |        | Not Reported |
|                                               | Xanax                | S | Oral |        | Not Reported |
|                                               | Triphasil-21         | S | Oral |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Oct-2011              | 8170912       | EXPEDITED (15-DAY) | Y                  | CA              | 1000024030           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                           | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|--------------|------------|-------------|----------------|------------------------|-----------------|--------------|
| Aortic Valve Disease;<br>Aphasia; Bicuspid Aortic<br>Valve; Craniosynostosis;<br>Intellectual Disability;<br>Maternal Drugs Affecting<br>Foetus | Lexapro                                                      |              |            | S           | Transplacental | (10 Mg),Transplacental |                 | Not Reported |
|                                                                                                                                                 | Prenatal Vitamins (Prenatal<br>Vitamins) (Prenatal Vitamins) |              |            | C           |                |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2011              | 8189298       | EXPEDITED (15-DAY) | Y                  | LT, OT          | FR-SANOFI-AVENTIS-<br>2011SA054192 |                      | 21 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress<br>Syndrome; Dyspnoea;<br>Eosinophilic Pneumonia | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Depakote             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Ferrous Sulfate      |              |            | S           |              |                    |                 | Not Reported |
|                                                                             | Xanax                |              |            | S           |              |                    |                 | Not Reported |
|                                                                             | Triphasil-21         |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Oct-2011              | 8189740       | EXPEDITED (15-DAY) | Y                  | HO              | AU-PFIZER INC-<br>2011245315 |                      |            | Female     | AUS            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hepatitis             | Pristiq Extended Release |              |            | S           |              |                    |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                                                      |                    |                    |                 |                          |                               |                 |              |                |
|--------------------------------------------|----------------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| Lexapro                                    |                                                                      | S                  |                    | Not Reported    |                          |                               |                 |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2011                                | 8189948                                                              | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2011245079 |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Bipolar Disorder; Pain                     | Zoloft                                                               |                    |                    | S               |                          | Unk                           |                 | Pfizer       |                |
|                                            | Lexapro                                                              |                    |                    | S               |                          | Unk                           |                 | Not Reported |                |
|                                            | Oxycontin                                                            |                    |                    | S               |                          | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2011                                | 8192610                                                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000024483               |                               | 75 YR           | Female       | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Jittery; Overdose; Suicide Attempt | Escitalopram Oxalate                                                 |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                            | Methotrexate (Methotrexate)                                          |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Pariet (Rabeprazole Sodium) (Tablets) (Rabeprazole Sodium)           |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Mabthera (Rituximab) (Rituximab)                                     |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Endoxan (Cyclophosphamide) (Cyclophosphamide)                        |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Doxorubicin Hydrochloride                                            |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Vincristine Sulfate                                                  |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            | Cardiospirin (Acetylsalicylic Acid) (Tablets) (Acetylsalicylic Acid) |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                            |                                                                      |                    |                    |                 |                          |                               |                 |              |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Oct-2011                                | 8200410                                                              | EXPEDITED (15-DAY) | Y                  | HO              | 1000024628               |                               | 69 YR           | Female       | DNK            |
| <u>Preferred Term</u>                      | <u>Product</u>                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                                                                                        |   |      |                                    |              |
|----------------------------------------------------|----------------------------------------------------------------------------------------|---|------|------------------------------------|--------------|
| Delirium; Drug Ineffective;<br>Withdrawal Syndrome | Escitalopram Oxalate                                                                   | S | Oral | 20 Mg (10 Mg, 2 In 1 D),<br>Oral   | Not Reported |
|                                                    | Trazodone Hydrochloride                                                                | S | Oral | 100 Mg (100 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                    | Praxiten (Oxazepam)<br>(Oxazepam)                                                      | C |      |                                    | Not Reported |
|                                                    | Mirtabene (Mirtazapine)<br>(Mirtazapine)                                               | C |      |                                    | Not Reported |
|                                                    | Tenormin                                                                               | C |      |                                    | Not Reported |
|                                                    | Pantoloc (Pantoprazole Sodium<br>Sesquihydrate) (Pantoprazole<br>Sodium Sesquihydrate) | C |      |                                    | Not Reported |

| <u>FDA Received Date</u>                                                      | <u>Case #</u>                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2011                                                                   | 8211350                                                                                        | EXPEDITED (15-DAY) | Y                  | HO              | 1000024711           |                      | 88 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                         | <u>Product</u>                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Fatigue;<br>Pruritus; Purpura; Rash<br>Papular; Weight<br>Decreased | Escitalopram Oxalate                                                                           |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                                               | Co-Aprovel (Irbesartan,<br>Hydrochlorothiazide) (Tablets)<br>(Irbesartan, Hydrochlorothiazide) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Redoxon (Ascorbic Acid)<br>(Tablets) (Ascorbic Acid)                                           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                               | Movicol                                                                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 19-Oct-2011                                                      | 8216895              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024667           |                      | 41 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Disorder; Incorrect<br>Dose Administered;<br>Suicide Attempt | Escitalopram Oxalate |                    |                    | S               |                      | 2 Boxes (Once)       |                 | Not Reported |                |
|                                                                  | Lexomil (Bromazepam) |                    |                    | S               |                      | (Once)               |                 | Not Reported |                |
|                                                                  | Voltaren             |                    |                    | S               |                      | (Once)               |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2011              | 8164680       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 2011MA013053         |                      | 69 YR      | Female     | POL            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                                                                       | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Antiphospholipid Antibodies Positive; Condition Aggravated; Depression; Embolism Venous; Pulmonary Embolism | Mirtazapine              |              |            | S           |              | 45 Mg;Qd           |                 | Purepac      |
|                                                                                                             | Paroxetine Hydrochloride |              |            | S           |              | 20 Mg;Qd           |                 | Not Reported |
|                                                                                                             | Sertraline Hydrochloride |              |            | S           |              | 100 Mg;Qd          |                 | Not Reported |
|                                                                                                             | Venlafaxine              |              |            | S           |              | 225 Mg;Qd          |                 | Not Reported |
|                                                                                                             | Reboxetine               |              |            | S           |              | 4 Mg;Qd            |                 | Not Reported |
|                                                                                                             | Quetiapine Fumarate      |              |            | S           |              | 300 Mg;Qd          |                 | Not Reported |
|                                                                                                             | Escitalopram Oxalate     |              |            | S           |              | 20 Mg;Qd           |                 | Not Reported |
|                                                                                                             | Olanzapine (Olanzapine)  |              |            | S           |              | 5 Mg;Qd            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Oct-2011              | 8195052       | DIRECT           | N                  | RI, OT          |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Gait Inability; Hyperhidrosis; Skin Odour Abnormal; Vein Disorder; Weight Increased | Cymbalta       |              |            | S           |              | 1 Pill @ Bedtime 1 - 1 1/2 Yrs | 12 MTH          | Not Reported |
|                                                                                     | Lexapro        |              |            | S           |              | 1 Pill @ Bedtime               | 3 MTH           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2011              | 8187875       | EXPEDITED (15-DAY) | Y                  | DE, HO          | IE-ASTRAZENECA-2011SE61980 |                      | 76 YR      | Male       | IRL            |

| <u>Preferred Term</u>            | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Hepatic Failure; Hepatitis | Seroquel               |              |            | S           | Oral         |                    | 5 DAY           | Not Reported |
|                                  | Nexium                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Rifadin                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Fucidin (Fusidic Acid) |              |            | S           | Unknown      |                    |                 | Not Reported |
|                                  | Lexapro                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Augmentin              |              |            | S           | Unknown      | 875/125 Mg         |                 | Not Reported |
|                                  | Metronidazole          |              |            | S           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 21-Oct-2011                         | 8192572              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2011US-49338        |                      | 30 YR           | Unknown      | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                   | Fluoxetine           |                    |                    | S               | Oral                           | Unk, Unk             |                 | Ranbaxy      |                |
|                                     | Escitalopram Oxalate |                    |                    | S               | Oral                           | Unk, Unk             |                 | Not Reported |                |
|                                     | Liothyronine Sodium  |                    |                    | S               | Oral                           | Unk, Unk             |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2011                         | 8192850              | EXPEDITED (15-DAY) | N                  | HO              | TR-US-EMD SERONO, INC.-7089068 |                      | 26 YR           | Female       | TUR            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asthenia; Fatigue; Thrombocytopenia | Rebif                |                    |                    | S               | Subcutaneous                   |                      |                 | Not Reported |                |
|                                     | Lyrica               |                    |                    | S               | Oral                           |                      | 4 MTH           | Not Reported |                |
|                                     | Escitalopram Oxalate |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Oct-2011                         | 8194074              | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2011252344       |                      |                 | Female       | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased         | Lipitor              |                    |                    | S               | Oral                           | 10 Mg, 1x/Day        |                 | Pfizer       |                |
|                                     | Lexapro              |                    |                    | S               | Oral                           | 10 Mg, 1x/Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Oct-2011                         | 8186357              | EXPEDITED (15-DAY) | Y                  | HO              | FR-ABBOTT-11P-056-0864075-00   |                      | 80 YR           | Female       | FRA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatitis                           | Clarithromycin       |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                     | Escitalopram Oxalate |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |              |
|-------------|---|------|--------------|
| Amoxicillin | S | Oral | Not Reported |
| Aricept     | S | Oral | Not Reported |
| Inexium     | S | Oral | Not Reported |
| Flagyl      | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2011              | 8111890       | EXPEDITED (15-DAY) | Y                  | OT              | 2011SP038021         |                      | 38 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                                                                                                                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain;<br>Diarrhoea; Drug<br>Interaction; Drug Level<br>Decreased; Insomnia;<br>Irritability; Loss Of<br>Personal Independence In<br>Daily Activities; Mood<br>Altered; Myoclonus;<br>Serotonin Syndrome;<br>Tremor | Remeron        |              |            | S           | Oral         | 15 Mg;Qd;Po        |                 | Not Reported |
|                                                                                                                                                                                                                              | Cipraxel       |              |            | S           | Oral         | 20 Mg;Qd;Po        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Oct-2011              | 8112759       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ABBOTT-11P-056-0849667-00 |                      | 21 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress<br>Syndrome; Dyspnoea;<br>Eosinophilic Pneumonia | Depakote             |              |            | S           | Oral         | 750mg Daily        |                 | Not Reported |
|                                                                             | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Daily        |                 | Not Reported |
|                                                                             | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Ferrous Sulfate      |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Xanax                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                             | Triphasil-21         |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-Oct-2011              | 8194817       | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20111008995 |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| Blood Triglycerides Increased                    | Concerta             |                    |                    | S               | Unknown              |                                       |                 | Not Reported |                |
|                                                  | Lexapro              |                    |                    | S               | Oral                 |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2011                                      | 8195691              | DIRECT             | Y                  | OT              |                      |                                       | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Malaise; Withdrawal Syndrome   | Lexapro              |                    |                    | S               | Oral                 | 20 Mg                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2011                                      | 8215627              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024769           |                                       | 60 DAY          | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Restlessness    | Escitalopram Oxalate |                    |                    | S               | Transmammary         | 10 Mg (10 Mg, 1 In 1 D), Transmammary |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Oct-2011                                      | 8216894              | EXPEDITED (15-DAY) | N                  | CA              | 1000024784           |                                       | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Talipes         | Lexapro              |                    |                    | S               | Transplacental       | Transplacental                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Oct-2011                                      | 7661231              | EXPEDITED (15-DAY) |                    | DS, HO, OT      | PHHO2010IL16347      |                                       | 34 YR           | Female       | ISR            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Asthenia; Ataxia; Brain Oedema; Central | Fty 720              |                    |                    | S               | Oral                 | Dose Blinded                          |                 | Novartis     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |                            |              |                                   |                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------|--------------|-----------------------------------|------------------------------------------------------------------------------------------|
| Nervous System Lesion;<br>Cerebral Atrophy; Colour<br>Blindness; Constipation;<br>Cyanosis; Depressed<br>Mood; Disinhibition;<br>Disorientation;<br>Disturbance In Attention;<br>Dysarthria; Dysmetria;<br>Dysmetropsia; Dysphonia;<br>Executive Dysfunction;<br>Gait Disturbance; Gait<br>Inability; Gamma-<br>Glutamyltransferase<br>Increased; Headache;<br>Hemianopia<br>Homonymous;<br>Hypertension; Irritability;<br>Joint Injury; Loss Of<br>Consciousness; Memory<br>Impairment;<br>Metamorphopsia; Muscle<br>Spasticity; Muscular<br>Weakness; Nausea;<br>Paresis; Peripheral<br>Coldness; Pyramidal Tract<br>Syndrome; Seizure; Status<br>Epilepticus; Tongue Biting;<br>Tonic Clonic Movements;<br>Unresponsive To Stimuli;<br>Urinary Incontinence;<br>Vasospasm; Visual<br>Impairment | Fty 720<br>Lioresal<br>Escitalopram<br>Cipralext<br>Modafinil<br>Ferrous Sulfate | S<br>S<br>S<br>C<br>C<br>C | Oral<br>Oral | 0.5mg<br>Unk<br>Unk<br>Unk<br>Unk | Novartis<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------|--------------|-----------------------------------|------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 25-Oct-2011              | 8163288       | EXPEDITED (15-DAY) | Y                  | OT              | US-SANOFI-AVENTIS-<br>2011SA063852 |                      | 82 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                       | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>    | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                   |
|-----------------------------------------------------------------------------|-------------------|--------------|------------|-------------|-----------------|--------------------|-----------------|------------------------------|
| Bundle Branch Block Left;<br>Electrocardiogram Qt<br>Prolonged; Ventricular | Multaq<br>Lexapro |              |            | S<br>S      | Oral<br>Unknown |                    |                 | Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |                      |   |              |
|-------------|----------------------|---|--------------|
| Tachycardia | Aspirin              | C | Not Reported |
|             | Xanax                | C | Not Reported |
|             | Aciphex              | C | Not Reported |
|             | Dabigatran Etexilate | C | Not Reported |
|             | Metoprolol           | C | Not Reported |

| <u>FDA Received Date</u>              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Oct-2011                           | 8199520        | DIRECT           | N                  | OT              |                      |                      | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Vertigo; Visual Impairment | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Lundbeck   |                |

| <u>FDA Received Date</u>                                                 | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 26-Oct-2011                                                              | 8040317                  | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021853           |                               | 46 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Conversion Disorder; Crying; Drug Interaction; Suicidal Ideation; Tremor | Escitalopram Oxalate     |                    |                    | S               |                      |                               | 2 DAY           | Not Reported |                |
|                                                                          | Enbrel                   |                    |                    | S               |                      | 7.1429 Mg (50 Mg, 1 In 1 Wk); |                 | Not Reported |                |
|                                                                          | Paroxetine Hydrochloride |                    |                    | S               |                      |                               |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------|-----------------|-----------------|----------------|
| 26-Oct-2011                  | 8200603                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-GLAXOSMITHKLINE-B0756543A |                           | 78 YR           | Male            | FRA            |
| <u>Preferred Term</u>        | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>      |                |
| Vertigo; Vestibular Neuritis | Avodart                 |                    |                    | S               | Oral                         | .5mg Per Day              |                 | Glaxosmithkline |                |
|                              | Metformin Hydrochloride |                    |                    | S               | Oral                         | 700mg Three Times Per Day |                 | Unknown         |                |
|                              | Gliclazide              |                    |                    | S               | Oral                         | 20mg Three Times Per Day  |                 | Unknown         |                |
|                              | Indapamide              |                    |                    | S               | Oral                         |                           |                 | Unknown         |                |
|                              | Bisoprolol Fumarate     |                    |                    | S               | Oral                         |                           |                 | Unknown         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |      |               |         |
|------------------------|---|------|---------------|---------|
| Cordarone              | S | Oral | 200mg Per Day | Unknown |
| Previscan (Fluindione) | S | Oral | 20mg Per Day  | Unknown |
| Escitalopram Oxalate   | S | Oral |               | Unknown |
| Crestor                | S | Oral |               | Unknown |

| <u>FDA Received Date</u>                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------------|-----------------|--------------|----------------|
| 26-Oct-2011                                                                             | 8201174                | EXPEDITED (15-DAY) | N                  | OT              | BR-PFIZER INC-2011251253 |                                     | 42 YR           | Female       | BRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction                                                                        | Lyrica                 |                    |                    | S               | Oral                     | 75 Mg, 1 Capsule Daily              | 7 DAY           | Pfizer       |                |
|                                                                                         | Lyrica                 |                    |                    | S               | Oral                     | 150mg (Two Capsules Of 75mg), Daily |                 | Pfizer       |                |
|                                                                                         | Alprazolam             |                    |                    | S               |                          | Unk                                 |                 | Pfizer       |                |
|                                                                                         | Lexapro                |                    |                    | S               |                          | Unk                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2011                                                                             | 8201413                | EXPEDITED (15-DAY) | Y                  | OT              | FR-WATSON-2011-17096     |                                     | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Hyponatraemia;<br>Inappropriate Antidiuretic<br>Hormone Secretion | Indapamide             |                    |                    | S               |                          |                                     |                 | Watson       |                |
|                                                                                         | Escitalopram Oxalate   |                    |                    | S               |                          |                                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Oct-2011                                                                             | 8202048                | EXPEDITED (15-DAY) | Y                  | HO              | 1000024656               |                                     | 80 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastroduodenal Ulcer;<br>Helicobacter Infection;<br>Hepatitis                           | Escitalopram Oxalate   |                    |                    | S               | Oral                     | Oral                                |                 | Not Reported |                |
|                                                                                         | Aricept                |                    |                    | S               | Oral                     | Oral                                |                 | Not Reported |                |
|                                                                                         | Inexium (Esomeprazole) |                    |                    | S               | Oral                     | Oral                                |                 | Not Reported |                |

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|                |   |      |      |              |
|----------------|---|------|------|--------------|
| Amoxicillin    | S | Oral | Oral | Not Reported |
| Clarithromycin | S | Oral | Oral | Not Reported |
| Flagyl         | S | Oral | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Oct-2011              | 8222077       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024860           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Blood Sodium Decreased;<br>Generalised Tonic-Clonic<br>Seizure; Polydipsia;<br>Suicide Attempt; Teething | Escitalopram Oxalate    |              |            | S           | Oral         | 1 Df (1 Dosage Forms, 1<br>In 1 D), Oral |                 | Not Reported |
|                                                                                                          | Tramadol                |              |            | S           | Oral         | 100 Mg (50 Mg, 2 In 1 D),<br>Oral        |                 | Not Reported |
|                                                                                                          | Zyprexa                 |              |            | S           |              | 7.5 Mg (7.5 Mg, 1 In 1 D),               |                 | Not Reported |
|                                                                                                          | Haldol                  |              |            | S           |              | 5 Mg (5 Mg, 1 In 1 D)                    |                 | Not Reported |
|                                                                                                          | Oxazepam                |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                          | Vitamin B1              |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                          | Vitamin B6              |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                          | Nicobion (Nicotinamide) |              |            | C           |              |                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2011              | 6549166       | EXPEDITED (15-DAY) | N                  | RI, OT          | S08-USA-00249-01     |                      | 24 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                    | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Aggression; Agitation;<br>Akathisia; Anxiety;<br>Depression; Discomfort;<br>Ejaculation Failure;<br>Feeling Abnormal; Feeling<br>Of Despair; Impulsive<br>Behaviour; Irritability;<br>Mania; Nervousness;<br>Palpitations; Paranoia;<br>Personality Change;<br>Product Quality Issue;<br>Suicide Attempt | Lexapro                  |              |            | S           | Oral         | 20 Mg (10 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Sertraline Hydrochloride |              |            | S           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                          | Hypericum                |              |            | S           |              | 900 Mg (900 Mg, 1 In 1 D)        |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2011              | 8060601       | EXPEDITED (15-DAY) | N                  | HO              | 1000022129           |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u>            | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Fall; Mobility Decreased; Tremor | Escitalopram Oxalate       |              |            | S           | Oral         | Daily Dose Not Reported, Oral   |                 | Not Reported |
|                                  | Amiodarone Hydrochloride   |              |            | S           | Oral         | 200 Mg (200 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                  | Gluconorm (Repaglinide)    |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Asa (Acetylsalicylic Acid) |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Ativan                     |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Lasix                      |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Lipitor                    |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Metformin Hydrochloride    |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Micardis                   |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Oxazepam                   |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Plavix                     |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Synthroid                  |              |            | C           |              |                                 |                 | Not Reported |
|                                  | Vitamin D (Colecalciferol) |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2011              | 8228618       | EXPEDITED (15-DAY) | N                  | CA              | 1000024864           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Fallot'S Tetralogy; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Ventricular Septal Defect | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Oct-2011              | 8228703       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000024878           |                      | 76 YR      | Male       | DNK            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Hepatic Failure; | Lexapro        |              |            | S           | Oral         | (15 Mg),Oral       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                         |                                                                                 |                                |  |                                                                                                                       |                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------|--|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Agitation; Bacterial Infection; Cardiac Failure; Confusional State; Dehydration; Escherichia Infection; Hepatitis; Skin Ulcer; Staphylococcal Infection | Nexium<br>Seroquel<br>Augmentin<br>Metronidazole<br>Fusidic Acid<br><br>Rifadin | S<br>S<br>S<br>S<br>S<br><br>S |  | (40 Mg)<br>(25 Mg)<br>Oral<br>Oral<br>400 Mg,Oral<br>500 Mg (250 Mg, 2 In 1 D),Oral<br>600 Mg (300 Mg, 2 In 1 D),Oral | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br><br>Not Reported |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------|--|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Oct-2011              | 8232509       | EXPEDITED (15-DAY) | N                  | HO              | 1000024810           |                      | 37 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>          | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                       |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------|------------|----------------------|--------------|-------------------------------|-----------------|------------------------------------------------------------------|
| Drug Screen False Positive; Dysarthria; Encephalopathy; Impaired Driving Ability; Mental Status Changes; Off Label Use | Lexapro<br><br>Iron (Iron) (Iron)<br>Clonazepam<br>Armour Thyroid ( Thyroid) (Thyroid) |              |            | S<br><br>C<br>C<br>C | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported<br><br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2011              | 8233265       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022160           |                      | 35 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Dizziness; Dyspnoea; Haemorrhage; Hallucination; Heart Rate Increased; Muscle Spasms; Muscular Weakness; Nausea; Nervousness; Serotonin Syndrome; Syncope | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 Total), Oral |                 | Not Reported |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2011              | 8233317       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024976           |                      | 20 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Confusional State;<br>Depression; Feeling<br>Abnormal; Generalised<br>Tonic-Clonic Seizure | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                               |                 | Not Reported |
|                                                                                            | Zyprexa        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                               |                 | Not Reported |
|                                                                                            | Flunitrazepam  |              |            | S           | Oral         | 2 Mg (2 Mg, 1 In 1 D),<br>Oral; 5 Mg (5 Mg, 1 In 1<br>D), Oral |                 | Not Reported |
|                                                                                            | Brotizolam     |              |            | S           | Oral         | 0.25 Mg (0.25 Mg, 1 In 1<br>D), Oral                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Oct-2011              | 8233376       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024131           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Glaucoma              | Escitalopram Oxalate                  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Valium                                |              |            | C           |              |                    |                 | Not Reported |
|                       | Depamide (Valpromide)<br>(Valpromide) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2011              | 8170834       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024140           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angle Closure Glaucoma | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Nov-2011              | 8202154       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000024583           |                      | 47 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>     |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------------------|-----------------|----------------|----------------|
| Pneumonia                                                                                                                                                                                                                                                         | Escitalopram Oxalate                                                   |                    |                    | S               | Oral                 | Daily Dose Not Reported,Gradually Increased (1 In 1 D),Oral, 30 Mg (30 Mg 1 In 1 D) |                 | Not Reported   |                |
|                                                                                                                                                                                                                                                                   |                                                                        |                    |                    |                 | Oral                 | Daily Dose Not Reported,Gradually Increased (1 In 1 D),Oral, 30 Mg (30 Mg 1 In 1 D) |                 |                |                |
|                                                                                                                                                                                                                                                                   | Wellbutrin (Bupropion Hydrochloride)(Tablets)(Bupropion Hydrochloride) |                    |                    | C               |                      | Oral                                                                                |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                          | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 01-Nov-2011                                                                                                                                                                                                                                                       | 8235913                                                                | EXPEDITED (15-DAY) | Y                  | HO              | 2011MA015283         |                                                                                     | 67 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>     |                |
| Anhedonia; Autonomic Nervous System Imbalance; Bradykinesia; Decreased Appetite; Depressed Mood; Family Stress; Flat Affect; Insomnia; Parkinsonian Crisis; Psychotic Disorder; Reduced Facial Expression; Somatic Delusion; Suicidal Ideation; Thinking Abnormal | Risperidone                                                            |                    |                    | S               |                      | 0.5 Mg;Bid;                                                                         |                 | Actavis Totowa |                |
|                                                                                                                                                                                                                                                                   | Clonazepam                                                             |                    |                    | S               |                      |                                                                                     |                 | Not Reported   |                |
|                                                                                                                                                                                                                                                                   | Escitalopram Oxalate                                                   |                    |                    | S               |                      |                                                                                     |                 | Not Reported   |                |
|                                                                                                                                                                                                                                                                   | Lisinopril And Hydrochlorothiazide                                     |                    |                    | C               |                      |                                                                                     |                 | Not Reported   |                |
|                                                                                                                                                                                                                                                                   | Rosuvastatin                                                           |                    |                    | C               |                      |                                                                                     |                 | Not Reported   |                |
|                                                                                                                                                                                                                                                                   | Paroxetine Hydrochloride                                               |                    |                    | C               |                      |                                                                                     |                 | Not Reported   |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                          | <u>Case #</u>                                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 01-Nov-2011                                                                                                                                                                                                                                                       | 8236845                                                                | NON-EXPEDITED      | N                  | OT              | DSA_44544_2010       |                                                                                     | 44 YR           | Female         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                             | <u>Product</u>                                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|          |                  |   |                           |              |
|----------|------------------|---|---------------------------|--------------|
| Overdose | Ativan           | S | Not The Prescribed Amount | Not Reported |
|          | Neurontin        | S | Df                        | Not Reported |
|          | Oxycontin        | S | Df                        | Not Reported |
|          | Morphine Sulfate | S | Df                        | Not Reported |
|          | Diazepam         | S | Df                        | Not Reported |
|          | Vicodin          | S | Df                        | Not Reported |
|          | Soma             | S | Df                        | Not Reported |
|          | Parafon Forte    | S | Df                        | Not Reported |
|          | Zanaflex         | S | Df                        | Not Reported |
|          | Klonopin         | S | Df                        | Not Reported |
|          | Phenergan        | S | Df                        | Not Reported |
|          | Lexapro          | S | Df                        | Not Reported |
|          | Relafen          | S | Df                        | Not Reported |
|          | Lidoderm         | S | Df                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2011              | 8170813       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024137           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Narrow Anterior Chamber Angle | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Nov-2011              | 8171102       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024130           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Glaucoma; Narrow Anterior Chamber Angle; Ocular Hypertension | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------------|--------------------------|---------------------|-------------------------|
| 02-Nov-2011                                                       | 8200237                 | EXPEDITED (15-DAY)        | Y                           | LT                       | 1000024644                    |                                        | < 1 DAY                  | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Neonatal Respiratory Depression | Lexapro                 |                           |                             | S                        | Transplacental                | 20 Mg (20 Mg, 1 In 1 D),Transplacental |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2011                                                       | 8200639                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000024702                    |                                        |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injury; Victim Of Sexual Abuse                                    | Lexapro                 |                           |                             | S                        | Oral                          | Oral                                   |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2011                                                       | 8237125                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000025019                    |                                        |                          | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Loss Of Consciousness                                  | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Daily Dose Not Reported,Oral           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2011                                                       | 8242491                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000024135                    |                                        | 64 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Narrow Anterior Chamber Angle                                     | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | Oral                                   |                          | Not Reported        |                         |
|                                                                   | Lexomil (Bromazepam)    |                           |                             | C                        |                               |                                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Nov-2011                                                       | 8242417                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000025048                    |                                        | 26 YR                    | Female              | DNK                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Anxiety; Fatigue;         | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
| Flashback; Movement       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),    |                 | Not Reported |
| Disorder; Musculoskeletal |                      |              |            |             |              | Oral                        |                 |              |
| Stiffness; Obsessive      | Atarax               |              |            | C           |              |                             |                 | Not Reported |
| Thoughts                  | Opamox (Oxazepam)    |              |            | C           |              |                             |                 | Not Reported |
|                           | (Oxazepam)           |              |            |             |              |                             |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8118922       | EXPEDITED (15-DAY) | Y                  | HO              | 1000023006           |                      | 78 YR      | Female     | DNK            |

| <u>Preferred Term</u>      | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|---------------------------------|--------------|------------|-------------|--------------|----------------------------|-----------------|--------------|
| Amnesia; Blood Lactic      | Escitalopram Oxalate            |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),   |                 | Not Reported |
| Acid Increased; Blood Ph   |                                 |              |            |             |              | Oral                       |                 |              |
| Decreased; C-Reactive      | Valacyclovir Hydrochloride      |              |            | S           | Oral         | 500 Mg (500 Mg, 1 In 1 D), |                 | Not Reported |
| Protein Increased; Clonus; |                                 |              |            |             |              | Oral, 500 Mg (500 Mg, 1 In |                 |              |
| Convulsive Threshold       |                                 |              |            |             |              | 1 D), Oral                 |                 |              |
| Lowered; Drug Abuse;       | Zolmitriptan                    |              |            | S           | Oral         | (2.5 Mg, On Request),      |                 | Not Reported |
| Dyspnoea; Flatulence;      |                                 |              |            |             |              | Oral                       |                 |              |
| Headache; Infection; Loss  | Unspecified Ingredient          |              |            | S           | Oral         | 1 Mg (0.5 Mg, 2 In 1 D),   |                 | Not Reported |
| Of Consciousness; Partial  |                                 |              |            |             |              | Oral                       |                 |              |
| Seizures; Pco2 Increased;  |                                 |              |            |             |              |                            |                 |              |
| Pyrexia                    | Transilane (Herbals\Plantago    |              |            | C           |              |                            |                 | Not Reported |
|                            | Ovata Leaf)                     |              |            |             |              |                            |                 |              |
|                            | Seresta (Oxazepam)              |              |            | C           |              |                            |                 | Not Reported |
|                            | (Oxazepam)                      |              |            |             |              |                            |                 |              |
|                            | Lescol                          |              |            | C           |              |                            |                 | Not Reported |
|                            | Imovane (Zopiclone) (Zopiclone) |              |            | C           |              |                            |                 | Not Reported |
|                            | Cardensiel (Bisoprolol          |              |            | C           |              |                            |                 | Not Reported |
|                            | Fumarate) (Bisoprolol Fumarate) |              |            |             |              |                            |                 |              |
|                            | Actonel (Risedronate Sodium)    |              |            | C           |              |                            |                 | Not Reported |
|                            | (Risedronate Sodium)            |              |            |             |              |                            |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8176225       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DK-WATSON-2011-15919 |                      |            | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                              |                      |   |         |                 |              |
|------------------------------|----------------------|---|---------|-----------------|--------------|
| Coma; Mutism; Overdose;      | Baclofen             | S | Oral    | 1850 Mg, Single | Watson       |
| Respiratory Acidosis;        | Baclofen             | S | Unknown | 2500 Mg, Single | Watson       |
| Seizure; Sinus               | Mirtazapine          | S | Oral    | 230 Mg, Single  | Watson       |
| Bradycardia; Suicide Attempt | Escitalopram Oxalate | S | Oral    | 160 Mg, Single  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8179999       | EXPEDITED (15-DAY) | Y                  | OT              | 1000024251           |                      | 39 YR      | Female     | DNK            |

| <u>Preferred Term</u>        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Systemic Lupus Erythematosus | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                              | Thalidomide          |              |            | C           |              |                               |                 | Not Reported |
|                              | Nivaquine            |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8190093       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024312           |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| No Adverse Event      | Lexapro                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                       | Zyprexa                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral  |                 | Not Reported |
|                       | Trazodone Hydrochloride       |              |            | S           |              | 300 Mg (300 Mg, 1 In 1 D);     |                 | Not Reported |
|                       | Pristiq Extended Release      |              |            | S           | Oral         | (50 Mg, Every Other Dya), Oral |                 | Not Reported |
|                       | Benicar                       |              |            | C           |              |                                |                 | Not Reported |
|                       | Cymbalta                      |              |            | C           |              |                                |                 | Not Reported |
|                       | Levothroid                    |              |            | C           |              |                                |                 | Not Reported |
|                       | Omega 3 Fatty Acids           |              |            | C           |              |                                |                 | Not Reported |
|                       | Ativan                        |              |            | C           |              |                                |                 | Not Reported |
|                       | Spectravite (Multivitamins)   |              |            | C           |              |                                |                 | Not Reported |
|                       | Viatmin D3 (Colecalciferol)   |              |            | C           |              |                                |                 | Not Reported |
|                       | Deplin (Calcium Levomefolate) |              |            | C           |              |                                |                 | Not Reported |
|                       | Toprol XL                     |              |            | C           |              |                                |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                  | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Nov-2011                               | 8202779                                          | EXPEDITED (15-DAY) | Y                  | OT              | AU-ABBOTT-11P-008-0866676-00 |                      | 49 YR           | Male         | AUS            |
| <u>Preferred Term</u>                     | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Panic Attack; Suicidal Ideation           | Valproic Acid                                    |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                           | Lexapro                                          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Caffeine Citrate                                 |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Effexor Xr                                       |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Hypericum Perforatum                             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Lithium                                          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Abilify                                          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Alvesco                                          |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                           | Somac                                            |                    |                    | C               |                              |                      |                 | Not Reported |                |
|                                           | Chondroitin Sulfate (Bovine)\Glucosamine Sulfate |                    |                    | C               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Nov-2011                               | 8205552                                          | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2011259894     |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                     | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Vertigo; Vestibular Neuronitis | Cordarone                                        |                    |                    | S               | Oral                         | 200 Mg, 1x/Day       |                 | Pfizer       |                |
|                                           | Metformin Hydrochloride                          |                    |                    | S               | Oral                         | 700 Mg, 3x/Day       |                 | Not Reported |                |
|                                           | Gliclazide                                       |                    |                    | S               | Oral                         | 20 Mg, 3x/Day        |                 | Not Reported |                |
|                                           | Indapamide                                       |                    |                    | S               | Oral                         | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                           | Bisoprolol Fumarate                              |                    |                    | S               | Oral                         | 2 Df, 1x/Day         |                 | Not Reported |                |
|                                           | Previscan (Fluindione)                           |                    |                    | S               | Oral                         | 20 Mg, 1x/Day        |                 | Not Reported |                |
|                                           | Avodart                                          |                    |                    | S               | Oral                         | 0.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                           | Escitalopram Oxalate                             |                    |                    | S               | Oral                         | 1 Df, 1x/Day         |                 | Not Reported |                |
|                                           | Crestor                                          |                    |                    | S               | Oral                         | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                           | Crestor                                          |                    |                    | S               |                              | 10 Mg, 1x/Day        |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8229641       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20111011928 |                      |            | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>                                                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|---------------------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Confusional State; Fall | Durogesic                                                                                                           |              |            | S           | Transdermal  | One 12.5 Patch And One 25 Patch |                 | Not Reported |
|                         | Durogesic                                                                                                           |              |            | S           | Transdermal  |                                 |                 | Not Reported |
|                         | Durogesic                                                                                                           |              |            | S           | Transdermal  |                                 |                 | Not Reported |
|                         | Glucophage                                                                                                          |              |            | S           | Oral         | Initiated A Long Time Ago       |                 | Not Reported |
|                         | Candesartan Cilexetil                                                                                               |              |            | S           | Oral         | Initiated A Long Time Ago       |                 | Not Reported |
|                         | Oramorph Sr Sustained Release                                                                                       |              |            | S           | Oral         |                                 |                 | Not Reported |
|                         | Oramorph Sr Sustained Release                                                                                       |              |            | S           | Oral         | 8 Doses Three Times A Day       |                 | Not Reported |
|                         | Colchicine                                                                                                          |              |            | S           | Oral         | Initiated A Long Time Ago       |                 | Not Reported |
|                         | Prazepam                                                                                                            |              |            | S           | Oral         |                                 |                 | Not Reported |
|                         | Escitalopram Oxalate                                                                                                |              |            | S           | Oral         | Initiated A Long Time Ago       |                 | Not Reported |
|                         | Repaglinide                                                                                                         |              |            | C           |              | 1-1-1                           |                 | Not Reported |
|                         | Risperdal                                                                                                           |              |            | C           |              |                                 |                 | Not Reported |
|                         | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |              |            | C           |              | 1-1-1                           |                 | Not Reported |
|                         | Betahistine Hydrochloride                                                                                           |              |            | C           |              |                                 |                 | Not Reported |
|                         | Betahistine Hydrochloride                                                                                           |              |            | C           |              |                                 |                 | Not Reported |
|                         | Atacand                                                                                                             |              |            | C           |              |                                 |                 | Not Reported |
|                         | Acetaminophen                                                                                                       |              |            | C           |              |                                 |                 | Not Reported |
|                         | Econazole                                                                                                           |              |            | C           |              |                                 |                 | Not Reported |
|                         | Stilnox                                                                                                             |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Nov-2011              | 8239347       | EXPEDITED (15-DAY) | N                  | CA              | 1000025091           |                      |            | Female     | USA            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Foetal Exposure During Pregnancy; Spina Bifida Occulta | Lexapro                 |                           |                             | S                        | Transplacental                                  | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Nov-2011                                            | 8239600                 | EXPEDITED (15-DAY)        | Y                           | OT                       | 1000025069                                      |                               |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Gouty Arthritis                                        | Escitalopram Oxalate    |                           |                             | S                        |                                                 |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Nov-2011                                            | 8240320                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000025063                                      |                               | 77 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cardiac Valve Disease                                  | Escitalopram Oxalate    |                           |                             | S                        | Oral                                            | 5 Mg (5 Mg, 1 In 1 D), Oral   |                          | Not Reported        |                         |
|                                                        | Escitalopram Oxalate    |                           |                             | S                        | Oral                                            | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2011                                            | 8188449                 | EXPEDITED (15-DAY)        | Y                           | HO                       | TR-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR003288 |                               |                          | Unknown             | TUR                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Inappropriate Antidiuretic Hormone Secretion           | Alprazolam              |                           |                             | S                        | Unknown                                         | 0.5 Mg, Daily                 |                          | Par                 |                         |
|                                                        | Escitalopram Oxalate    |                           |                             | S                        | Unknown                                         | 10 Mg, Daily                  |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                      | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                   | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2011                                            | 8232540                 | EXPEDITED (15-DAY)        | Y                           | HO, LT, OT               | FR-PFIZER INC-<br>2011270641                    |                               | 94 YR                    | Male                | FRA                     |
| <a href="#">Preferred Term</a>                         | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                           | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Bradycardia; Cardiogenic                               | Ramipril                |                           |                             | S                        | Oral                                            | 2.5 Mg, Daily                 |                          | Pfizer              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|       |                      |   |      |                |              |
|-------|----------------------|---|------|----------------|--------------|
| Shock | Escitalopram Oxalate | S | Oral | Unk            | Not Reported |
|       | Bisoprolol Fumarate  | S | Oral | 2.5 Mg, 2x/Day | Not Reported |
|       | Digoxin              | S | Oral | 1 Df, Unk      | Not Reported |
|       | Aspirin              | C |      | Unk            | Not Reported |
|       | Lasix                | C |      | Unk            | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 07-Nov-2011              | 8232589       | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2011269175 |                      | 86 YR      | Female     | FRA            |

| <u>Preferred Term</u>                    | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Fall; Hypotension; Loss Of Consciousness | Inipomp                         |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                          | Urapidil                        |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                          | Amlodipine Besylate\Perindopril |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Escitalopram Oxalate            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                          | Plavix                          |              |            | C           | Oral         | 75 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2011              | 8233365       | DIRECT           | N                  | DE              |                      |                      | 63 YR      | Female     | USA            |

| <u>Preferred Term</u>                      | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Sudden Death;<br>Toxicologic Test Abnormal | Lexapro             |              |            | S           |              |                    |                 | Forest       |
|                                            | Hydrochlorothiazide |              |            | C           | Oral         |                    |                 | Not Reported |
|                                            | Neurontin           |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2011              | 8240719       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025196           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Mouth Haemorrhage;<br>Seizure; Tongue Biting | Escitalopram Oxalate |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

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|           |   |      |                                  |              |
|-----------|---|------|----------------------------------|--------------|
| Mianserin | S | Oral | 30 Mg (30 Mg, 1 In 1 D),<br>Oral | Not Reported |
|-----------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Nov-2011              | 8240861       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025118           |                      | 24 YR      | Female     | DNK            |

| <u>Preferred Term</u>             | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Seizure | Lexapro                    |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                   | Amoxapine                  |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Meilax (Ethyl Loflazepate) |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Dogmatyl (Sulpiride)       |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Amoban (Zopiclone)         |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Gaster (Omeprazole)        |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Metligine (Midodrine)      |              |            | C           |              |                                  |                 | Not Reported |
|                                   | Hydrochloride)             |              |            |             |              |                                  |                 |              |
|                                   | Inderal                    |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Nov-2011              | 8242895       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025142           |                      | 64 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Haematuria            | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Nov-2011              | 8243059       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025140           |                      | 88 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------|-----------------|--------------|
| Confusional State; Fall | Escitalopram Oxalate |              |            | S           |              | 10 Mg (10 Mg,1 In 1 D)                                         |                 | Not Reported |
|                         | Durogesic            |              |            | S           | Transdermal  | 0.3333 Dosage Form (1<br>Dosage Forms,1 In 3<br>D),Transdermal |                 | Not Reported |
|                         | Durogesic            |              |            | S           | Transdermal  | Transdermal                                                    |                 | Not Reported |

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|                                                                                         |   |      |                                                 |              |
|-----------------------------------------------------------------------------------------|---|------|-------------------------------------------------|--------------|
| Morphine Sulfate                                                                        | S | Oral | 24 Dosage Form (8 Dosage Forms, 3 In 1 D), Oral | Not Reported |
| Morphine Sulfate                                                                        | S | Oral | 24 Dosage Form (8 Dosage Forms, 3 In 1 D), Oral | Not Reported |
| Colchicine                                                                              | S | Oral | Oral                                            | Not Reported |
| Prazepam                                                                                | S | Oral | 3 Dosage Form (1 Dosage Form, 3 In 1 D), Oral   | Not Reported |
| Glucophage (Metformin Hydrochloride) (850 Milligram, Tablets) (Metformin Hydrochloride) | C |      |                                                 | Not Reported |
| Candesartan (Candesartan Cilexetil) (4 Milligram, Tablets) (Candesartan Cilexetil)      | C |      |                                                 | Not Reported |
| Novonorm (Repaglinide) (2 Milligram) (Repaglinide)                                      | C |      |                                                 | Not Reported |
| Transipeg (Macrogol)                                                                    | C |      |                                                 | Not Reported |
| Betaserc (Betahistine) (Betahistine)                                                    | C |      |                                                 | Not Reported |
| Doliprane (Paracetamol) (Paracetamol)                                                   | C |      |                                                 | Not Reported |
| Econazole (Econazole) (Econazole)                                                       | C |      |                                                 | Not Reported |
| Risperidone                                                                             | C |      |                                                 | Not Reported |
| Stilnox (Zolpidem Tartrate) (Zolpidem Tartrate)                                         | C |      |                                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2011              | 8237385        | EXPEDITED (15-DAY) | Y                  | OT              | ES-UCBSA-044757      |                      | 39 YR           | Female       | ESP            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea              | Keppra         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Ciprallex      |                    |                    | S               | Oral                 | Unknown Dose         |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 09-Nov-2011                                                                     | 8242675        | DIRECT           | N                  | HO, RI, OT      |                      |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Cholesterol Increased; Dysgeusia; Hypertension; Pyrexia; Weight Increased | Lexapro        |                  |                    | S               |                      | 10mg 1x Per Day      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                               | <u>Case #</u>                                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|-----------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 09-Nov-2011                                            | 8244797                                                   | EXPEDITED (15-DAY) | Y                  | HO              | 1000025246           |                           | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                  | <u>Product</u>                                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Dysphagia; Infection | Escitalopram Oxalate                                      |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D)    |                 | Not Reported |                |
|                                                        | Rasagiline Mesylate                                       |                    |                    | S               | Oral                 | 1 Mg (1 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                        | Zolpidem (Zolpidem) (Tablets)                             |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Stalevo (Stalevo) (Tablets ) (Stalevo)                    |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Movicol                                                   |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Acetylcystein Alternova (Acetylcysteine) (Acetylcysteine) |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Omeprazol Actavis (Omeprazole) (Tablets)                  |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Triobe (Hepagrisevit Forte-N /01079901/) (Tablets)        |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | (Hepagrisevit Forte-N /01079901/)                         |                    |                    |                 |                      |                           |                 |              |                |
|                                                        | Warfarin Sodium                                           |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | Stesold (Diazepam) (Tablets)                              |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | (Diazepam)                                                |                    |                    |                 |                      |                           |                 |              |                |
|                                                        | Madopark (Madopar) (Tablets)                              |                    |                    | C               |                      |                           |                 | Not Reported |                |
|                                                        | (Madopar)                                                 |                    |                    |                 |                      |                           |                 |              |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 09-Nov-2011                                                                                 | 8244812                                                                            | EXPEDITED (15-DAY) | Y                  | DS, HO, RI, OT  | 1000025271           |                                                                                                          | 70 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness;<br>Electrocardiogram Qt<br>Prolonged; Fall;<br>Progressive Supranuclear<br>Palsy | Escitalopram Oxalate                                                               |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1<br>D),Oral                                                                           |                 | Not Reported |                |
|                                                                                             | Ramipril (Ramipril) (Capsules)<br>(Ramipril)                                       |                    |                    | C               |                      |                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2011                                                                                 | 8244843                                                                            | EXPEDITED (15-DAY) | Y                  | DE              | 1000025231           |                                                                                                          | 53 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Asphyxia; Completed<br>Suicide; Hyperhidrosis                                               | Escitalopram Oxalate                                                               |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D) ;<br>10 Mg (10 Mg,1 In 1 D)<br>10 Mg (10 Mg,1 In 1 D) ;<br>10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |                |
|                                                                                             | Temesta (Lorazepam)<br>(Lorazepam)                                                 |                    |                    | C               |                      |                                                                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                    | <u>Case #</u>                                                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2011                                                                                 | 8244906                                                                            | EXPEDITED (15-DAY) | Y                  | HO              | 1000025241           |                                                                                                          | 85 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                       | <u>Product</u>                                                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hypotension;<br>Iatrogenic Injury; Loss Of<br>Consciousness                           | Escitalopram Oxalate                                                               |                    |                    | S               | Oral                 | Oral                                                                                                     |                 | Not Reported |                |
|                                                                                             | Urapidil                                                                           |                    |                    | S               | Oral                 | Oral                                                                                                     |                 | Not Reported |                |
|                                                                                             | Coveram                                                                            |                    |                    | S               | Oral                 | Oral                                                                                                     |                 | Not Reported |                |
|                                                                                             | Pantoprazole                                                                       |                    |                    | S               | Oral                 | Oral                                                                                                     |                 | Not Reported |                |
|                                                                                             | Plavix (Clopidogrel Bisulfate) (75<br>Milligram, Tablets) (Clopidogrel<br>Sulfate) |                    |                    | C               |                      |                                                                                                          |                 | Not Reported |                |
|                                                                                             | Omeprazole                                                                         |                    |                    | C               |                      |                                                                                                          |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 09-Nov-2011                                                                                      | 8244955              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025238           |                        | 54 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Feeling Abnormal; Impaired Work Ability; Joint Contracture; Memory Impairment; Migraine | Escitalopram Oxalate |                    |                    | S               | Oral                 | Oral                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2011                                                                                      | 8245024              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025205           |                        | 23 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Haematuria                                                                                       | Escitalopram Oxalate |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2011                                                                                      | 8245906              | DIRECT             | N                  | RI, OT          |                      |                        | 29 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour; Aggression; Agitation; Drug Ineffective; Mood Swings                         | Lexapro              |                    |                    | S               | Oral                 | 20mg 1xd Oral          |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Nov-2011                                                                                      | 8246219              | EXPEDITED (15-DAY) | Y                  | OT              | USA/USA/11/0021819   |                        |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Mania                                                                                | Augmentin            |                    |                    | S               | Oral                 | 875 Mg, 2 In 1 D, Oral |                 | Not Reported |                |
|                                                                                                  | Abilify              |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                  | Topamax              |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                  | Lexapro              |                    |                    | S               |                      |                        |                 | Not Reported |                |

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|                                                                                                                 | Seroquel                |                    |                    | S               |                              |                                           |                 |                 | Not Reported   |
|-----------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------------------------|-----------------|-----------------|----------------|
|                                                                                                                 | Vimpat                  |                    |                    | C               |                              |                                           |                 |                 | Not Reported   |
|                                                                                                                 | Metformin Hydrochloride |                    |                    | C               |                              |                                           |                 |                 | Not Reported   |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Nov-2011                                                                                                     | 8239736                 | NON-EXPEDITED      | N                  |                 | US-ASTRAZENECA-2011SE51937   |                                           | 59 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Alopecia; Drug Interaction                                                                                      | Lisinopril              |                    |                    | S               | Oral                         |                                           |                 | Zeneca          |                |
|                                                                                                                 | Toprol XL               |                    |                    | S               | Oral                         |                                           |                 | Not Reported    |                |
|                                                                                                                 | Lexapro                 |                    |                    | S               | Oral                         |                                           |                 | Not Reported    |                |
|                                                                                                                 | Simvastatin             |                    |                    | S               | Unknown                      |                                           |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Nov-2011                                                                                                     | 8239933                 | EXPEDITED (15-DAY) | Y                  | HO              | DE-GLAXOSMITHKLINE-D0073294A |                                           | 36 YR           | Female          | DEU            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Somnolence; Sopor; Suicide Attempt; Vomiting                                                                    | Lamictal                |                    |                    | S               | Oral                         |                                           | 1 DAY           | Glaxosmithkline |                |
|                                                                                                                 | Trimipramine Maleate    |                    |                    | S               | Oral                         |                                           | 1 DAY           | Not Reported    |                |
|                                                                                                                 | Ciprallex               |                    |                    | S               | Oral                         | 20mg See Dosage Text                      | 1 DAY           | Not Reported    |                |
|                                                                                                                 | Tavor (Lorazepam)       |                    |                    | S               | Oral                         |                                           | 1 DAY           | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                        | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Nov-2011                                                                                                     | 8246236                 | EXPEDITED (15-DAY) | Y                  | LT              | 1000025167                   |                                           | 94 YR           | Male            | DNK            |
| <u>Preferred Term</u>                                                                                           | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>      |                |
| Acute Kidney Injury; Bradycardia; Cardioactive Drug Level Decreased; Cardiogenic Shock; Hyperkalaemia; Overdose | Escitalopram Oxalate    |                    |                    | S               | Oral                         | Oral                                      |                 | Not Reported    |                |
|                                                                                                                 | Bisoprolol Fumarate     |                    |                    | S               | Oral                         | 5 Mg (2.5 Mg, 2 In 1 D),Oral              |                 | Not Reported    |                |
|                                                                                                                 | Digoxin                 |                    |                    | S               | Oral                         | 0.8571 Dosage Form (1 Dosage Forms,6 In 1 |                 | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |   |      |                                                              |              |
|---------------------------------------|---|------|--------------------------------------------------------------|--------------|
| Ramipril                              | S | Oral | Wk),Oral<br>1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),Oral | Not Reported |
| Kardegic (Acetylsalicylate<br>Lysine) | C |      |                                                              | Not Reported |
| Furosemide                            | C |      |                                                              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Nov-2011              | 8241010       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-TEVA-308374USA    |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>      | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|-------------------|--------------------|-----------------|--------------|
| Cardiogenic Shock;      | Atenolol             |              |            | S           |                   |                    |                 | Not Reported |
| Hypoglycaemia;          | Quinapril            |              |            | S           |                   |                    |                 | Not Reported |
| Hypokalaemia; Overdose; | Venlafaxine          |              |            | S           |                   |                    |                 | Not Reported |
| Overdose                | Amitriptyline        |              |            | S           |                   |                    |                 | Not Reported |
|                         | Escitalopram Oxalate |              |            | S           |                   |                    |                 | Not Reported |
|                         | Insulin Nos          |              |            | S           | Intravenous bolus |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2011              | 7962169       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000020555           |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Colitis Ulcerative; Gastric<br>Dilatation; Haemorrhoids; | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
| Off Label Use                                            | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Nov-2011              | 8053844       | EXPEDITED (15-DAY) | Y                  | CA, DS          | 1000021972           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|-------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Attention                                        | Citalopram Hydrobromide |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |
| Deficit/Hyperactivity<br>Disorder; Developmental | Escitalopram Oxalate    |              |            | S           | Transplacental | See Image          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Delay; Disturbance In  
Social Behaviour;  
Maternal Drugs Affecting  
Foetus; Speech Disorder  
Developmental

Transplacental  
Transplacental

See Image  
See Image

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Nov-2011                       | 8200250                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000024627                    |                               | 36 YR               | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                | <a href="#">Product</a>                                     | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>          | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------|-------------------------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|--------------------------------------|--------------------------|---------------------|
| Abortion Missed; Maternal<br>Exposure During<br>Pregnancy;<br>Oligohydramnios | Escitalopram Oxalate                                        |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral          |                          | Not Reported        |
|                                                                               | Trazodone Hydrochloride                                     |                       |                     | S                    | Oral                  | 12.5 Mg (12.5 Mg, 1 In 1<br>D), Oral |                          | Not Reported        |
|                                                                               | Folic Acid                                                  |                       |                     | C                    |                       |                                      |                          | Not Reported        |
|                                                                               | L-Thyroxin (Levothyroxine<br>Sodium) (Levothyroxine Sodium) |                       |                     | C                    |                       |                                      |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Nov-2011                       | 8202211                | EXPEDITED (15-DAY)        | Y                           | HO, RI, OT               | 1000024629                    |                               |                     | Unknown             | DNK                     |

| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Caesarean Section;<br>Pregnancy; Premature<br>Baby | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 5 Mg (5 Mg, 1 In 1 D), Oral |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 14-Nov-2011                       | 8210958                | EXPEDITED (15-DAY)        | Y                           | CA, HO                   | 1000024638                    |                               | < 1 DAY             | Female              | DNK                     |

| <a href="#">Preferred Term</a>                                                                                                            | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>              | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|------------------------------------------|--------------------------|---------------------|
| Caesarean Section;<br>Developmental Hip<br>Dysplasia; Foetal Growth<br>Restriction; Maternal<br>Drugs Affecting Foetus;<br>Premature Baby | Escitalopram Oxalate    |                       |                     | S                    | Transplacental        | 5 Mg (5 Mg, 1 In 1 D),<br>Transplacental |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------------------------|-----------------|--------------|----------------|
| 14-Nov-2011                                                                                                                    | 8224781                                                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000024747           |                                                                 | 19 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Aphasia; Dysphagia;<br>Neuroleptic Malignant<br>Syndrome; Pneumothorax;<br>Respiratory Distress                                | Escitalopram Oxalate                                              |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Risperidone                                                       |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Olanzapine                                                        |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Lithium Carbonate                                                 |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Biperiden Hydrochloride                                           |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Lorazepam                                                         |                    |                    | S               |                      |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2011                                                                                                                    | 8254323                                                           | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025141           |                                                                 | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block Left;<br>Electrocardiogram Qt<br>Prolonged; Ventricular<br>Tachycardia                                     | Lexapro                                                           |                    |                    | S               |                      | (20 Dosage Forms)                                               |                 | Not Reported |                |
|                                                                                                                                | Multaq                                                            |                    |                    | S               | Oral                 | 800 Mg (400 Mg, 2 In 1 D), Oral                                 |                 | Not Reported |                |
|                                                                                                                                | Aspirin                                                           |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Xanax                                                             |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Aciphex (Rabeprazole Sodium)(Rabeprazole Sodium)                  |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Dabigatran Etexilate (Dabigatran Etexilate)(Dabigatran Etexilate) |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
|                                                                                                                                | Metoprolol Succinate                                              |                    |                    | C               |                      |                                                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Nov-2011                                                                                                                    | 8254608                                                           | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000025257           |                                                                 | 40 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Cellulitis;<br>Constipation; Flatulence;<br>Hyperhidrosis; Irritable<br>Bowel Syndrome;<br>Oedema; Vision Blurred; | Lexapro                                                           |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                |                                                                   |                    |                    |                 | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D)       |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weight Decreased

D), Oral

Synthroid (Levothyroxine Sodium) (Levothyroxine Sodium)  
Wellbutrin (Bupropion Hydrochloride) (Bupropion Hydrochloride)

C

C

Not Reported

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 15-Nov-2011              | 8245223       | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16219719 |                      | 27 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------|-----------------|--------------|
| Head Injury; Increased Appetite; Logorrhoea; Loss Of Consciousness; Pollakiuria; Psychomotor Hyperactivity | Abilify        |              |            | S           | Oral         | Continued In 2006; Stopped And Restarted On 07oct2011(10-15mg) Also Taken 30mg |                 | Not Reported |
|                                                                                                            | Abilify        |              |            | S           | Oral         | Continued In 2006; Stopped And Restarted On 07oct2011(10-15mg) Also Taken 30mg |                 | Not Reported |
|                                                                                                            | Lexapro        |              |            | S           |              | Duration:7years Ago                                                            |                 | Not Reported |
|                                                                                                            | Lexapro        |              |            | S           |              | Duration:7years Ago                                                            |                 | Not Reported |
|                                                                                                            | Gabitril       |              |            | S           |              |                                                                                |                 | Not Reported |
|                                                                                                            | Gabitril       |              |            | S           |              |                                                                                |                 | Not Reported |
|                                                                                                            | Ibuprofen      |              |            | C           |              |                                                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2011              | 8245456       | EXPEDITED (15-DAY) | N                  | HO, OT          | PHEH2011US009069     |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder; Dehydration; Fall; Infection; Migraine; Urinary Tract Infection | Loratadine     |              |            | S           |              | 10 Mg, Unk         |                 | Novartis     |
|                                                                                   | Gilenya        |              |            | S           | Oral         | 0.5 Mg, Qd         |                 | Not Reported |
|                                                                                   | Nitrofurantoin |              |            | S           |              | 100 Mg, Bid        |                 | Not Reported |
|                                                                                   | Lexapro        |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |                               |              |
|-----------|---|-------------------------------|--------------|
| Lyrica    | S | 100 Mg, Tid                   | Not Reported |
| Adderall  | S | 10 Mg, Bid                    | Not Reported |
| Ambien    | S | 5 Mg, Qd                      | Not Reported |
| Singulair | S | 10 Mg, Unk                    | Not Reported |
| Mirapex   | S | 0.75 Mg, (0.25 Mg And 0.5 Mg) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Nov-2011              | 8257182       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025452           |                      | 36 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypertonia;           | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
| Hypervigilance;       | Zoloft               |              |            | S           |              |                    |                 | Not Reported |
| Respiratory Disorder; | Zyprexa              |              |            | C           |              |                    |                 | Not Reported |
| Seizure; Tachycardia  |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2011              | 8201994       | EXPEDITED (15-DAY) | Y                  | CA, HO          | 1000024659           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|------------------------------------------------------------------------------|-----------------|--------------|
| Caesarean Section; Foetal Distress Syndrome; Hyperinsulinism; Hypoglycaemia Neonatal; Macrocephaly; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Periventricular Leukomalacia; Premature Baby | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental |                 | Not Reported |
|                                                                                                                                                                                                             |                      |              |            |             | Transplacental | 10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental |                 |              |
|                                                                                                                                                                                                             |                      |              |            |             | Transplacental | 10 Mg (10 Mg, 1 In 1 D), Transplacental 5 Mg (5 Mg, 1 In 1 D) Transplacental |                 |              |
|                                                                                                                                                                                                             | Bromazepam           |              |            | S           | Transplacental | 3 Mg (1.5 Mg, 2 In 1 D), Transplacental 1.5 Mg (1.5 Mg, 1 In 1 D),           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transplacental  
Transplacental  
3 Mg (1.5 Mg, 2 In 1 D),  
Transplacental 1.5 Mg (1.5  
Mg, 1 In 1 D),  
Transplacental

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 16-Nov-2011                                                                                           | 8237124               | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025051                                      |                                                                                           | 43 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Energy Increased;<br>Hypersexuality; Libido<br>Increased; Middle<br>Insomnia; Weight<br>Decreased     | Escitalopram Oxalate  |                    |                    | S               | Oral                                            | 5;10 Mg (5; 10 Mg,1 In 1<br>D), Oral                                                      |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate  |                    |                    | S               | Oral                                            | 20;5 Mg (20;5 Mg, 1 In 1<br>D), Oral                                                      |                 | Not Reported |                |
|                                                                                                       | Zopiclone (Zopiclone) |                    |                    | C               |                                                 |                                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2011                                                                                           | 8247068               | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16220139 |                                                                                           |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Amenorrhoea; Anxiety;<br>Menopausal Symptoms;<br>Sjogren'S Syndrome;<br>Swelling; Weight<br>Increased | Abilify               |                    |                    | S               |                                                 | Duration Of Therapy:About<br>5 Yrs Dose Reduced To<br>2.5mg/D Dose Increased<br>To 15mg/D |                 | Not Reported |                |
|                                                                                                       | Lexapro               |                    |                    | S               |                                                 |                                                                                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                              | <u>Case #</u>         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                                      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2011                                                                                           | 8248000               | EXPEDITED (15-DAY) | N                  | OT              | CA-ASTRAZENECA-<br>2011SE67517                  |                                                                                           | 56 YR           | Male         | CAN            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                                        | <u>Duration</u> | <u>Mfr</u>   |                |
| Constipation; Depression;                                                                             | Seroquel              |                    |                    | S               | Oral                                            |                                                                                           | 2 YR            | Zeneca       |                |
| Dizziness; Dry Mouth;                                                                                 | Clonazepam            |                    |                    | S               | Oral                                            |                                                                                           | 2 YR            | Not Reported |                |
| Erection Increased;                                                                                   | Ciprallex             |                    |                    | S               | Oral                                            |                                                                                           |                 | Not Reported |                |
| Fatigue; Increased                                                                                    |                       |                    |                    |                 |                                                 |                                                                                           |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                        |                                                                      |                  |                              |      |                                                              |
|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|------------------|------------------------------|------|--------------------------------------------------------------|
| Appetite; Muscular Weakness; Nausea; Somnolence; Suicidal Ideation; Tinnitus; Tremor; Weight Increased | Wellbutrin XL<br>Echinacea<br>Horse Chestnut Extract<br>Milk Thistle | S<br>C<br>C<br>C | Oral<br>Oral<br>Oral<br>Oral | 3 YR | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|------------------|------------------------------|------|--------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2011              | 8258391       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025369           |                      | 59 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                 | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Adrenal Neoplasm; Aortic Valve Calcification; Aortic Valve Incompetence; Diarrhoea; Ejection Fraction Decreased; Hyperkinetic Heart Syndrome; Iatrogenic Injury; Left Atrial Dilatation; Left Ventricular Hypertrophy | Escitalopram Oxalate                        |              |            | S           | Oral         | Oral                                           |                 | Not Reported |
|                                                                                                                                                                                                                       | Benfluorex Hydrochloride                    |              |            | S           | Oral         | 300 Mg (300 Mg, 1 In 1 D), Oral                |                 | Not Reported |
|                                                                                                                                                                                                                       | Fenfluramine                                |              |            | S           | Oral         | 2 Dosage Form (2 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                       | Dexfenfluramine Hydrochloride               |              |            | S           |              | 2 Dosage Form (2 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                       | Dihydroergotamine Mesylate                  |              |            | S           | Oral         | Oral                                           |                 | Not Reported |
|                                                                                                                                                                                                                       | Boniva                                      |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Arava                                       |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Prednisone                                  |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Biguanide (Biguanide)                       |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Beta Blocking Agents (Beta Blocking Agents) |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Sartan (Losartan Potassium)                 |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Diuretic (Diuretics)                        |              |            | C           |              |                                                |                 | Not Reported |
|                                                                                                                                                                                                                       | Januvia                                     |              |            | C           |              |                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Nov-2011              | 8258426       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025368           |                      | 39 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Amenorrhoea           | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, In 1 D), Oral |                 | Not Reported |
|                       | Levetiracetam        |              |            | S           | Oral         | 1000 Mg (500 Mg, 2 In 1     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

D), Oral

| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 16-Nov-2011                                                                                                                                                          | 8258709                                    | EXPEDITED (15-DAY) | N                  | CA              | 1000025339           |                               | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Stenosis; Bicuspid Aortic Valve; Congenital Hydrocephalus; Maternal Drugs Affecting Foetus; Patent Ductus Arteriosus; Spina Bifida; Ventricular Septal Defect | Lexapro                                    |                    |                    | S               | Transplacental       | Transplacental                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2011                                                                                                                                                          | 8258728                                    | EXPEDITED (15-DAY) | N                  | CA              | 1000025347           |                               | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Heart Disease Congenital; Maternal Drugs Affecting Foetus; Talipes                                                                                                   | Lexapro                                    |                    |                    | S               | Transplacental       | Transplacental                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Nov-2011                                                                                                                                                          | 8259144                                    | EXPEDITED (15-DAY) | Y                  | DS              | 1000025373           |                               | 40 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Incontinence; Diarrhoea                                                                                                                                         | Escitalopram Oxalate                       |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                      | Betolvex (Cyanocobalamin) (Cyanocobalamin) |                    |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2011                                                                                                                                                          | 8169158                                    | EXPEDITED (15-DAY) | Y                  | HO              | 1000023889           |                               | 21 YR           | Female       | DNK            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| Intentional Overdose;<br>Suicide Attempt | Lexapro                                |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                          | Paxil                                  |                    |                    | S               | Oral                         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                          | Constan (Alprazolam)<br>(Alprazolam)   |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Nov-2011                              | 8249189                                | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-<br>2011277847 |                                  | 46 YR           | Male         | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Valve                             | Effexor                                |                    |                    | S               | Oral                         | Unk                              |                 | Pfizer       |                |
| Incompetence; Cardiac                    | Benfluorex Hydrochloride               |                    |                    | S               | Oral                         | 150 Mg, 3x/Day                   |                 | Not Reported |                |
| Murmur; Mitral Valve                     | Paroxetine Hydrochloride               |                    |                    | S               | Oral                         | Unk                              |                 | Not Reported |                |
| Incompetence; Tricuspid                  | Escitalopram Oxalate                   |                    |                    | S               | Oral                         |                                  |                 | Not Reported |                |
| Valve Incompetence                       |                                        |                    |                    |                 |                              |                                  |                 |              |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2011                              | 8174965                                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024027                   |                                  |                 | Unknown      | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Fall;                        | Escitalopram Oxalate                   |                    |                    | S               | Oral                         | 20 Mg (20 Mg,1 In 1<br>D),Oral   |                 | Not Reported |                |
| Generalised Tonic-Clonic                 | Lisinopril                             |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| Seizure; Hyperlipidaemia;                | Metoprolol Succinate                   |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| Hypertension; Nightmare;                 | Lovastatin                             |                    |                    | C               |                              |                                  |                 | Not Reported |                |
| Red Blood Cell Count                     | (Lovastatin)(Lovastatin)               |                    |                    |                 |                              |                                  |                 |              |                |
| Decreased; Seizure                       | Benadryl                               |                    |                    | C               |                              |                                  |                 | Not Reported |                |
|                                          | (Diphenhydramine)(Diphenhydra<br>mine) |                    |                    |                 |                              |                                  |                 |              |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Nov-2011                              | 8264038                                | EXPEDITED (15-DAY) | Y                  | DE              | 1000025527                   |                                  |                 | Male         | DNK            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------------------|-----------------|-----------------|----------------|
| Accident At Work; Fall                                                                                                 | Escitalopram Oxalate                          |                    |                    | S               |                                      |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 18-Nov-2011                                                                                                            | 8264066                                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025502                           |                                  |                 | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Confusional State;<br>Headache; Muscle<br>Twitching                                                                    | Lexapro                                       |                    |                    | S               | Oral                                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported    |                |
|                                                                                                                        | Etizolam                                      |                    |                    | S               | Oral                                 | Oral                             |                 | Not Reported    |                |
|                                                                                                                        | Tandospirone (Tandospirone)<br>(Tandospirone) |                    |                    | C               |                                      |                                  |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 21-Nov-2011                                                                                                            | 8256930                                       | EXPEDITED (15-DAY) | Y                  | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0708135A |                                  | 87 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>      |                |
| Akathisia; Confusional<br>State; Decreased<br>Appetite; Dehydration;<br>Hepatitis; Hypernatraemia;<br>Thrombocytopenia | Augmentin                                     |                    |                    | S               | Oral                                 | 2g Per Day                       | 5 DAY           | Glaxosmithkline |                |
|                                                                                                                        | Allopurinol                                   |                    |                    | S               | Oral                                 |                                  |                 | Unknown         |                |
|                                                                                                                        | Simvastatin                                   |                    |                    | S               | Oral                                 |                                  |                 | Unknown         |                |
|                                                                                                                        | Escitalopram Oxalate                          |                    |                    | S               | Oral                                 | 15mg Per Day                     |                 | Unknown         |                |
|                                                                                                                        | Omeprazole                                    |                    |                    | S               | Oral                                 |                                  |                 | Unknown         |                |
|                                                                                                                        | Memantine                                     |                    |                    | S               | Oral                                 | 20mg Per Day                     |                 | Unknown         |                |
|                                                                                                                        | Exelon                                        |                    |                    | S               | Transdermal                          | 4.6mg Per Day                    |                 | Unknown         |                |
|                                                                                                                        | Isosorbide Dinitrate                          |                    |                    | C               | Unknown                              | 1unit Per Day                    |                 | Unknown         |                |
|                                                                                                                        | Amlodipine Besylate                           |                    |                    | C               | Unknown                              |                                  |                 | Unknown         |                |
| Sectral                                                                                                                |                                               |                    | C                  | Unknown         |                                      |                                  | Unknown         |                 |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 21-Nov-2011                                                                                                            | 8266280                                       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | AMIT20110068                         |                                  | 65 YR           | Female          | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anoxia; Cardiac Arrest;<br>Cardiogenic Shock;<br>Confusional State;<br>Hypokalaemia;<br>Hypoperfusion; Injury;<br>Overdose; Pulseless<br>Electrical Activity | Amitriptyline Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                              | Venlafaxine Hydrochloride   |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                              | Atenolol (Atenolol)         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                              | Escitalopram Oxalate        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                              | Escitalopram Oxalate        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                                                                              | Quinapril Hydrochloride     |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2011              | 8266864       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025501           |                      | 45 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>                                           | <u>Product</u>                                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                         | <u>Dosage Text</u>                                                                     | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|--------------------------------------------------------------|--------------|------------|-------------|--------------------------------------|----------------------------------------------------------------------------------------|-----------------|--------------|
| Disturbance In Attention;<br>Laryngeal Oedema;<br>Lichen Planus | Escitalopram Oxalate                                         |              |            | S           | Oral                                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                                       |                 | Not Reported |
|                                                                 | Lamictal                                                     |              |            | S           | Oral<br>Oral<br>Oral<br>Oral<br>Oral | See Image Oral<br>See Image Oral<br>See Image Oral<br>See Image Oral<br>See Image Oral |                 | Not Reported |
|                                                                 | Valdoxan (Agomelatine)                                       |              |            | C           |                                      |                                                                                        |                 | Not Reported |
|                                                                 | (Agomelatine)                                                |              |            | C           |                                      |                                                                                        |                 | Not Reported |
|                                                                 | Multiple Vitamins (Multiple<br>Vitamins) (Multiple Vitamins) |              |            |             |                                      |                                                                                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Nov-2011              | 8280047       | NON-EXPEDITED    | N                  |                 | 1000023867           |                      | 75 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Agitation;<br>Diarrhoea | Viibryd        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |
|                                                                  | Lexapro        |              |            | S           | Oral         | 20 Mg, (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                  | Ambien         |              |            | S           |              |                                   |                 | Not Reported |

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|                                              |   |              |
|----------------------------------------------|---|--------------|
| Crestor                                      | C | Not Reported |
| Gabapentin (Gabapentin)                      | C | Not Reported |
| Metformin Hydrochloride                      | C | Not Reported |
| Lorazepam                                    | C | Not Reported |
| Benicar                                      | C | Not Reported |
| Enalapril Maleate                            | C | Not Reported |
| Hydrochlorothiazide<br>(Hydrochlorothiazide) | C | Not Reported |
| Acetaminophen                                | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2011              | 7862861       | EXPEDITED (15-DAY) | Y                  | DE, HO          | PHHY2011FR21042      |                      | 87 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour; Atrial Fibrillation; Confusional State; Decreased Appetite; Dehydration; Delirium; Diet Refusal; Hepatitis; Hypernatraemia; Leukocytosis; Pneumonia; Productive Cough; Psychomotor Hyperactivity; Pulmonary Embolism; Thrombocytopenia | Allopurinol          |              |            | S           |              | Unk                |                 | Novartis     |
|                                                                                                                                                                                                                                                            | Exelon Patch         |              |            | S           | Transdermal  | 4.6 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Exelon Patch         |              |            | S           | Transdermal  | 4.6 Mg, Qd         |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Omeprazole           |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Simvastatin          |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Simvastatin          |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Augmentine           |              |            | S           |              | 2 G, Daily         | 5 DAY           | Not Reported |
|                                                                                                                                                                                                                                                            | Escitalopram Oxalate |              |            | S           |              | 15 Mg Daily        |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Escitalopram Oxalate |              |            | S           |              | 15 Mg Daily        |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Ebixa                |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Ebixa                |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Isosorbide Dinitrate |              |            | C           | Oral         | 1 Df, Qd           |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Isosorbide Dinitrate |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Sectral              |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                            | Amlodipine Besylate  |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2011              | 8192625       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024486           |                      | 32 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u> | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Seizure               | Lexapro                         |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                       | Amoxan                          |              |            | C           |              |                         |                 | Not Reported |
|                       | (Amoxapine)(Amoxapine)          |              |            |             |              |                         |                 |              |
|                       | Lexotan (Bromazepam)            |              |            | C           |              |                         |                 | Not Reported |
|                       | (Tablets) (Bromazepam)          |              |            |             |              |                         |                 |              |
|                       | Flunitrazepam (Flunitrazepam)   |              |            | C           |              |                         |                 | Not Reported |
|                       | (Flunitrazepam)                 |              |            |             |              |                         |                 |              |
|                       | Irribow (Ramosetron             |              |            | C           |              |                         |                 | Not Reported |
|                       | Hydrochloride)(Ramosetron       |              |            |             |              |                         |                 |              |
|                       | Hydrochloride)                  |              |            |             |              |                         |                 |              |
|                       | Benzalin                        |              |            | C           |              |                         |                 | Not Reported |
|                       | (Nitrazepam)(Nitrazepam)        |              |            |             |              |                         |                 |              |
|                       | Ravona (Pentobarbital           |              |            | C           |              |                         |                 | Not Reported |
|                       | Calcium)(Pentobarbital Calcium) |              |            |             |              |                         |                 |              |
|                       | Cymbalta                        |              |            | C           |              |                         |                 | Not Reported |
|                       | Seniran (Bromazepam)            |              |            | C           |              |                         |                 | Not Reported |
|                       | (Bromazepam)                    |              |            |             |              |                         |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Nov-2011              | 8193979       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024257           |                      | 86 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Blood Electrolytes Decreased; Blood Potassium Decreased; Blood Sodium Decreased; Diarrhoea; Fall; Nausea | Escitalopram Oxalate         |              |            | S           | Oral         | 5 Mg (5 Mg, 1in 1 D),Oral,      |                 | Not Reported |
|                                                                                                          |                              |              |            |             | Oral         | 2.5 Mg (2.5 Mg, 1 ,In 1 D),Oral |                 |              |
|                                                                                                          | Indapamide                   |              |            | S           | Oral         | 5 Mg (5 Mg, 1in 1 D),Oral,      |                 | Not Reported |
|                                                                                                          |                              |              |            |             |              | 2.5 Mg (2.5 Mg, 1 ,In 1 D),Oral |                 |              |
|                                                                                                          | Ativan (Lorazepam) (Tablets) |              |            | C           |              | (1.25 Mg),Oral                  |                 | Not Reported |
|                                                                                                          | (Lorazepam)                  |              |            |             |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 22-Nov-2011              | 8260189       | EXPEDITED (15-DAY) |                    | HO, LT          | US-ARROW GEN-2011-19493 |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |                           |   |     |              |
|----------------------|---------------------------|---|-----|--------------|
| Cardiogenic Shock;   | Quinapril Hydrochloride   | S | Unk | Watson       |
| Overdose; Pulseless  | Citalopram Hydrobromide   | S | Unk | Watson       |
| Electrical Activity; | Atenolol                  | S | Unk | Watson       |
| Respiratory Arrest   | Venlafaxine Hydrochloride | S | Unk | Not Reported |
|                      | Amitriptyline             | S | Unk | Not Reported |
|                      | Escitalopram Oxalate      | S | Unk | Not Reported |

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
| 22-Nov-2011                             | 8268868        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025531           |                               | 25 YR           | Male         | DNK            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Seizure | Lexapro        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Nov-2011                                                                                                                                                                                                                              | 8269585                 | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2011MA016244         |                      | 77 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ataxia; Decreased Appetite; Delusion; Depression; Drug Interaction; Essential Tremor; Gait Disturbance; General Physical Health Deterioration; Hypotonia; Insomnia; Irritability; Psychotic Disorder; Toxicity To Various Agents; Tremor | Carbamazepine           |                    |                    | S               |                      | 200 Mg;Q12hr         |                 | Purepac      |                |
|                                                                                                                                                                                                                                          | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg;Qd             |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Trazodone Hydrochloride |                    |                    | S               |                      | 100 Mg;Qd            |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Amiodarone              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Glibenclamide           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                          | Omeprazole              |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 23-Nov-2011              | 8259909        | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000025488           |                      | 65 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                      |                             |   |              |
|--------------------------------------------------------------------------------------|-----------------------------|---|--------------|
| Balance Disorder; Cardiac Arrest; Confusional State; Hypokalaemia; Hypoxic-Ischaemic | Escitalopram Oxalate        | S | Not Reported |
| Encephalopathy; Overdose; Pulseless Electrical Activity                              | Amitriptyline Hydrochloride | S | Not Reported |
|                                                                                      | Atenolol (Atenolol)         | S | Not Reported |
|                                                                                      | Venlafaxine                 | S | Not Reported |
|                                                                                      | Quinapril Hydrochloride     | S | Not Reported |

| <u>FDA Received Date</u>        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
| 23-Nov-2011                     | 8262297                     | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-2011283133 |                               | 16 YR           | Female       | USA            |
| <u>Preferred Term</u>           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Epistaxis                       | Revatio                     |                    |                    | S               |                          | Unk                           |                 | Pfizer       |                |
|                                 | Tyvaso                      |                    |                    | S               |                          | 216 Mcg (54 Mcg, 4 In 1 D)    |                 | Not Reported |                |
|                                 | Lexapro                     |                    |                    | S               |                          | Unk                           |                 | Not Reported |                |
|                                 | Tracleer                    |                    |                    | C               |                          | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2011                     | 8270838                     | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025583               |                               | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness                       | Lexapro                     |                    |                    | S               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>        | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Nov-2011                     | 8274010                     | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000025647               |                               | 77 YR           | Female       | DNK            |
| <u>Preferred Term</u>           | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dehydration; Torsade De Pointes | Escitalopram Oxalate        |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                 | Digitoxin                   |                    |                    | S               |                          |                               |                 | Not Reported |                |
|                                 | Loesnesium (Magnosolv)      |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                 | Beloc Zok Mite (Metoprolol) |                    |                    | C               |                          |                               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |   |              |
|---------------------------------------------------|---|--------------|
| Succinate) (Metoprolol Succinate)                 |   |              |
| Aldactone                                         | C | Not Reported |
| Torem Cor (Torasemide) (Torasemide)               | C | Not Reported |
| Enoxaparin Sodium                                 | C | Not Reported |
| Cefuroxim (Cefuroxime Sodium) (Cefuroxime Sodium) | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Nov-2011              | 8274138       | EXPEDITED (15-DAY) | Y                  | RI              | 1000025643           |                      |            | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Metrorrhagia          | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       |                      |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Nov-2011              | 8222200       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024832           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Legal Problem; Road Traffic Accident | Escitalopram Oxalate |              |            | S           | Oral         | (10 Mg),Oral       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Nov-2011              | 8270159       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025619           |                      | 46 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                                | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------|--------------------------|--------------|------------|-------------|--------------|-------------------------------------------------|-----------------|--------------|
| Cardiac Murmur; Ejection Fraction Decreased; Mitral Valve Incompetence; Tricuspid Valve Incompetence | Escitalopram Oxalate     |              |            | S           | Oral         | Oral                                            | 12 MTH          | Not Reported |
|                                                                                                      | Benfluorex Hydrochloride |              |            | S           | Oral         | 3 Dosage Forms (1 Dosage Forms, 3 In 1 D), Oral |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                      | Paroxetine Hydrochloride |                    | S                  | Oral            | Oral                            |                      |                 | Not Reported |                |
|------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
|                                                      | Effexor                  |                    | S                  | Oral            | Oral                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2011                                          | 8198861                  | EXPEDITED (15-DAY) | Y                  | DE, HO          | IE-SANOFI-AVENTIS-2011SA067252  |                      | 76 YR           | Male         | IRL            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Hepatic Failure; Hepatitis; Jaundice; Vomiting | Rifadin                  |                    |                    | S               | Oral                            |                      | 6 DAY           | Not Reported |                |
|                                                      | Fusidic Acid             |                    |                    | S               | Oral                            |                      | 3 WEEK          | Not Reported |                |
|                                                      | Metronidazole            |                    |                    | S               | Unknown                         |                      | 3 WEEK          | Not Reported |                |
|                                                      | Augmentin                |                    |                    | S               | Unknown                         |                      |                 | Not Reported |                |
|                                                      | Seroquel                 |                    |                    | S               | Oral                            |                      | 2 MTH           | Not Reported |                |
|                                                      | Lexapro                  |                    |                    | S               | Oral                            |                      | 2 MTH           | Not Reported |                |
|                                                      | Esomeprazole             |                    |                    | S               | Oral                            |                      | 2 MTH           | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2011                                          | 8264238                  | DIRECT             | N                  | OT              |                                 |                      | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Gastrointestinal Disorder                   | Lexapro                  |                    |                    | S               | Oral                            | 7.5 Mg               | 2 DAY           | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Nov-2011                                          | 8264832                  | EXPEDITED (15-DAY) | N                  | HO, OT          | US-EISAI INC-E3810-05091-SPO-US |                      | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Lung Neoplasm Malignant; Pruritus                    | Aciphex                  |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                      | Lexapro                  |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                                      | Levothyroxine            |                    |                    | C               | Oral                            |                      |                 | Not Reported |                |
|                                                      | Pindolol                 |                    |                    | C               | Oral                            |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |              |
|------------|---|------|--------------|
| Diovan     | C | Oral | Not Reported |
| Zantac     | C | Oral | Not Reported |
| Prednisone | C | Oral | Not Reported |
| Xanax      | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2011              | 8242422       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000025057           |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Back Pain; Crying; Depression; Nasal Congestion; Speech Disorder; Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Nov-2011              | 8274775       | EXPEDITED (15-DAY) | Y                  | HO              | DSA_48207_2011       |                      | 60 YR      | Male       | KOR            |

| <u>Preferred Term</u>                                                                                                                                                                                                                        | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety; Asthenia; Blood Chloride Decreased; Blood Osmolarity Decreased; Blood Urea Increased; Carcinoembryonic Antigen Increased; Fatigue; Hyponatraemia; Insomnia; Po2 Decreased; Secondary Adrenocortical Insufficiency; Weight Increased | Bupropion Hydrochloride |              |            | S           |              | (Df), (Df)                       |                 | Not Reported |
|                                                                                                                                                                                                                                              | Escitalopram Oxalate    |              |            | S           |              | (10 Mg, Frequency Unknown), (Df) |                 | Not Reported |
|                                                                                                                                                                                                                                              | Mirtazapine             |              |            | S           |              | (15 Mg, Frequency Unknown), (Df) |                 | Not Reported |
|                                                                                                                                                                                                                                              | Alprazolam              |              |            | S           |              | (0.25 Mg Bid), (Df)              |                 | Not Reported |
|                                                                                                                                                                                                                                              | Clonazepam              |              |            | S           |              | (0.5 Mg, Frequency Unknown)      |                 | Not Reported |
|                                                                                                                                                                                                                                              | Aspirin                 |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                              | Clopidogrel             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                              | Simvastatin             |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                                                                                                                                                              | Telmisartan             |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>             | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------------|----------------------|------------|------------|----------------|
| 30-Nov-2011              | 8164852       | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY- |                      | 19 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

16109340

| <u>Preferred Term</u>            | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Hepatic Failure; Suicide Attempt | Abilify                 |              |            | S           |              | Started 6 Years Ago: Before 2005 |                 | Not Reported |
|                                  | Abilify                 |              |            | S           |              | Started 6 Years Ago: Before 2005 |                 | Not Reported |
|                                  | Lexapro                 |              |            | S           |              | Started 6 Years Ago              |                 | Not Reported |
|                                  | Lexapro                 |              |            | S           |              | Started 6 Years Ago              |                 | Not Reported |
|                                  | Topamax                 |              |            | S           |              |                                  |                 | Not Reported |
|                                  | Imitrex                 |              |            | C           |              |                                  |                 | Not Reported |
|                                  | Trazodone Hydrochloride |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2011              | 7851686       | EXPEDITED (15-DAY) | Y                  |                 | 1000018765           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                    | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|---------------------------------------------------------------------------------------|-----------------|--------------|
| Abortion Induced; Arnold-Chiari Malformation; Congenital Anomaly; Maternal Drugs Affecting Foetus; Spina Bifida; Talipes | Escitalopram Oxalate |              |            | S           | Transplacental | Transplacental                                                                        |                 | Not Reported |
|                                                                                                                          | Lidocaine            |              |            | S           | Transplacental | 0.25 Dosage For (0.5 Dosage Forms, 1 in 2 D), Transplacenta, 0-22 Weeks Of Amenorrhea | 22 WEEK         | Not Reported |
|                                                                                                                          | Atarax               |              |            | S           | Transplacental | 3.5714 Mg (25 Mg, 1 In 1 Wk), Transplacental, 0-22 Weeks Of Amenorrhea                | 22 WEEK         | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2011              | 7927928       | EXPEDITED (15-DAY) | Y                  | HO              | 1000019810           |                      | 87 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Abnormal Behaviour; Atrial Fibrillation; Bedridden; C- | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 |                 | Not Reported |



## Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2011              | 8202020       | EXPEDITED (15-DAY) | Y                  | CA, HO          | 1000024660           |                      |            | Unknown    | DNK            |

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|                      |   |                |                                                                                          |              |
|----------------------|---|----------------|------------------------------------------------------------------------------------------|--------------|
| Lexatin (Bromazepam) | S | Transplacental | Transplacental, 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental, 5 Mg (5 Mg, 1 In 1           | Not Reported |
|                      |   |                | 3 Mg (1.5 Mg, 2 In 1 D),<br>Transplacental, 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Transplacental |              |
|                      |   | Transplacental | 3 Mg (1.5 Mg, 2 In 1 D),<br>Transplacental, 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Transplacental |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2011              | 8239934       | EXPEDITED (15-DAY) | Y                  | HO              | 2011SP050759         |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Bundle Branch Block Right; Dyskinesia; Dystonia; Heart Rate Increased; Stress; Tremor | Remeron        |              |            | S           | Oral         | 30 Mg;Qd;Po               |                 | Not Reported |
|                                                                                       | Ciprallex      |              |            | S           | Oral         | 20 Mg;Qd;Po ; 10 Mg;Qd;Po |                 | Not Reported |
|                                                                                       |                |              |            |             | Oral         | 20 Mg;Qd;Po ; 10 Mg;Qd;Po |                 |              |
|                                                                                       | Alvesco        |              |            | C           |              |                           |                 | Not Reported |
|                                                                                       | Spiriva        |              |            | C           |              |                           |                 | Not Reported |
|                                                                                       | Indacaterol    |              |            | C           |              |                           |                 | Not Reported |
|                                                                                       | Oxygen         |              |            | C           |              |                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Dec-2011              | 8257397       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025390           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                       | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------|--------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------|-----------------|--------------|
| Chest Discomfort; Feeling Hot; Hyperhidrosis; Insomnia; Peripheral Coldness | Lexapro                                                |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |
|                                                                             | Reflex (Picolamine Salicylate) (Picolamine Salicylate) |              |            | C           |              |                              |                 | Not Reported |
|                                                                             | Wypax (Lorazepam)                                      |              |            | C           |              |                              |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

(Lorazepam)

| <u>FDA Received Date</u>                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------|-----------------|--------------|----------------|
| 01-Dec-2011                                                                | 8277479              | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000025742                   |                                  | 83 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychiatric<br>Decompensation;<br>Pulmonary Embolism;<br>Urinary Retention | Escitalopram Oxalate |                    |                    | S               | Oral                         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2011                                                                | 8271866              | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2011291102 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                           | Pristiq              |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                            | Xanax                |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                            | Atenolol             |                    |                    | S               |                              | Unk                              |                 | Pfizer       |                |
|                                                                            | Zyprexa              |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                            | Lexapro              |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                            | Zocor                |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                            | Levothroid           |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
|                                                                            | Cymbalta             |                    |                    | S               |                              | Unk                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Dec-2011                                                                | 8281558              | EXPEDITED (15-DAY) | Y                  | LT              | 1000025745                   |                                  | 65 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Myocardial<br>Infarction;<br>Electrocardiogram Qt<br>Prolonged       | Escitalopram Oxalate |                    |                    | S               | Oral                         | 20 Mg (20 Mg, 1 In 1 D,<br>Oral  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2011              | 8283445       | EXPEDITED (15-DAY) | Y                  | CA, HO          | 1000025785           |                      | < 1 DAY    | Male       | DNK            |

| <u>Preferred Term</u>                                                                | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                                                                               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|----------------|------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Congenital<br>Hydronephrosis; Maternal<br>Drugs Affecting Foetus;<br>Urethral Valves | Escitalopram Oxalate                  |              |            | S           | Transplacental | 15 Mg (15 Mg, 1 In 1 D),<br>Transplacental, 8 Mg<br>(Temporarily Reduced<br>Dosage) (8 Mg, 1 In 1 D),<br>Transpl |                 | Not Reported |
|                                                                                      |                                       |              |            |             | Transplacental | 15 Mg (15 Mg, 1 In 1 D),<br>Transplacental, 8 Mg<br>(Temporarily Reduced<br>Dosage) (8 Mg, 1 In 1 D),<br>Transpl |                 |              |
|                                                                                      | Escitalopram Oxalate                  |              |            | S           | Transplacental | 15 Mg (15 Mg, 1 In 1 D),<br>Transplacental                                                                       |                 | Not Reported |
|                                                                                      | Embolex                               |              |            | S           | Transplacental | 3000 Iu (3000 Iu, 1 In 1 D),<br>Transplacental                                                                   |                 | Not Reported |
|                                                                                      | Amoxicillin                           |              |            | S           | Transplacental | Transplacental                                                                                                   |                 | Not Reported |
|                                                                                      | Cotrim                                |              |            | S           | Transplacental | Transplacental                                                                                                   |                 | Not Reported |
|                                                                                      | Acetaminophen                         |              |            | S           | Transplacental | 500 Mg, As Needed,<br>Transplacental                                                                             |                 | Not Reported |
|                                                                                      | Femibion (Folic Acid) (Folic<br>Acid) |              |            | C           |                |                                                                                                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2011              | 8283624       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025218           |                      | 85 YR      | Female     | DNK            |

| <u>Preferred Term</u>                  | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Diarrhoea; Hypokalaemia;<br>Hypophagia | Lexapro                   |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                        | Memantine Hydrochloride   |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) |                 | Not Reported |
|                                        | Risperidone (Risperidone) |              |            | S           |              |                         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------|--------------------|-----------------|-----------------------|---------------------------|-----------------|--------------|----------------|
| 05-Dec-2011                                                                                                            | 8284746                            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025783            |                           | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Campylobacter Infection;<br>Induced Labour; Maternal<br>Drugs Affecting Foetus;<br>Pregnancy; Sinusitis                | Escitalopram Oxalate               |                    |                    | S               | Oral                  | See Image                 |                 | Not Reported |                |
|                                                                                                                        |                                    |                    |                    |                 | Oral                  | See Image                 |                 |              |                |
|                                                                                                                        |                                    |                    |                    |                 | Oral                  | See Image                 |                 |              |                |
|                                                                                                                        | Embolex                            |                    |                    | S               | Subcutaneous          | 3000 lu, Subcutaneous     |                 | Not Reported |                |
|                                                                                                                        | Acetaminophen                      |                    |                    | S               | Oral                  | (500 Mg, As Needed), Oral |                 | Not Reported |                |
|                                                                                                                        | Femibion (Folic Acid) (Folic Acid) |                    |                    | C               |                       |                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2011                                                                                                            | 8228540                            | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-JNJFOC-20111012396 |                           | 16 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Overdose;<br>Somnolence; Suicide Attempt                                                                   | Risperdal                          |                    |                    | S               | Oral                  | 1-0-0                     |                 | Not Reported |                |
|                                                                                                                        | Risperdal                          |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                        | Cipralelex                         |                    |                    | S               | Oral                  |                           |                 | Not Reported |                |
|                                                                                                                        | Cipralelex                         |                    |                    | S               | Oral                  | 1-0-0                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                               | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2011                                                                                                            | 8246297                            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025239            |                           | 38 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyperventilation;<br>Hypoaesthesia; Insomnia;<br>Loss Of Consciousness;<br>Muscle Contracture;<br>Nausea; Palpitations | Lexapro                            |                    |                    | S               |                       | 10 Mg (10 Mg, 1 In 1 D)   |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------------------------|-----------------|--------------|----------------|
| 06-Dec-2011                                                                                                  | 8282243                    | DIRECT             | Y                  | OT              |                      |                                               | 11 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Hallucination, Auditory                                                                                      | Lexapro                    |                    |                    | S               | Oral                 | 5mg Hs Po 047                                 |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Dec-2011                                                                                                  | 8286160                    | EXPEDITED (15-DAY) | Y                  | CA, OT          | 1000025965           |                                               |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Developmental Delay;<br>Maternal Drugs Affecting<br>Foetus; Motor<br>Developmental Delay;<br>Speech Disorder | Escitalopram Oxalate       |                    |                    | S               | Transplacental       | 20-30 Mg Daily (1 In 1 D),<br>Transplacental  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2011                                                                                                  | 8165769                    | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000023101           |                                               | 33 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Intraocular Pressure<br>Increased                                                                            | Citalopram Hydrobromide    |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral              |                 | Not Reported |                |
|                                                                                                              | Escitalopram Oxalate       |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral              |                 | Not Reported |                |
|                                                                                                              | Promethazine Hydrochloride |                    |                    | S               | Oral                 | (12.5 Mg, Once), Oral, 1<br>Week Before Event |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                     | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2011                                                                                                  | 8182633                    | EXPEDITED (15-DAY) | Y                  | HO, OT          | 1000024269           |                                               | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                        | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Dreams;                                                                                             | Viibryd                    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                |         |   |      |                                                                                                                                                                                                                                                                                                                                                                                          |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Anxiety; Condition<br>Aggravated; Depressed<br>Mood; Dyspnoea;<br>Eczema; Insomnia;<br>Myoclonus; Panic Attack;<br>Paraesthesia; Serotonin<br>Syndrome; Tremor | Viibryd | S | Oral | Oral, 20 Mg (20 Mg, 1 In 1 D),Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D),Oral<br>40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral<br>40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral<br>40 Mg (40 Mg, 1 In 1 D),Oral, 20 Mg (20 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D),Oral | Not Reported |
| Lexapro                                                                                                                                                        |         | S |      |                                                                                                                                                                                                                                                                                                                                                                                          | Not Reported |
| Adderall (Obetrol)-(Obetrol)                                                                                                                                   |         | C |      |                                                                                                                                                                                                                                                                                                                                                                                          | Not Reported |
| Klonopin                                                                                                                                                       |         | C |      |                                                                                                                                                                                                                                                                                                                                                                                          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2011              | 8194928       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024554           |                      | 91 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Overdose; Product<br>Prescribing Error; Upper<br>Gastrointestinal<br>Haemorrhage | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |
|                                                                                  | Nexium               |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral, 40 Mg (40 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                  |                      |              |            |             | Oral         | 40 Mg (40 Mg, 1 In 1 D),<br>Oral, 40 Mg (40 Mg, 1 In 1 D), Oral |                 |              |
|                                                                                  | Coumadin             |              |            | C           |              |                                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Dec-2011              | 8198322       | EXPEDITED (15-DAY) | Y                  | HO              | 1000024555           |                      | 90 YR      | Male       | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                      | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------|-----------------|--------------|----------------|
| Asthenia; Dizziness;<br>Neutropenia                                                                                                                                                                                                        | Escitalopram Oxalate                                        |                    |                    | S               | Oral                 | (10 Milligram, Tablets) 5<br>Mg (5 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Atrovent (Ipratropium<br>Bromide)(20 Microgram,<br>Tablets) |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Pulmicort Turbuhaler                                        |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                   | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2011                                                                                                                                                                                                                                | 8200305                                                     | EXPEDITED (15-DAY) | Y                  | CA, DE, HO      | 1000024563           |                                                       |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                      | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;<br>Congenital Bladder<br>Anomaly; Congenital<br>Renal Cyst; Congenital<br>Spondylolysis; Maternal<br>Drugs Affecting Foetus;<br>Oligohydramnios; Renal<br>Dysplasia; Renal Fusion<br>Anomaly; Single Umbilical<br>Artery | Escitalopram Oxalate                                        |                    |                    | S               | Transplacental       | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental            |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Ranitidine                                                  |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Alprazolam                                                  |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Doxylamine Succinate                                        |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | (Doxylamine Succinate)                                      |                    |                    |                 |                      |                                                       |                 |              |                |
|                                                                                                                                                                                                                                            | (Doxylamine Succinate)                                      |                    |                    |                 |                      |                                                       |                 |              |                |
| Materna (Materna) (Materna)                                                                                                                                                                                                                |                                                             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| Pyridoxine Hydrochloride                                                                                                                                                                                                                   |                                                             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                   | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Dec-2011                                                                                                                                                                                                                                | 8200371                                                     | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000024559           |                                                       | 61 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                      | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Bruxism; Confusional<br>State; Dizziness;<br>Headache; Insomnia;<br>Myalgia; Seizure; Suicidal<br>Ideation; Visual<br>Impairment                                                                                                           | Escitalopram Oxalate                                        |                    |                    | S               | Oral                 | 20 Mg (10 Mg,2 In 1<br>D),Oral                        |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | Ezetrol (Ezetimibe) (Tablets)                               |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
|                                                                                                                                                                                                                                            | (Ezetimibe)                                                 |                    |                    |                 |                      |                                                       |                 |              |                |
|                                                                                                                                                                                                                                            | Losec (Omeprazole)                                          |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| (Omeprazole)                                                                                                                                                                                                                               |                                                             |                    |                    |                 |                      |                                                       |                 |              |                |
| Vasotec (Enalapril Maleate)                                                                                                                                                                                                                |                                                             |                    |                    | C               |                      |                                                       |                 | Not Reported |                |
| (Enalapril Maleate)                                                                                                                                                                                                                        |                                                             |                    |                    |                 |                      |                                                       |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| 08-Dec-2011                                                             | 8286281                                            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025945            |                               |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Heart Rate Irregular; Malaise; Somnolence; Suicidal Ideation | Escitalopram Oxalate                               |                    |                    | S               | Oral                  | 20 Mg (10 Mg,2 In 1 D),Oral   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2011                                                             | 8182663                                            | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-JNJFOC-20111004931 |                               | 45 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Psychotic Disorder; Pulmonary Embolism                                  | Risperdal Consta                                   |                    |                    | S               | Intramuscular         |                               |                 | Not Reported |                |
|                                                                         | Escitalopram Oxalate                               |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                         | Zopiclone                                          |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2011                                                             | 8199906                                            | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000024588            |                               | 10 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Leukopenia; Neutropenia; Off Label Use                                  | Escitalopram Oxalate                               |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                         | Atomoxetine (Atomoxetine) (Capsules) (Atomoxetine) |                    |                    | C               |                       |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Dec-2011                                                             | 8200145                                            | EXPEDITED (15-DAY) | Y                  | DE              | 1000024578            |                               | 51 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Antidepressant Drug Level Above Therapeutic;                            | Escitalopram Oxalate                               |                    |                    | S               | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |

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|                                                  |                         |                           |                             |                          |                               |                                                 |                                   |                     |                         |
|--------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------------------------|-----------------------------------|---------------------|-------------------------|
| Toxicity To Various Agents                       |                         | Elavil                    |                             | S                        | Oral                          |                                                 | 150 Mg (50 Mg, 3 In 1 D),<br>Oral |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>               | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Dec-2011                                      | 8292306                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000025955                    |                                                 | 2 YR                              | Male                | USA                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a>          | <a href="#">Mfr</a> |                         |
| Maternal Drugs Affecting<br>Foetus; Spina Bifida | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                                  |                                   |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>               | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Dec-2011                                      | 8292354                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000026001                    |                                                 | 55 YR                             | Male                | DNK                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a>          | <a href="#">Mfr</a> |                         |
| Arrhythmia                                       | Escitalopram Oxalate    |                           |                             | S                        |                               | 10 Mg (10 Mg,1 In 1 D)                          |                                   |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>               | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Dec-2011                                      | 8292746                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000025974                    |                                                 |                                   | Female              | DNK                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a>          | <a href="#">Mfr</a> |                         |
| Haematochezia                                    | Escitalopram Oxalate    |                           |                             | S                        |                               | 0.5 Dosage Form (0.5<br>Dosage Forms, 1 In 1 D) |                                   |                     | Not Reported            |
| <a href="#">FDA Received Date</a>                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                   | <a href="#">Age</a>               | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Dec-2011                                      | 8341760                 | NON-EXPEDITED             | N                           | OT                       | SPV1-2011-00627               |                                                 | 34 YR                             | Female              | USA                     |
| <a href="#">Preferred Term</a>                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                     | <a href="#">Duration</a>          | <a href="#">Mfr</a> |                         |
| Weight Decreased                                 | Adderall Xr             |                           |                             | S                        | Oral                          | 15 Mg, 1x/Day: Qd, Oral                         |                                   |                     | Not Reported            |
|                                                  | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg, 1x/Day: Qd, Oral                         |                                   |                     | Not Reported            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------------------------|-----------------|--------------|----------------|
| 11-Dec-2011                                                                                                                                           | 8283300              | EXPEDITED (15-DAY) | Y                  | LT              | NO-MYLANLABS-2011S1024476 |                                            | 44 YR           | Male         | NOR            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Confusional State; Eye Movement Disorder; Hyporeflexia; Hypoventilation; Muscle Rigidity; Mydriasis; Stupor; Suicide Attempt; Tachycardia | Baclofen             |                    |                    | S               | Oral                      | 10mgx1 From 201102 = 4mths. Not Used       |                 | Mylan        |                |
|                                                                                                                                                       | Cipralext            |                    |                    | S               | Oral                      | 20110623-20110626 = 4 Days' Break          |                 | Not Reported |                |
|                                                                                                                                                       | Hiprex               |                    |                    | C               | Oral                      | 5 Mg X 1 First 2 Days                      | 7 DAY           | Not Reported |                |
|                                                                                                                                                       | Ascorbic Acid        |                    |                    | C               | Oral                      | Not Used 20110623-20110626 = 4 Days' Break |                 | Not Reported |                |
|                                                                                                                                                       | Marevan              |                    |                    | C               | Oral                      | Not Used 20110623-20110626 = 4 Days' Break |                 | Not Reported |                |
|                                                                                                                                                       | Oxazepam             |                    |                    | C               | Oral                      | Not Used 20110623-20110626 = 4 Days Break  |                 | Not Reported |                |
|                                                                                                                                                       | Zopiclone            |                    |                    | C               | Oral                      |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2011                                                                                                                                           | 7724299              | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2010175733  |                                            | 87 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Bone Marrow Failure; Pancytopenia                                                                                                                     | Inipomp              |                    |                    | S               | Oral                      | 40 Mg, 1x/Day                              |                 | Pfizer       |                |
|                                                                                                                                                       | Ramipril             |                    |                    | S               | Oral                      | 10 Mg, Unk                                 |                 | Pfizer       |                |
|                                                                                                                                                       | Nifedipine           |                    |                    | S               | Oral                      | 30 Mg, Daily                               |                 | Not Reported |                |
|                                                                                                                                                       | Escitalopram Oxalate |                    |                    | S               | Oral                      | 5 Mg, As Needed                            |                 | Not Reported |                |
|                                                                                                                                                       | Acetaminophen        |                    |                    | S               | Oral                      | 1 G, 3x/Day                                |                 | Not Reported |                |
|                                                                                                                                                       | Diclofenac           |                    |                    | S               | Cutaneous                 | 1 Df, As Needed                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2011                                                                                                                                           | 8261210              | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2011285355  |                                            | 56 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Back Pain; Depression;<br>Drug Ineffective;<br>Emotional Disorder; Social<br>Avoidant Behaviour | Zoloft         |              |            | S           | Oral         | 25 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                                 | Zoloft         |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                                 | Zoloft         |              |            | S           |              |                    |                 | Pfizer       |
|                                                                                                 | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                 | Cymbalta       |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                 | Ativan         |              |            | C           |              | Unk                |                 | Not Reported |
|                                                                                                 | Abilify        |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2011              | 8263123       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011IT100889     |                      | 61 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Bradyphrenia; Drug Level<br>Increased; Feeling<br>Abnormal; Intentional<br>Overdose; Mood Altered;<br>Self-Injurious Ideation;<br>Sopor | Tegretol                |              |            | S           | Oral         | 200 Mg, Unk          |                 | Novartis     |
|                                                                                                                                         | Tegretol                |              |            | S           | Oral         | 9 Posological Units  | 1 DAY           | Novartis     |
|                                                                                                                                         | Escitalopram Oxalate    |              |            | S           | Oral         | 20 Mg, Unk           |                 | Not Reported |
|                                                                                                                                         | Escitalopram Oxalate    |              |            | S           | Oral         | 14 Posological Units | 1 DAY           | Not Reported |
|                                                                                                                                         | Prazepam                |              |            | S           | Oral         | 15 Posological Units | 1 DAY           | Not Reported |
|                                                                                                                                         | Brotizolam              |              |            | S           | Oral         | 0.25 Mg, Unk         |                 | Not Reported |
|                                                                                                                                         | Brotizolam              |              |            | S           | Oral         | One Posological Unit | 1 DAY           | Not Reported |
|                                                                                                                                         | Simvastatin             |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                                                         | Acetylsalicylic Acid    |              |            | C           | Oral         | 100 Mg, Unk          |                 | Not Reported |
|                                                                                                                                         | Atenolol                |              |            | C           | Oral         | 100 Mg, Unk          |                 | Not Reported |
|                                                                                                                                         | Metformin Hydrochloride |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                                                         | Tavor (Lorazepam)       |              |            | C           | Oral         | 2 Posological Unit   |                 | Not Reported |
|                                                                                                                                         | Isoptin                 |              |            | C           | Oral         | 2 Posological Unit   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Dec-2011              | 8298304       | EXPEDITED (15-DAY) | Y                  |                 | 1000026049           |                      | 48 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                                                |                      |                    |                    |                 |                              |                         |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|--------------|----------------|
| Adverse Event; Cough;<br>Sleep Disorder                                                                                                                                        |                      | Lexapro            |                    | S               |                              | Not Reported            |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Dec-2011                                                                                                                                                                    | 8301924              | EXPEDITED (15-DAY) | Y                  | HO              | 1000025993                   |                         | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure<br>Decreased; Eczema;<br>Feeling Hot;<br>Hypersensitivity; Malaise;<br>Nausea; Pharyngeal<br>Oedema; Presyncope;<br>Rash Pustular; Urticaria;<br>Vision Blurred | Escitalopram Oxalate |                    |                    | S               |                              |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2011                                                                                                                                                                    | 8281392              | EXPEDITED (15-DAY) | Y                  | HO, OT          | CH-PFIZER INC-<br>2011297228 |                         | 18 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Drug<br>Interaction; Extrapramidal<br>Disorder; Gait<br>Disturbance; Nystagmus;<br>Somnolence; Speech<br>Disorder; Suicidal Ideation                         | Effexor Xr           |                    |                    | S               | Oral                         | 75 Mg, 1x/Day           |                 | Pfizer       |                |
|                                                                                                                                                                                | Levomepromazine      |                    |                    | S               | Oral                         | 30 Mg, Single           | 1 DAY           | Not Reported |                |
|                                                                                                                                                                                | Levomepromazine      |                    |                    | S               |                              |                         |                 | Not Reported |                |
|                                                                                                                                                                                | Seroquel             |                    |                    | S               | Oral                         | 50 Mg, 1x/Day           |                 | Not Reported |                |
|                                                                                                                                                                                | Ciprallex            |                    |                    | S               |                              | 20 Mg, 1x/Day           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Dec-2011                                                                                                                                                                    | 8285495              | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2011300006 |                         |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Nausea; Tremor                                                                                                                                          | Diflucan             |                    |                    | S               |                              | Unk                     |                 | Pfizer       |                |
|                                                                                                                                                                                | Lexapro              |                    |                    | S               |                              | 5 Mg, 1x/Day (1 In 1 D) |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 14-Dec-2011                                                                | 8243040                                                                     | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000025120           |                                      |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adrenal Disorder                                                           | Escitalopram Oxalate                                                        |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),Oral         |                 | Not Reported |                |
|                                                                            | Methylphenidate                                                             |                    |                    | S               | Oral                 | Oral                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2011                                                                | 8304998                                                                     | EXPEDITED (15-DAY) | Y                  | HO              | 2011MA017469         |                                      | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Emotional Distress; Fatigue; Overdose; Toxicity To Various Agents | Diazepam                                                                    |                    |                    | S               | Oral                 | Po                                   |                 | Not Reported |                |
|                                                                            | Zyprexa                                                                     |                    |                    | S               | Oral                 | Po                                   |                 | Not Reported |                |
|                                                                            | Cipralex                                                                    |                    |                    | S               | Oral                 | Po                                   |                 | Not Reported |                |
|                                                                            | Lyrica                                                                      |                    |                    | S               | Oral                 | Po                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>                                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-Dec-2011                                                                | 8306638                                                                     | EXPEDITED (15-DAY) | Y                  | HO              | 1000026141           |                                      | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u>                                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Altered State Of Consciousness; Disorientation; Hyponatraemia              | Escitalopram Oxalate                                                        |                    |                    | S               | Oral                 | 1 Df (1 Dosage Forms, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                            | Ofloxacin                                                                   |                    |                    | S               | Oral                 | 2 Df (2 Dosage Forms, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                            | Flagyl                                                                      |                    |                    | S               | Oral                 | 3 Df (3 Dosage Forms, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                            | Cordarone (Cordarone)                                                       |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                            | Coaprovel (Irbesartan, Hydrochlorothiazide)(Irbesartan Hydrochlorothiazide) |                    |                    | C               |                      |                                      |                 | Not Reported |                |
|                                                                            | Lercan (Lercanidipine)                                                      |                    |                    | C               |                      |                                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrochloride)(Lercanidipine  
Hydrochloride)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Dec-2011              | 8306800       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026104           |                      | 53 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Cerebral Haemorrhage  | Escitalopram Oxalate                                                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |
|                       | Aspirin                                                                    |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1<br>D),Oral |                 | Not Reported |
|                       | Isoptin (Verapamil<br>Hydrochloride)(Tablets)(Verapa<br>mil Hydrochloride) |              |            | C           |              |                                   |                 | Not Reported |
|                       | Dancor (Nicorandil) (Tablets)<br>(Nicorandil)                              |              |            | C           |              |                                   |                 | Not Reported |
|                       | Torem (Torasemide<br>Sodium)(Tablets)(Torasemide<br>Sodium)                |              |            | C           |              |                                   |                 | Not Reported |
|                       | Pantozol                                                                   |              |            | C           |              |                                   |                 | Not Reported |
|                       | Lyrica (Pregabalin) (Tablets)<br>(Pregabalin)                              |              |            | C           |              |                                   |                 | Not Reported |
|                       | Levemir                                                                    |              |            | C           |              |                                   |                 | Not Reported |
|                       | Novorapid (Insulin<br>Aspart)(Insulin Aspart)                              |              |            | C           |              |                                   |                 | Not Reported |
|                       | Imovan<br>(Zopiclone)(Tablets)(Zopiclone)                                  |              |            | C           |              |                                   |                 | Not Reported |
|                       | Recormon (Epoetin<br>Beta)(Epoetin Beta)                                   |              |            | C           |              |                                   |                 | Not Reported |
|                       | Ferinject(Ferric<br>Carboxymaltose)(Ferric<br>Carboxymaltose)              |              |            | C           |              |                                   |                 | Not Reported |
|                       | Calcitrol (Calcitriol)(Calcitriol)                                         |              |            | C           |              |                                   |                 | Not Reported |
|                       | Vitamin D<br>(Colecalciferol)(Colecalciferol)                              |              |            | C           |              |                                   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-Dec-2011              | 8256730       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025275           |                      | 72 YR      | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| Uveitis                                                                                                               | Lexapro                                                               |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2011                                                                                                           | 8306548                                                               | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000025998           |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Crying; Depression; Drug<br>Ineffective; Emotional<br>Disorder; Social Avoidant<br>Behaviour | Lexapro                                                               |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                       | Zoloft                                                                |                    |                    | S               |                      |                                  |                 | Not Reported |                |
|                                                                                                                       | Cymbalta                                                              |                    |                    | S               |                      |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-Dec-2011                                                                                                           | 8313175                                                               | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000026154           |                                  |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective;<br>Withdrawal Syndrome                                                                              | Escitalopram Oxalate                                                  |                    |                    | S               | Oral                 | Oral                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                              | <u>Case #</u>                                                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                                                           | 7876122                                                               | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000019124           |                                  | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                 | <u>Product</u>                                                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase<br>Increased; Anti Factor X<br>Antibody Positive;                                            | Escitalopram Oxalate                                                  |                    |                    | S               | Oral                 | 20 Mg, (20 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |
| Antiphospholipid<br>Antibodies Positive; Blood                                                                        | Escitalopram Oxalate                                                  |                    |                    | S               | Oral                 | 5 Mg Or 2.5 Mg, Oral             |                 | Not Reported |                |
| Immunoglobulin G<br>Increased; Blood                                                                                  | Telfast (Fexofenadine)<br>(Fexofenadine)                              |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| Immunoglobulin M<br>Increased; Blood Uric Acid                                                                        | Ranitidin (Ranitidine<br>Hydrochloride) (Ranitidine<br>Hydrochloride) |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| Increased; Drug                                                                                                       | Pentatop (Cromoglicate Sodium)<br>(Cromoglicate Sodium)               |                    |                    | C               |                      |                                  |                 | Not Reported |                |
| Ineffective; Gamma-<br>Glutamyltransferase                                                                            | L-Thyroxin (Levothyroxine)                                            |                    |                    | C               |                      |                                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                        |                                                          |   |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---|--------------|
| Increased; Paraesthesia;<br>Perichondritis; Plasmin<br>Inhibitor Increased;<br>Plasminogen Activator<br>Inhibitor Decreased;<br>Systemic Lupus<br>Erythematosis; Urge<br>Incontinence; Von<br>Willebrand'S Factor<br>Antigen Decreased | Sodium) (Levothyroxine Sodium)<br>Tramadol Hydrochloride | C | Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Dec-2011              | 8254345       | EXPEDITED (15-DAY) | N                  | OT              | AUR-APL-2011-05774   |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u>        | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;       | Mirtazapine (Mirtazapine) |              |            | S           |              |                    |                 | Not Reported |
| Anger; Constipation;         | Zolof                     |              |            | S           |              |                    |                 | Not Reported |
| Deafness; Disturbance In     | Skelaxin                  |              |            | S           |              |                    |                 | Not Reported |
| Attention; Drug Ineffective; | Effexor                   |              |            | S           |              | 3.75 Mg            |                 | Not Reported |
| Erection Increased;          | Effexor Xr                |              |            | S           |              |                    |                 | Not Reported |
| Fatigue; Gastric Ulcer;      | Celebrex                  |              |            | S           |              |                    |                 | Not Reported |
| Gynaecomastia; Head          | Geodon                    |              |            | S           |              |                    |                 | Not Reported |
| Injury; Headache;            | Depakote                  |              |            | S           |              |                    |                 | Not Reported |
| Influenza; Insomnia;         | Zomig                     |              |            | S           |              |                    |                 | Not Reported |
| Memory Impairment;           | Imitrex (Sumatriptan)     |              |            | S           |              |                    |                 | Not Reported |
| Mood Altered; Muscle         | Soma                      |              |            | S           |              |                    |                 | Not Reported |
| Spasms; Rash; Rectal         | Lithium (Lithium)         |              |            | S           |              |                    |                 | Not Reported |
| Haemorrhage;                 | Risperdal                 |              |            | S           |              |                    |                 | Not Reported |
| Somnolence; Suicidal         | Seroquel                  |              |            | S           |              |                    |                 | Not Reported |
| Ideation; Tinnitus; Weight   | Zyprexa                   |              |            | S           |              |                    |                 | Not Reported |
| Increased                    | Lexapro                   |              |            | S           |              |                    |                 | Not Reported |
|                              | Lamictal                  |              |            | S           |              |                    |                 | Not Reported |
|                              | Tegretol                  |              |            | S           |              |                    |                 | Not Reported |
|                              | Wellbutrin                |              |            | S           |              |                    |                 | Not Reported |
|                              | Buspar                    |              |            | S           |              |                    |                 | Not Reported |
|                              | Valium                    |              |            | S           |              |                    |                 | Not Reported |
|                              | Trazodone Hydrochloride   |              |            | S           |              |                    |                 | Not Reported |
|                              | Paxil                     |              |            | S           |              |                    |                 | Not Reported |
|                              | Cymbalta                  |              |            | S           |              |                    |                 | Not Reported |
|                              | Elavil                    |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                | Klonopin         |                    | S               |                                                 |                                            |                 |              | Not Reported   |
|--------------------------|----------------|------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------------------|-----------------|--------------|----------------|
|                          |                | Ritalin          |                    | S               |                                                 |                                            |                 |              | Not Reported   |
|                          |                | Pamelor          |                    | S               |                                                 |                                            |                 |              | Not Reported   |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011              | 8295157        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15478886 |                                            |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Tardive Dyskinesia       | Abilify        |                  |                    | S               | Oral                                            |                                            |                 | Not Reported |                |
|                          | Lamictal       |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
|                          | Ambien         |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011              | 8295309        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15867856 |                                            | 61 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Spasms            | Abilify        |                  |                    | S               |                                                 | 5mg Increased To 10 Mg<br>Abt 6 Months Ago | 6 MTH           | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011              | 8295368        | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15512361 |                                            |                 | Unknown      | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia               | Abilify        |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
|                          | Adderall       |                  |                    | S               |                                                 |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011              | 8295381        | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15878747 |                                            | 30 YR           | Female       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                          | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>                   |                |
|------------------------------------------------|--------------------|------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------------------------------------------|-----------------|------------------------------|----------------|
| Weight Increased                               | Abilify<br>Lexapro |                  |                    | S<br>S          |                                                 | Started With 10 Mg,<br>Increased To 20mg                                    |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Dec-2011                                    | 8295490            | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15896525 |                                                                             | 22 YR           | Female                       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bradycardia; Dizziness;<br>Fatigue             | Abilify            |                  |                    | S               | Oral                                            | Restarted On 11mar2011                                                      |                 | Not Reported                 |                |
|                                                | Abilify            |                  |                    | S               | Oral                                            | Restarted On 11mar2011                                                      |                 | Not Reported                 |                |
|                                                | Abilify            |                  |                    | S               | Oral                                            | Restarted On 11mar2011                                                      |                 | Not Reported                 |                |
|                                                | Lexapro            |                  |                    | S               |                                                 | 10mg On 12aug10 Few<br>Weeks Rest 20mg On<br>11mar11 Again 30mg<br>16may11. |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Dec-2011                                    | 8295571            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15531163 |                                                                             |                 | Male                         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>                   |                |
| Tardive Dyskinesia                             | Abilify            |                  |                    | S               |                                                 |                                                                             |                 | Not Reported                 |                |
|                                                | Zoloft             |                  |                    | S               |                                                 |                                                                             |                 | Not Reported                 |                |
|                                                | Lexapro            |                  |                    | S               |                                                 |                                                                             |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                        | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 16-Dec-2011                                    | 8295617            | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15925662 |                                                                             | 19 YR           | Female                       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                          | <u>Duration</u> | <u>Mfr</u>                   |                |
| Blood Thyroid Stimulating<br>Hormone Decreased | Abilify            |                  |                    | S               | Oral                                            | On 23may2011 Increased<br>To 15mg                                           |                 | Not Reported                 |                |

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|                                                                              | Lexapro                |                  |                    | S               |                                                 |                                  |                 |              | Not Reported   |
|------------------------------------------------------------------------------|------------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------------------|-----------------|--------------|----------------|
|                                                                              | Wellbutrin             |                  |                    | S               |                                                 |                                  |                 |              | Not Reported   |
|                                                                              | Dexedrine              |                  |                    | C               |                                                 |                                  |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                  | 8295670                | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15536444 |                                  | 72 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Tremor                                                                       | Abilify                |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Alcohol                |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Lexapro                |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Unspecified Ingredient |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                  | 8295732                | NON-EXPEDITED    |                    | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15962277 |                                  | 40 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Suicidal Ideation                                                            | Abilify                |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Lexapro                |                  |                    | S               |                                                 |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                     | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                  | 8295735                | NON-EXPEDITED    | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15962616 |                                  | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Catatonia; Depression;<br>Extrapyramidal Disorder;<br>Fall; Hypersensitivity | Abilify                |                  |                    | S               |                                                 | Dose Increased:15mg<br>16dec2008 |                 | Not Reported |                |
|                                                                              | Lexapro                |                  |                    | S               |                                                 | Dose Reduced To 10 Mg            |                 | Not Reported |                |
|                                                                              | Klonopin               |                  |                    | C               |                                                 | As Necessary                     |                 | Not Reported |                |
|                                                                              | Spirolactone           |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Simvastatin            |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Ambien Cr              |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Lanoxin                |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Citalopram             |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |
|                                                                              | Seroquel               |                  |                    | C               |                                                 |                                  |                 | Not Reported |                |

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|                          |                                                                              |                  |                    |                 |                                                 |                      |                    |                 |                                                                                                              |
|--------------------------|------------------------------------------------------------------------------|------------------|--------------------|-----------------|-------------------------------------------------|----------------------|--------------------|-----------------|--------------------------------------------------------------------------------------------------------------|
| Celexa                   |                                                                              |                  | C                  |                 |                                                 | Not Reported         |                    |                 |                                                                                                              |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>                                                                                               |
| 16-Dec-2011              | 8295822                                                                      | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15568058 |                      |                    | Female          | USA                                                                                                          |
| <u>Preferred Term</u>    | <u>Product</u>                                                               |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
| Pyrexia                  | Abilify<br>Lexapro                                                           |                  |                    |                 | S<br>S                                          |                      |                    |                 | Not Reported<br>Not Reported                                                                                 |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>                                                                                               |
| 16-Dec-2011              | 8295837                                                                      | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15993371 |                      | 48 YR              | Female          | USA                                                                                                          |
| <u>Preferred Term</u>    | <u>Product</u>                                                               |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
| Oedema                   | Abilify<br>Abilify<br>Abilify<br>Seroquel<br>Seroquel<br>Seroquel<br>Lexapro |                  |                    |                 | S<br>S<br>S<br>S<br>S<br>S<br>S                 |                      |                    |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>                                                                                               |
| 16-Dec-2011              | 8295928                                                                      | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15583974 |                      | 42 YR              | Female          | USA                                                                                                          |
| <u>Preferred Term</u>    | <u>Product</u>                                                               |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
| Weight Increased         | Abilify<br>Lexapro                                                           |                  |                    |                 | S<br>S                                          |                      |                    |                 | Not Reported<br>Not Reported                                                                                 |
| <u>FDA Received Date</u> | <u>Case #</u>                                                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u>                                                                                               |
| 16-Dec-2011              | 8296064                                                                      | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15603087 |                      | 40 YR              | Male            | USA                                                                                                          |
| <u>Preferred Term</u>    | <u>Product</u>                                                               |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                                     | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                                                                   |
| Restless Legs Syndrome   | Abilify                                                                      |                  |                    |                 | S                                               |                      |                    |                 | Not Reported                                                                                                 |



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| Lexapro                                  |                           |                  | S                  |                 |                                                 | Not Reported                                               |                 |              |                |
|------------------------------------------|---------------------------|------------------|--------------------|-----------------|-------------------------------------------------|------------------------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                 | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                              | 8296378                   | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16172702 |                                                            | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Crying; Screaming | Abilify                   |                  |                    | S               |                                                 | 2 Tablets At Bedtime.                                      |                 | Not Reported |                |
|                                          | Abilify                   |                  |                    | S               |                                                 | 2 Tablets At Bedtime.                                      |                 | Not Reported |                |
|                                          | Lexapro                   |                  |                    | S               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Depakote                  |                  |                    | S               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Glyburide                 |                  |                    | C               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Insulin Nos               |                  |                    | C               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Lexapro                   |                  |                    | C               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Celexa                    |                  |                    | C               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Blood Pressure Medication |                  |                    | C               |                                                 |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                              | 8296398                   | NON-EXPEDITED    | Y                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16189060 |                                                            | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscle Twitching                         | Abilify                   |                  |                    | S               |                                                 |                                                            |                 | Not Reported |                |
|                                          | Lexapro                   |                  |                    | S               |                                                 |                                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>             | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                              | 8296452                   | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15659600 |                                                            | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>            | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                         | Abilify                   |                  |                    | S               |                                                 | Then Increased To 5mg<br>And Finally Increased To<br>7.5mg |                 | Not Reported |                |
|                                          | Lexapro                   |                  |                    | S               |                                                 | Maximum Dose                                               |                 | Not Reported |                |
|                                          | Mirtazapine               |                  |                    | S               |                                                 | Maximum Dose                                               |                 | Not Reported |                |
|                                          | Lorazepam                 |                  |                    | S               |                                                 |                                                            |                 | Not Reported |                |

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| <u>FDA Received Date</u>                      | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
|-----------------------------------------------|-------------------------------|------------------|--------------------|-----------------|-------------------------------------------------|-------------------------------------------------------|-----------------|----------------------------------------------|----------------|
| 16-Dec-2011                                   | 8296459                       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15662539 |                                                       |                 | Unknown                                      | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Blood Cholesterol Increased; Weight Increased | Abilify<br>Lexapro            |                  |                    | S<br>S          |                                                 |                                                       |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 16-Dec-2011                                   | 8296663                       | NON-EXPEDITED    | N                  | LT, OT          | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15697436 |                                                       |                 | Female                                       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Drug Ineffective; Suicidal Ideation           | Abilify<br>Lexapro            |                  |                    | S<br>S          | Oral<br>Oral                                    |                                                       |                 | Not Reported<br>Not Reported                 |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 16-Dec-2011                                   | 8296673                       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15703598 |                                                       | 39 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Tardive Dyskinesia                            | Abilify<br>Lexapro<br>Ritalin |                  |                    | S<br>S<br>S     |                                                 |                                                       | 9 MTH<br>9 MTH  | Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                 | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                  | <u>Age</u>      | <u>Sex</u>                                   | <u>Country</u> |
| 16-Dec-2011                                   | 8296738                       | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15368665 |                                                       | 45 YR           | Female                                       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                    | <u>Duration</u> | <u>Mfr</u>                                   |                |
| Sensation Of Foreign Body                     | Abilify                       |                  |                    | S               |                                                 | Initial Dose:2mg Dose<br>Decreased From 5mg To<br>2mg |                 | Not Reported                                 |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                   |                  |                    |                 |                                                 |                                       |                 |              |                |
|-------------------------------------------|-------------------|------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------|-----------------|--------------|----------------|
| Topamax                                   |                   |                  | S                  |                 |                                                 | Not Reported                          |                 |              |                |
| Lexapro                                   |                   |                  | S                  |                 |                                                 | Not Reported                          |                 |              |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                               | 8296764           | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15375462 |                                       | 55 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysarthria                                | Abilify           |                  |                    | S               |                                                 | Started From 2mg<br>Increased To 5 Mg |                 | Not Reported |                |
|                                           | Lexapro           |                  |                    | S               |                                                 |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                               | 8296790           | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15721988 |                                       | 62 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain Upper;<br>Weight Decreased | Abilify           |                  |                    | S               |                                                 |                                       |                 | Not Reported |                |
|                                           | Lexapro           |                  |                    | S               |                                                 |                                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                               | 8296925           | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15750771 |                                       | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Oedema<br>Peripheral; Tremor  | Abilify           |                  |                    | S               |                                                 | Restart With 1 Mg Daily               |                 | Not Reported |                |
|                                           | Lexapro           |                  |                    | S               |                                                 | Initially 10mg Given, Then<br>5mg.    |                 | Not Reported |                |
|                                           | Diazepam          |                  |                    | C               |                                                 |                                       |                 | Not Reported |                |
|                                           | Premarin          |                  |                    | C               |                                                 | But Not Sunday                        |                 | Not Reported |                |
|                                           | Prednisone        |                  |                    | C               |                                                 |                                       |                 | Not Reported |                |
|                                           | Clonidine         |                  |                    | C               |                                                 |                                       |                 | Not Reported |                |
|                                           | Albuterol Sulfate |                  |                    | C               | Respiratory<br>(inhalation)                     |                                       |                 | Not Reported |                |
|                                           | Percocet          |                  |                    | C               |                                                 | 1df=7.5/325mg                         |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|-------------------------|------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------|-----------------|--------------|----------------|
| 16-Dec-2011                                                                                                         | 8297036                 | NON-EXPEDITED    | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15797848 |                                 | 58 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Abnormal;<br>Depression; Drug<br>Ineffective; Fatigue; Food<br>Craving; Insomnia; Weight<br>Increased | Abilify                 |                  |                    | S               |                                                 | Taken As Conmed Past 3<br>Years |                 | Not Reported |                |
|                                                                                                                     | Lexapro                 |                  |                    | S               |                                                 |                                 |                 | Not Reported |                |
|                                                                                                                     | Dostinex                |                  |                    | C               |                                                 |                                 | 3 YR            | Not Reported |                |
|                                                                                                                     | Quinapril               |                  |                    | C               |                                                 |                                 | 3 YR            | Not Reported |                |
|                                                                                                                     | Revatio                 |                  |                    | C               |                                                 |                                 | 3 YR            | Not Reported |                |
|                                                                                                                     | Diltiazem Hydrochloride |                  |                    | C               |                                                 |                                 | 3 YR            | Not Reported |                |
|                                                                                                                     | Ritalin                 |                  |                    | C               |                                                 |                                 | 3 YR            | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                                                         | 8297058                 | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15803414 |                                 | 17 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Weight Increased                                                                                                    | Abilify                 |                  |                    | S               |                                                 |                                 | 6 MTH           | Not Reported |                |
|                                                                                                                     | Vyvanse                 |                  |                    | S               |                                                 |                                 |                 | Not Reported |                |
|                                                                                                                     | Lexapro                 |                  |                    | S               |                                                 |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>           | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Dec-2011                                                                                                         | 8297122                 | NON-EXPEDITED    | N                  |                 | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>15432214 |                                 | 78 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>          | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Dysphonia                                                                                                           | Abilify                 |                  |                    | S               | Oral                                            |                                 |                 | Not Reported |                |
|                                                                                                                     | Lexapro                 |                  |                    | S               | Oral                                            |                                 |                 | Not Reported |                |
|                                                                                                                     | Amlodipine              |                  |                    | C               | Oral                                            |                                 |                 | Not Reported |                |
|                                                                                                                     | Aspirin                 |                  |                    | C               | Oral                                            |                                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------------------|-----------------|--------------|----------------|
| 19-Dec-2011                                                                                                                                        | 8082019                                                                                              | EXPEDITED (15-DAY) | Y                  | DS              | 1000022125                |                                   | 55 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Agitation; Blood Pressure<br>Increased; Depression;<br>Macular Oedema; Retinal<br>Vein Thrombosis; Visual<br>Acuity Reduced | Escitalopram Oxalate                                                                                 |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                    | Escitalopram Oxalate                                                                                 |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D),<br>Oral  |                 | Not Reported |                |
|                                                                                                                                                    | Isradipine                                                                                           |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Dexamethasone                                                                                        |                    |                    | C               |                           |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2011                                                                                                                                        | 8291856                                                                                              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025941                |                                   | 48 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaphylactic Reaction;<br>Blood Pressure<br>Decreased; Diarrhoea;<br>Feeling Abnormal;<br>Peripheral Coldness                                      | Lexapro                                                                                              |                    |                    | S               | Oral                      | 10 Mg (10 Mg , 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                                    | Dogmatyl (Sulpiride) (Tablets)<br>(Sulpiride)                                                        |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Milnacipran Hydrochloride<br>(Milnacipran Hydrochloride)<br>(Tablets) (Milnacipran<br>Hydrochloride) |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Wypax (Lorazepam (Tablets)<br>(Lorazepam)                                                            |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Evamyl (Lormetazepam)<br>(Tablets) (Lormetazepam)                                                    |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Halcion (Triazolam) (Tablets)<br>(Triazolam)                                                         |                    |                    | C               |                           |                                   |                 | Not Reported |                |
|                                                                                                                                                    | Luvox                                                                                                |                    |                    | C               |                           |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                           | <u>Case #</u>                                                                                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Dec-2011                                                                                                                                        | 8298157                                                                                              | EXPEDITED (15-DAY) | Y                  | OT              | GB-JNJFOC-<br>20111206543 |                                   |                 | Male         | GBR            |
| <u>Preferred Term</u>                                                                                                                              | <u>Product</u>                                                                                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                  |                               |   |      |              |
|------------------|-------------------------------|---|------|--------------|
| Adrenal Disorder | Methylphenidate Hydrochloride | S | Oral | Not Reported |
|                  | Cipralex                      | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 19-Dec-2011              | 8299688       | EXPEDITED (15-DAY) | N                  | OT              | DE-ASTRAZENECA-2011SE19881 |                      | 35 YR      | Female     | DEU            |

  

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gestational Diabetes;<br>Maternal Exposure During<br>Pregnancy | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                | Seroquel       |              |            | S           | Oral         |                    |                 | Zeneca       |
|                                                                | Cipralex       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Insulin Nos    |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 19-Dec-2011              | 8300489       | EXPEDITED (15-DAY) | Y                  | HO              | US-PFIZER INC-US-WYE-H07238408 |                      | 48 YR      | Female     | USA            |

  

| <u>Preferred Term</u>                                                                                                  | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Condition Aggravated;<br>Dysarthria; Hypertension;<br>Hypokalaemia; Mental<br>Status Changes; Multiple<br>Drug Therapy | Desvenlafaxine         |              |            | S           | Oral         | Blinded Therapy Daily | 75 DAY          | Pfizer       |
|                                                                                                                        | Unspecified Ingredient |              |            | S           | Oral         | Blinded Therapy Daily | 75 DAY          | Pfizer       |
|                                                                                                                        | Unspecified Ingredient |              |            | S           | Oral         | Blinded Therapy Daily | 75 DAY          | Pfizer       |
|                                                                                                                        | Desvenlafaxine         |              |            | S           | Oral         | Blinded Therapy Daily | 26 DAY          | Pfizer       |
|                                                                                                                        | Unspecified Ingredient |              |            | S           | Oral         | Blinded Therapy Daily | 26 DAY          | Pfizer       |
|                                                                                                                        | Unspecified Ingredient |              |            | S           | Oral         | Blinded Therapy Daily | 26 DAY          | Pfizer       |
|                                                                                                                        | Ibuprofen              |              |            | S           | Unknown      | 800 Mg, 3x/Day        |                 | Pfizer       |
|                                                                                                                        | Lyrica                 |              |            | S           | Unknown      | 75 Mg, 1x/Day         |                 | Pfizer       |
|                                                                                                                        | Clonazepam             |              |            | S           | Unknown      | 1 Mg, 2x/Day          |                 | Not Reported |
|                                                                                                                        | Loratadine             |              |            | S           | Unknown      | 10 Mg, 1x/Day         |                 | Pfizer       |
|                                                                                                                        | Robaxin                |              |            | S           | Oral         | 750 Mg, 3x/Day        |                 | Pfizer       |
|                                                                                                                        | Lexapro                |              |            | S           | Unknown      | 20 Mg, 1x/Day         |                 | Not Reported |
|                                                                                                                        | Abilify                |              |            | S           | Unknown      | 15 Mg, 2x/Day         |                 | Not Reported |
|                                                                                                                        | Fluticasone            |              |            | S           | Unknown      | 2 Sprays Daily        |                 | Not Reported |

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|            |   |             |               |              |
|------------|---|-------------|---------------|--------------|
| Vicodin    | S | Unknown     | 5/500 Prn     | Not Reported |
| Zestoretic | S | Unknown     | 20/12.5 Daily | Not Reported |
| Ambien     | S | Oral        | 10 Mg, 1x/Day | Not Reported |
| Vivelle    | S | Transdermal | 0.1 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2011              | 8314939       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026208           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>      | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|---------------------------------------|--------------|------------|-------------|-------------------|------------------------------------------------|-----------------|--------------|
| Leukopenia; Neutropenia | Escitalopram Oxalate                  |              |            | S           | Oral              | 10 Mg (10 Mg, 1 In 1 D),<br>Oral               |                 | Not Reported |
|                         | Benzylpenicillinic Acid<br>Ethoxymide |              |            | S           | Intravenous bolus | 12 Gram (3 Gm, 4 In 1 D),<br>Intravenous Bolus |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2011              | 8316107       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000026121           |                      | 69 YR      | Male       | USA            |

| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Off Label Use; Vomiting | Lexapro        |              |            | S           | Oral         | 10 Mg(10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Dec-2011              | 8316557       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000026207           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Feeling<br>Abnormal; Loss Of<br>Consciousness; Speech<br>Disorder; Thought<br>Blocking | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                                 | Lorazepam            |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>                                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------|----------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------------------------|--------------------------|---------------------|-------------------------|
| 19-Dec-2011                                                            | 8316636                                                  | EXPEDITED (15-DAY)        | N                           | DE                       | 1000026205                    |                                                    |                          | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a>                                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dissociative Identity Disorder; Irritability; Suicidal Ideation        | Escitalopram Oxalate                                     |                           |                             | S                        |                               |                                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>                                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Dec-2011                                                            | 8316654                                                  | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000026206                    |                                                    |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a>                                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Burning Sensation; Insomnia; Paraesthesia                              | Escitalopram Oxalate                                     |                           |                             | S                        | Oral                          | Oral                                               |                          | Not Reported        |                         |
|                                                                        | Escitalopram Oxalate                                     |                           |                             | S                        | Oral                          | 0.3333 Dosage Form (1 Dosage Forms, 1 In 3 D),Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>                                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2011                                                            | 7970533                                                  | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000020771                    |                                                    | 51 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a>                                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anosmia; Cough; Nasal Obstruction; Oedema Mucosal; Rhinitis; Sinusitis | Escitalopram Oxalate                                     |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral                      |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                      | <a href="#">Case #</a>                                   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                      | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2011                                                            | 8192657                                                  | EXPEDITED (15-DAY)        | Y                           | HO, RI, OT               | 1000024112                    |                                                    | 66 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                         | <a href="#">Product</a>                                  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                        | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Off Label Use; Pancreatitis Acute                                      | Escitalopram Oxalate                                     |                           |                             | S                        | Oral                          | 15 Mg (15 Mg, 1 In 1 D), Oral                      |                          | Not Reported        |                         |
|                                                                        | Truxal Dragees (Chlorprothixene Hydrochloride) (Tablets) |                           |                             | C                        |                               |                                                    |                          | Not Reported        |                         |



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|                                              |   |              |
|----------------------------------------------|---|--------------|
| (Chlorprothixene Hydrochloride)              |   |              |
| Zolpidem Tartrate                            | C | Not Reported |
| Lorazepam                                    | C | Not Reported |
| Remeron                                      | C | Not Reported |
| Creon                                        | C | Not Reported |
| Novothyral (Novothyral)                      | C | Not Reported |
| (Tablets) (Novothyral)                       |   |              |
| Pantozol (Pantoprazole Sodium Sesquihydrate) | C | Not Reported |
| Novalgine (Metamizole Sodium)                | C | Not Reported |
| Dafalgan (Paracetamol)                       | C | Not Reported |
| (Tablets) (Paracetamol)                      |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Dec-2011              | 8303058       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011306325 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Inappropriate Schedule Of Product Administration; Neuralgia; Paraesthesia | Lyrice         |              |            | S           | Oral         | 75 Mg, Daily       |                 | Pfizer       |
|                                                                                    | Lexapro        |              |            | S           |              | 5 Mg, Unk          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Dec-2011              | 8316043       | EXPEDITED (15-DAY) | Y                  | CA, HO          | 1000026311           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-----------------------------------------|-----------------|--------------|
| Anaemia; Bone Marrow Disorder; Caesarean Section; Congenital Anomaly; Infection; Maternal Drugs Affecting Foetus; Respiratory Disorder; Therapy Non-Responder | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg (10 Mg, 1 In 1 D), Transplacental |                 | Not Reported |
|                                                                                                                                                               | Xanax                |              |            | C           |                |                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2011              | 8100072       | EXPEDITED (15-DAY) | Y                  | LT              | 1000022516           |                      | 44 YR      | Male       | DNK            |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| Aggression; Asphyxia;<br>Blood Creatine<br>Phosphokinase Increased;<br>Confusional State; Eye<br>Movement Disorder;<br>General Physical Health<br>Deterioration;<br>Hyporeflexia;<br>Hypoventilation; Muscle<br>Rigidity; Mydriasis;<br>Neuroleptic Malignant<br>Syndrome; Serotonin<br>Syndrome; Stupor; Suicide<br>Attempt; Tachycardia | Escitalopram Oxalate                            |                    |                    | S               | Oral                 | 5 Mg (5 Mg,1 In 1 D),Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Escitalopram Oxalate                            |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Baclofen                                        |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Baclofen                                        |                    |                    | S               | Oral                 | 25 Mg (25 Mg,1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Hiprex (Methenamine Hippurate)                  |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | (Methenamine Hippurate)                         |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Imovane (Zopiclone) (Zopiclone)                 |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Marevan                                         |                    |                    | C               |                      |                             |                 | Not Reported |                |
| Bio-C-Vitamin (Ascorbic Acid)                                                                                                                                                                                                                                                                                                             |                                                 |                    | C                  |                 |                      |                             | Not Reported    |              |                |
| (Ascorbic Acid)                                                                                                                                                                                                                                                                                                                           |                                                 |                    | C                  |                 |                      |                             | Not Reported    |              |                |
| Alopam (Oxazepam)                                                                                                                                                                                                                                                                                                                         |                                                 |                    | C                  |                 |                      |                             |                 | Not Reported |                |
| (Oxazepam)                                                                                                                                                                                                                                                                                                                                |                                                 |                    | C                  |                 |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                  | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                                                                                                                                                                                                                                                                               | 8170865                                         | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024145           |                             | 47 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Angle Closure Glaucoma;<br>Optic Neuritis; Visual Field<br>Defect                                                                                                                                                                                                                                                                         | Escitalopram Oxalate                            |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                                                  | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                                                                                                                                                                                                                                                                               | 8281540                                         | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025748           |                             | 31 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                     | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Arterial<br>Pressure Increased;<br>Pulmonary Hypertension;<br>Tricuspid Valve<br>Incompetence                                                                                                                                                                                                                                   | Escitalopram Oxalate                            |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Benfluorex Hydrochloride                        |                    |                    | S               | Oral                 | Oral                        |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Levothyroxine Sodium                            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Lantus (Insulin Glargine) (Insulin<br>Glargine) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                                                           | Humalog                                         |                    |                    | C               |                      |                             |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2011                                                                                                                   | 8294525                 | EXPEDITED (15-DAY) | Y                  | HO              | 2011AP002854               |                      | 65 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anoxia; Balance Disorder;<br>Cardiac Arrest;<br>Cardiogenic Shock;<br>Confusional State;<br>Hypokalaemia; Injury;<br>Overdose | Quinapril Hydrochloride |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                               | Venlafaxine             |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                               | Amitriptyline           |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                               | Atenolol                |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                               | Escitalopram Oxalate    |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                               | Insulin Nos             |                    |                    | S               | Intravenous bolus          | 80 lu;lvbol          |                 | Not Reported |                |
|                                                                                                                               | Insulin Nos             |                    |                    | S               | Intravenous drip           | lvdrp                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                                                                   | 8305676                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE76852 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                                                    | Quetiapine              |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Gabapentin              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                                                                   | 8306241                 | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE76936 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Toxicity To Various Agents                                                | Atenolol                |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                                                               | Venlafaxine             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Citalopram              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Lamotrigine             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Hydroxyzine             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                                                               | Alcohol                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 21-Dec-2011                                                                    | 8306283                              | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE76787 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                               | Esomeprazole                         |                    |                    | S               | Oral                       |                      |                 | Astrazeneca  |                |
|                                                                                | Metoprolol Succinate                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Metformin Hydrochloride              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Unspecified Ingredient               |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Acetaminophen\Unspecified Ingredient |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                    | 8306288                              | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE76743 |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                               | Lisinopril                           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                | Carvedilol                           |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Diltiazem Hydrochloride              |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Escitalopram Oxalate                 |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Diazepam                             |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Dec-2011                                                                    | 8306295                              | EXPEDITED (15-DAY) | Y                  | DE              | US-ASTRAZENECA-2011SE76519 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Toxicity To Various Agents | Quetiapine                           |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |
|                                                                                | Oxcarbazepine                        |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Bupropion                            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |
|                                                                                | Lorazepam                            |                    |                    | S               | Oral                       |                      |                 | Not Reported |                |

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|                      |   |      |              |
|----------------------|---|------|--------------|
| Escitalopram Oxalate | S | Oral | Not Reported |
| Zolpidem             | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2011              | 8316995       | DIRECT           | Y                  | RI              |                      |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Skin Hyperpigmentation;<br>Skin Lesion | Lexapro        |              |            | S           |              | 10mg Po Qd         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2011              | 8318424       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026421           |                      |            | Unknown    | DNK            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Drug Dependence;<br>Withdrawal Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Dec-2011              | 8318469       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026358           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                           | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Abdominal Distension;<br>Agitation; Bladder<br>Dilatation; Blood Glucose<br>Increased; Blood Pressure<br>Systolic Increased; Coma;<br>Convulsive Threshold<br>Lowered; Drug Interaction;<br>Generalised Tonic-Clonic<br>Seizure; Postictal State;<br>Right Atrial Hypertrophy;<br>Sinus Tachycardia;<br>Treatment Noncompliance | Escitalopram Oxalate                      |              |            | S           | Oral         | 1 Df (Dosage Forms, 1 In<br>1 D), Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                 | Baclofen                                  |              |            | S           | Oral         | Oral                                     |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                 | Lithium Carbonate                         |              |            | S           | Oral         | 2 Df (Dosage Forms, 1 In<br>1 D), Oral   |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                 | Amoxapine                                 |              |            | S           | Oral         | 2 Df (2 Dosage Forms, 1<br>In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                 | Stilnox (Zolpidem Tartrate)               |              |            | C           |              |                                          |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                 | Avlocardyl (Propranolol)<br>(Propranolol) |              |            | C           |              |                                          |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2011              | 8278467       | EXPEDITED (15-DAY) | N                  | DS              | US-TEVA-311528USA    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                  | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Apathy; Confusional State;<br>Depression; Drug<br>Interaction; Flat Affect;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Memory<br>Impairment; Oedema<br>Peripheral; Pain;<br>Somnolence; Wrong<br>Product Administered | Carbamazepine                                       |              |            | S           |              | 200 Milligram;       |                 | Not Reported |
|                                                                                                                                                                                                                                        | Docusate Sodium                                     |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                                                                                                                                                        | Ascorbic Acid                                       |              |            | C           |              | 1000 Milligram;      |                 | Not Reported |
|                                                                                                                                                                                                                                        | Allium Sativum                                      |              |            | C           |              | 1000 Milligram;      |                 | Not Reported |
|                                                                                                                                                                                                                                        | Calcium Citrate                                     |              |            | C           |              | 1000 Unknown;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Cyanocobalamin                                      |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                                                                                                                                                        | Fish Oil                                            |              |            | C           |              | 1200 Unknown;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Tocopherol                                          |              |            | C           |              |                      |                 | Not Reported |
|                                                                                                                                                                                                                                        | Ergocalciferol                                      |              |            | C           |              | 2000 Unknown;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Chondroitin Sulfate<br>(Bovine)\Glucosamine Sulfate |              |            | C           |              | 600/560              |                 | Not Reported |
|                                                                                                                                                                                                                                        | Trazodone Hydrochloride                             |              |            | S           |              | 50 Milligram;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Warfarin Sodium                                     |              |            | S           |              | 1-7 Pills Evening    |                 | Not Reported |
|                                                                                                                                                                                                                                        | Escitalopram Oxalate                                |              |            | S           |              | 20 Milligram;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Levothyroxine Sodium                                |              |            | S           |              | 225 Microgram;       |                 | Not Reported |
|                                                                                                                                                                                                                                        | Celecoxib                                           |              |            | S           |              | 200 Milligram;       |                 | Not Reported |
|                                                                                                                                                                                                                                        | Toviaz                                              |              |            | S           |              | 8 Milligram;         |                 | Not Reported |
|                                                                                                                                                                                                                                        | Omeprazole                                          |              |            | S           |              | 1:00 Am              |                 | Not Reported |
|                                                                                                                                                                                                                                        | Furosemide                                          |              |            | S           |              | 80 Milligram;        |                 | Not Reported |
|                                                                                                                                                                                                                                        | Bupropion Hydrochloride                             |              |            | S           |              | 300 Unknown;         |                 | Not Reported |
|                                                                                                                                                                                                                                        | Potassium Chloride                                  |              |            | S           |              | 20 Milliequivalents; |                 | Not Reported |
|                                                                                                                                                                                                                                        | Vicodin                                             |              |            | S           |              | 10/325 Mg            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2011              | 8280449       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025759           |                      | 61 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                              |                                                                    |   |      |                                                         |              |
|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------|---|------|---------------------------------------------------------|--------------|
| Drug Level Increased;<br>Intentional Overdose;<br>Mood Altered; Social<br>Avoidant Behaviour | Escitalopram Oxalate                                               | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 280 Mg, Once, Oral    | Not Reported |
|                                                                                              |                                                                    |   | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral, 280 Mg, Once, Oral    |              |
|                                                                                              | Tegretol                                                           | S | Oral | 200 Mg (200 Mg, 1 In 1 D),<br>Oral, 1800 Mg, Once, Oral | Not Reported |
|                                                                                              |                                                                    |   | Oral | 200 Mg (200 Mg, 1 In 1 D),<br>Oral, 1800 Mg, Once, Oral |              |
|                                                                                              | Brotizolam                                                         | S | Oral | 0.25 Mg (0.25 Mg, 1 In 1<br>D), Oral, Dose Ingested     | Not Reported |
|                                                                                              |                                                                    |   | Oral | Not Reported (Once), Oral                               |              |
|                                                                                              |                                                                    |   |      | 0.25 Mg (0.25 Mg, 1 In 1<br>D), Oral, Dose Ingested     |              |
|                                                                                              |                                                                    |   |      | Not Reported (Once), Oral                               |              |
|                                                                                              | Prazepam                                                           | S | Oral | 150 Mg, Once, Oral                                      | Not Reported |
|                                                                                              | Simvastatin                                                        | C |      |                                                         | Not Reported |
|                                                                                              | Aspirin                                                            | C |      |                                                         | Not Reported |
|                                                                                              | Atenolol                                                           | C |      |                                                         | Not Reported |
|                                                                                              | Metforal (Metformin<br>Hydrochloride) (Metformin<br>Hydrochloride) | C |      |                                                         | Not Reported |
|                                                                                              | Tavor (Lorazepam)                                                  | C |      |                                                         | Not Reported |
|                                                                                              | Isoptin (Verapamil<br>Hydrochloride) (Verapamil<br>Hydrochloride)  | C |      |                                                         | Not Reported |

| <u>FDA Received Date</u>           | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|-----------------------------------------|-----------------|----------------------|----------------|
| 22-Dec-2011                        | 8292257                               | EXPEDITED (15-DAY) | N                  | HO              | IT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16274714 |                                         | 84 YR           | Female               | ITA            |
| <u>Preferred Term</u>              | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>           |                |
| Hyponatraemia; Nausea;<br>Vomiting | Irbesartan And<br>Hydrochlorothiazide |                    |                    | S               | Oral                                            | 1 Dosage Form = 1<br>Posological Unit   | 3 YR            | Bristol Myers Squibb |                |
|                                    | Escitalopram Oxalate                  |                    |                    | S               | Oral                                            | On 20-Sep-2011, Dose<br>Reduced To 10mg |                 | Not Reported         |                |
|                                    | Seroquel                              |                    |                    | C               | Oral                                            |                                         |                 | Not Reported         |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 22-Dec-2011              | 8306177       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2010102880 |                      | 57 YR      | Male       | USA            |

| <u>Preferred Term</u>                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|---------------------------|-----------------|--------------|
| Drug Ineffective; Drug Interaction; Incorrect Dose Administered | Viagra         |              |            | S           | Oral         | Unk                       |                 | Pfizer       |
|                                                                 | Naspro         |              |            | C           |              | Unk                       |                 | Not Reported |
|                                                                 | Naproxen       |              |            | C           |              | 500 Mg, Daily             |                 | Not Reported |
|                                                                 | Vitamin D2     |              |            | C           |              | Unk                       |                 | Not Reported |
|                                                                 | Viagra         |              |            | S           | Oral         | Unk, As Needed            |                 | Pfizer       |
|                                                                 | Viagra         |              |            | S           | Oral         | 100mg Or 150mg, As Needed |                 | Pfizer       |
|                                                                 | Viagra         |              |            | S           |              | 100 Mg, Unk               |                 | Pfizer       |
|                                                                 | Lexapro        |              |            | S           |              | Unk                       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2011              | 8323291       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026322           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>                                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|------------------------------------------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Daydreaming; Dizziness; Nausea; Panic Attack | Escitalopram Oxalate                                                   |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                              | Yasmin (Drospirenone, Ethylestradiol) (Drospirenone, Ethinylestradiol) |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Dec-2011              | 8343368       | EXPEDITED (15-DAY) | N                  | OT              | DSA_48567_2011       |                      |            | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Stress; Suicidal Ideation; Thinking Abnormal | Wellbutrin     |              |            | S           |              | 300 Mg, Bid        |                 | Not Reported |
|                                              | Effexor        |              |            | S           |              | Df                 |                 | Not Reported |
|                                              | Zyprexa        |              |            | S           |              | Df                 |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |    |              |
|-------------|---|----|--------------|
| Lexapro     | S | Df | Not Reported |
| Adderall Xr | S | Df | Not Reported |
| Ambien      | S | Df | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2011              | 8318853       | DIRECT           | N                  | DS, HO          |                      |                      | 36 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disability; Insomnia; Pain; Personality Change; Social Avoidant Behaviour; Weight Decreased; Withdrawal Syndrome | Lexapro        |              |            | S           |              | 10 Mg A Day 047    |                 | Forest       |
|                                                                                                                  | Geodon         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Paxil          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Amadryl        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Seroquel       |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Actos          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                  | Naproxin       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Dec-2011              | 8322839       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026475           |                      | 56 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Activation Syndrome; Aggression; Agitation; Anger; Blood Alkaline Phosphatase Increased; Blood Cholesterol Increased; Blood Lactate Dehydrogenase Increased; Personality Change | Lexapro           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                 | Ethyl Loflazepate |              |            | S           | Oral         | 8 Mg (4 Mg, 2 In 1 D), Oral   |                 | Not Reported |
|                                                                                                                                                                                 | Doral             |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Dec-2011              | 8324710       | EXPEDITED (15-DAY) | Y                  | OT              | 2011AP001167         |                      | 21 YR      | Female     | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                           |   |      |                              |              |
|----------------------------------------------------|---------------------------|---|------|------------------------------|--------------|
| Disturbance In Social Behaviour; Oculogyric Crisis | Risperidone (Risperidone) | S | Oral | Po, 1.5 Mg;Po                | Not Reported |
|                                                    | Cipralext                 | S | Oral | Po, 1.5 Mg;Po<br>20 Mg;Po;Qd | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2011              | 8270999       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025614           |                      | 21 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------------------|-----------------|--------------|
| Overdose; Sluggishness; Suicide Attempt | Escitalopram Oxalate |              |            | S           |              | Oral, Overdose: Unknown Amount (Once)<br>Oral, Overdose: Unknown Amount (Once) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2011              | 8310053       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026159           |                      | 89 YR      | Female     | DNK            |

  

| <u>Preferred Term</u>                                                                     | <u>Product</u>                                                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>                                               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------|------------|-------------|---------------------------------------|------------------------------------------------------------------|-----------------|--------------|
| Anaemia; International Normalised Ratio                                                   | Escitalopram Oxalate                                                    |              |            | S           | Oral                                  | 20 Mg (20 Mg, 1 In 1 D), Oral                                    |                 | Not Reported |
| Increased; Lung Infection; Melaena; Small Intestinal Haemorrhage; Urinary Tract Infection | Ketoprofen                                                              |              |            | S           | Intravenous (not otherwise specified) | 100 Mg (100 Mg, 1 In 1 D), Intravenous (Not Otherwise Specified) |                 | Not Reported |
|                                                                                           | Fluindione                                                              |              |            | S           | Oral                                  | 30 Mg (30 Mg, 1 In 1 D), Oral                                    |                 | Not Reported |
|                                                                                           | Amlodipine Besylate                                                     |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Furosemide                                                              |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Zestril (Lisinopril (20 Milligram, Tablets) (Lisinopril)                |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Tracleer (Bosentan) (125 Milligram, Tablets) (Bosentan)                 |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Stilnox (Zolpidem Tartrate) (10 Milligram, Tablets) (Zolpidem Tartrate) |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Eupantol                                                                |              |            | C           |                                       |                                                                  |                 | Not Reported |
|                                                                                           | Anafranil (Clomipramine Hydrochloride) (25 Milligram,                   |              |            | C           |                                       |                                                                  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                            |   |              |
|------------------------------------------------------------|---|--------------|
| Tablets) (Clomipramine Hydrochloride)                      | C | Not Reported |
| Adenuric (Febuxostat) (80 Milligram, Tablets) (Febuxostat) | C | Not Reported |
| Mopral (Omeprazole) (Tablets) (Omeprazole)                 | C | Not Reported |
| Aerius (Ebastine) (5 Milligram, Tablets) (Ebastine)        | C | Not Reported |
| Paracetamol (Paracetamol) (1 Gram) (Paracetamol)           | C | Not Reported |
| Durogesic                                                  | C | Not Reported |
| Oxygen (Oxygen) (Gas For Inhalation) (Oxygen)              | C | Not Reported |
| Tavanic (Levofloxacin) (500 Milligram) (Levofloxacin)      | C | Not Reported |
| Rocephin (Ceftriaxone Sodium) (Ceftriaxone Sodium)         | C | Not Reported |
| Speciafoldine (Folic Acid) (Tablets) (Folic Acid)          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 28-Dec-2011              | 8325374       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026483           |                      | 63 YR      | Male       | DNK            |

| <u>Preferred Term</u>                 | <u>Product</u>                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                         | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-----------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------------|-----------------|--------------|
| Arrhythmia; Ventricular Extrasystoles | Escitalopram Oxalate                                            |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                       |                                                                 |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral, 5 Mg (5 Mg, 1 In 1 D), Oral |                 |              |
|                                       | Escitalopram Oxalate                                            |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D), Oral                              |                 | Not Reported |
|                                       | Lipitor (Atorvastatin Calcium) (Tablets) (Atorvastatin Calcium) |              |            | C           |              |                                                            |                 | Not Reported |
|                                       | Alprazolam (Alprazolam) (Tablets) (Alprazolam)                  |              |            | C           |              |                                                            |                 | Not Reported |
|                                       | Cetirizine (Cetirizine) (Tablets) (Cetirizine)                  |              |            | C           |              |                                                            |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 28-Dec-2011                                                                                                         | 8325954                                | DIRECT             | Y                  | OT              |                          |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Blood Pressure Increased; Condition Aggravated; Confusional State; Depression; Insomnia; Suicidal Ideation | Paroxetine                             |                    |                    | S               | Oral                     | 30mg 1 Day Po        |                 | Cadila       |                |
|                                                                                                                     | Lexapro                                |                    |                    | S               | Oral                     | 10mg 1 Day Po        |                 | Not Reported |                |
|                                                                                                                     | Benazepril Hcl And Hydrochlorothiazide |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Phenergan                              |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Premarin                               |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Diclofenac                             |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2011                                                                                                         | 7935191                                | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2011096237 |                      | 26 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Overdose; Toxicity To Various Agents                                                                     | Xanax                                  |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                     | Hydroxyzine Hcl                        |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                     | Ibuprofen                              |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                                                                     | Morphine                               |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Cocaine                                |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Oxycontin                              |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Escitalopram                           |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Quetiapine                             |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                                                                     | Cannabis                               |                    |                    | S               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                            | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2011                                                                                                         | 8314938                                | EXPEDITED (15-DAY) | Y                  | HO, OT          | GB-UCBSA-048375          |                      |                 | Male         | GBR            |
| <u>Preferred Term</u>                                                                                               | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Adrenomegaly                                                                                                        | Metadate                               |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                                     | Cipralext                              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|---------------------------|-------------------------------|-----------------|--------------|----------------|
| 29-Dec-2011                                                                                                                | 8315143                                                       | EXPEDITED (15-DAY) | Y                  | HO, LT          | DK-MYLANLABS-2011S1025955 |                               |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt               | Baclofen                                                      |                    |                    | S               | Oral                      |                               |                 | Mylan        |                |
|                                                                                                                            | Baclofen                                                      |                    |                    | S               |                           |                               |                 | Mylan        |                |
|                                                                                                                            | Mirtazapine                                                   |                    |                    | S               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Escitalopram Oxalate                                          |                    |                    | S               |                           |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2011                                                                                                                | 8315379                                                       | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2011310059  |                               | 35 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Accidental Exposure To Product                                                                                             | Gabapentin                                                    |                    |                    | S               |                           |                               |                 | Pfizer       |                |
|                                                                                                                            | Escitalopram Oxalate                                          |                    |                    | S               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Quetiapine                                                    |                    |                    | S               |                           |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Dec-2011                                                                                                                | 8315587                                                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026247                |                               | 92 YR           | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Blood Pressure Systolic Increased; Gastrooesophageal Reflux Disease; Loss Of Consciousness; Therapy Non-Responder | Lexapro                                                       |                    |                    | S               | Oral                      | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                            | Rasilez (Aliskiren Fumarate)                                  |                    |                    | C               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | (Aliskiren Fumarate)                                          |                    |                    |                 |                           |                               |                 |              |                |
|                                                                                                                            | Aricept                                                       |                    |                    | C               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Carvedilol                                                    |                    |                    | C               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Risperdal                                                     |                    |                    | C               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Bup-4 (Propiverine Hydrochloride) (Propiverine Hydrochloride) |                    |                    | C               |                           |                               |                 | Not Reported |                |
|                                                                                                                            | Pariet (Rabeprazole Sodium) (Rabeprazole Sodium)              |                    |                    | C               |                           |                               |                 | Not Reported |                |

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| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|----------------------------------------|--------------------------|---------------------|-------------------------|
| 29-Dec-2011                                                                              | 8327595                                                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000026509                    |                                        | 35 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Optic Nerve Disorder                                                                     | Lexapro                                                |                           |                             | S                        | Oral                          | 10-20 Mg/Day, Oral                     |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Dec-2011                                                                              | 8328682                                                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000026532                    |                                        | 59 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Impaired Work Ability; Malaise; Sense Of Oppression; Suicidal Ideation | Escitalopram Oxalate                                   |                           |                             | S                        | Oral                          | 20 Mg (20 Mg, 1 In 1 D), Oral          |                          | Not Reported        |                         |
|                                                                                          | Escitalopram Oxalate                                   |                           |                             | S                        | Oral                          | 40 Mg (2 Dosage Forms, 1 In 1 D), Oral |                          | Not Reported        |                         |
|                                                                                          | Ixprim (Tramadol, Paracetamol) (Tramadol, Paracetamol) |                           |                             | C                        |                               |                                        |                          | Not Reported        |                         |
|                                                                                          | Seresta (Oxazepam) (Oxazepam)                          |                           |                             | C                        |                               |                                        |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Dec-2011                                                                              | 8328977                                                | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000026524                    |                                        | 67 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthenia; Muscular Weakness                                                              | Escitalopram Oxalate                                   |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral          |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                        | <a href="#">Case #</a>                                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>          | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Dec-2011                                                                              | 8318047                                                | EXPEDITED (15-DAY)        | Y                           |                          | 1000026351                    |                                        |                          | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                           | <a href="#">Product</a>                                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>            | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Dyspnoea; Fatigue; Swollen Tongue;                                            | Escitalopram Oxalate                                   |                           |                             | S                        |                               |                                        |                          | Not Reported        |                         |
|                                                                                          | Escitalopram Oxalate                                   |                           |                             | S                        |                               | 15 Mg (15 Mg, 1 In 1 D),               |                          | Not Reported        |                         |

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Vomiting; Weight Increased

10 Mg (10 Mg, 1 In 1 D)  
15 Mg (15 Mg, 1 In 1 D),  
10 Mg (10 Mg, 1 In 1 D)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Dec-2011              | 8329430       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026569           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Blood Creatine Phosphokinase Increased;                                                     | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |
| Blood Lactate Dehydrogenase Increased; Excessive Exercise; Myalgia; Transaminases Increased | Amisulpride          |              |            | S           | Oral         | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Jan-2012              | 8263280       | EXPEDITED (15-DAY) |                    | OT              | PHEH2011US009343     |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|-----------------------|-----------------|--------------|
| Abdominal Discomfort;                                                                                                                                                                                                                     | Diovan Hct              |              |            | S           |              | 1 Df, Qd              |                 | Not Reported |
| Anxiety; Atrophy; Blood Pressure Inadequately Controlled; Drug Ineffective; Feeling Abnormal; Hepatic Enzyme Abnormal; Limb Discomfort; Malaise; Memory Impairment; Muscle Spasms; Nightmare; Ocular Discomfort; Sciatica; Sleep Disorder | Diovan Hct              |              |            | S           |              | 1 Df (320/12.5mg), Qd |                 | Not Reported |
|                                                                                                                                                                                                                                           | Citalopram              |              |            | S           | Oral         | 20 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                                           | Oxycodone Hydrochloride |              |            | S           |              | 5 Mg, Unk             |                 | Not Reported |
|                                                                                                                                                                                                                                           | Fexofenadine            |              |            | S           |              | 180 Mg, Qd            |                 | Not Reported |
|                                                                                                                                                                                                                                           | Gabapentin              |              |            | S           |              | Unk                   |                 | Not Reported |
|                                                                                                                                                                                                                                           | Morphine                |              |            | S           |              | 30 Mg, Tid            |                 | Not Reported |
|                                                                                                                                                                                                                                           | Oxycontin               |              |            | S           |              | 30 Mg, Bid            |                 | Not Reported |
|                                                                                                                                                                                                                                           | Cymbalta                |              |            | S           |              | 30 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                                           | Cymbalta                |              |            | S           |              | 60 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                                           | Lyrica                  |              |            | S           |              | 25 Mg, Qd             |                 | Not Reported |
|                                                                                                                                                                                                                                           | Lexapro                 |              |            | S           |              | 10 Mg, Qd             |                 | Not Reported |

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|                                                                                                                          | Effexor                                                        |                    | S                  |                 |                          | Unk                           |                 | Not Reported |                |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                                                                          | Percocet                                                       |                    | S                  |                 |                          | 1 Df (5/325mg), Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Jan-2012                                                                                                              | 8317895                                                        | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2011311409 |                               | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest                                                                    | Alprazolam                                                     |                    |                    | S               | Oral                     | Unk                           |                 | Pfizer       |                |
|                                                                                                                          | Carbamazepine                                                  |                    |                    | S               | Oral                     | Unk                           |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate                                           |                    |                    | S               | Oral                     | Unk                           |                 | Not Reported |                |
|                                                                                                                          | Lamotrigine                                                    |                    |                    | S               | Oral                     | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2012                                                                                                              | 7150299                                                        | EXPEDITED (15-DAY) | Y                  | DS, HO          | 1000009122               |                               | 50 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Angiopathy; Aortic Arteriosclerosis; Aortic Valve Incompetence; Cerebral Artery Stenosis; Cerebral Haematoma; Hemiplegia | Escitalopram Oxalate                                           |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                          | Citalopram (Citalopram Hydrobromide) (Citalopram Hydrobromide) |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                                                                          | Derinox (Naphazoline Nitrate\Prednisolone)                     |                    |                    | C               |                          |                               |                 | Not Reported |                |
|                                                                                                                          | Relpax                                                         |                    |                    | C               |                          |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Jan-2012                                                                                                              | 8318159                                                        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2011316017 |                               | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Amenorrhoea; Influenza Like Illness                                                                            | Aldactone                                                      |                    |                    | S               |                          | 100 Mg, 1x/Day (1 In 1 D)     |                 | Pfizer       |                |
|                                                                                                                          | Lexapro                                                        |                    |                    | S               | Oral                     | 5 Mg, 1x/Day (1 In 1 D)       |                 | Not Reported |                |



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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jan-2012              | 8318615              | EXPEDITED (15-DAY) | Y                  | DE              | FR-SANOFI-AVENTIS-2011SA083215 |                      | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure   | Lasix                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Aspirin              |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                          | Inexium              |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                          | Levothyrox           |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                          | Perindopril          |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                          | Kaleorid             |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 03-Jan-2012                                                | 8318991        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2011315930 |                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective; Drug Interaction; Fatigue; Hallucination | Procardia XL   |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                            | Lexapro        |                    |                    | S               | Oral                     | 2.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                                            | Lexapro        |                    |                    | S               | Oral                     | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                                            | Lexapro        |                    |                    | S               | Oral                     | 7.5 Mg, 1x/Day       |                 | Not Reported |                |
|                                                            | Lexapro        |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |
|                                                            | Lexapro        |                    |                    | S               | Oral                     | 15 Mg, 1x/Day        |                 | Not Reported |                |
|                                                            | Remeron        |                    |                    | S               |                          | 15 Mg, 1x/Day        | 1 DAY           | Not Reported |                |
|                                                            | Protonix       |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                            | Miralax        |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                            | Vitamin D2     |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
|                                                            | Multivitamins  |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|--------------------------------|-----------------|--------------|----------------|
| 04-Jan-2012                                                                                                   | 8215374                 | EXPEDITED (15-DAY) | Y                  |                 | 1000024743                                      |                                | 40 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Disturbance In Attention;<br>Dizziness; Nausea;<br>Paraesthesia; Withdrawal<br>Syndrome | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | 10 Mg (10 Mg,1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | 5 Mg (5 Mg,1 In 1 D),Oral      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2012                                                                                                   | 8320266                 | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR003799 |                                | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death                                                        | Clonazepam              |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Par          |                |
|                                                                                                               | Trazodone Hydrochloride |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Bupropion Hydrochloride |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Lorazepam               |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2012                                                                                                   | 8320372                 | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR003872 |                                | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Death                                                                                      | Diazepam                |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Par          |                |
|                                                                                                               | Carvedilol              |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Diltiazem               |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Lisinopril              |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |
|                                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                                            | Unk, Unknown                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 04-Jan-2012                                                                               | 8321510              | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR113222     |                                                                                      | 78 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcoholism; Confusional State; Drug Interaction; Extrapyrimalidal Disorder; Hyponatraemia | Tegretol Lp          |                    |                    | S               | Oral                 | 400 Mg, Qd                                                                           |                 | Novartis     |                |
|                                                                                           | Loprazolam Mesilate  |                    |                    | C               |                      |                                                                                      |                 | Not Reported |                |
|                                                                                           | Bromazepam           |                    |                    | C               |                      |                                                                                      |                 | Not Reported |                |
|                                                                                           | Omeprazole           |                    |                    | C               |                      |                                                                                      |                 | Not Reported |                |
|                                                                                           | Symbicort            |                    |                    | C               |                      |                                                                                      |                 | Not Reported |                |
|                                                                                           | Bronchodual          |                    |                    | C               |                      |                                                                                      |                 | Not Reported |                |
|                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 1 Df, Qd                                                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2012                                                                               | 8333773              | EXPEDITED (15-DAY) | N                  | HO              | 1000026439           |                                                                                      | 75 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hallucination; Joint Injury                                                         | Viibryd              |                    |                    | S               | Oral                 | 10 Mg (10 Mg,1 In 1 D),Oral                                                          |                 | Not Reported |                |
|                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D) |                 | Not Reported |                |
|                                                                                           |                      |                    |                    |                 | Oral                 | 2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D) |                 |              |                |
|                                                                                           |                      |                    |                    |                 | Oral                 | 2.5 Mg (2.5 Mg,1 In 1 D),Oral ; 5 Mg (5 Mg,1 In 1 D),Oral ; 7.5 Mg (7.5 Mg,1 In 1 D) |                 |              |                |
|                                                                                           | Mirapex              |                    |                    | S               |                      |                                                                                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2012                                                                               | 8333982              | EXPEDITED (15-DAY) | Y                  | HO              | 2012SP000070         |                                                                                      | 55 YR           | Female       | TUR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------------|-----------------|--------------|----------------|
| Anger; Anhedonia;<br>Anxiety; Apathy;<br>Depression; Disease<br>Recurrence; Disturbance<br>In Attention; Illness<br>Anxiety Disorder;<br>Insomnia; Memory<br>Impairment; Psychotic<br>Disorder; Refusal Of<br>Treatment By Patient;<br>Somatic Delusion; Tardive<br>Dyskinesia; Therapy Non-<br>Responder | Remeron                     |                    |                    | S               |                              | 15 Mg/ Qd                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Escitalopram Oxalate        |                    |                    | S               |                              | 40 Mg; Qd                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Amitriptyline Hydrochloride |                    |                    | S               |                              | 75 Mg; Qd, 25 Mg; Qd, 60<br>Mg; Qd |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           |                             |                    |                    |                 |                              | 75 Mg; Qd, 25 Mg; Qd, 60<br>Mg; Qd |                 |              |                |
|                                                                                                                                                                                                                                                                                                           |                             |                    |                    |                 |                              | 75 Mg; Qd, 25 Mg; Qd, 60<br>Mg; Qd |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Jan-2012                                                                                                                                                                                                                                                                                               | 8335665                     | EXPEDITED (15-DAY) | Y                  | DE              | DSA_48633_2011               |                                    | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Intentional Product<br>Misuse; Toxicity To<br>Various Agents                                                                                                                                                                                                                        | Diltiazem Hydrochloride     |                    |                    | S               | Oral                         | (Df Oral)                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Carvedilol                  |                    |                    | S               |                              | (Df)                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Diazepam                    |                    |                    | S               |                              | (Df)                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Escitalopram Oxalate        |                    |                    | S               |                              | (Df)                               |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Lisinopril                  |                    |                    | S               |                              | (Df)                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                                                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Jan-2012                                                                                                                                                                                                                                                                                               | 8235024                     | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-<br>2011260551 |                                    | 38 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Drug<br>Hypersensitivity; Lip<br>Swelling; Swollen Tongue                                                                                                                                                                                                                                     | Lisinopril                  |                    |                    | S               |                              | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Penicillin                  |                    |                    | S               |                              | Unk                                |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Prinzide                    |                    |                    | S               | Oral                         | 20-12.5 Daily                      |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                                                           | Benadryl                    |                    |                    | S               |                              | Unk                                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |     |              |
|-------------|---|-----|--------------|
| Lexapro     | S | Unk | Not Reported |
| Mobic       | S | Unk | Not Reported |
| Celebrex    | C | Unk | Not Reported |
| Allegra-D   | C | Unk | Not Reported |
| Amoxicillin | C | Unk | Not Reported |
| Nasonex     | C | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8257154       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025384           |                      | 40 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Loss Of Consciousness | Lexapro                  |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                       | Fluvoxamine              |              |            | C           |              |                               |                 | Not Reported |
|                       | Cetirizine Hydrochloride |              |            | C           |              |                               |                 | Not Reported |
|                       | Losartan Potassium       |              |            | C           |              |                               |                 | Not Reported |
|                       | Goodmin (Britizolam)     |              |            | C           |              |                               |                 | Not Reported |
|                       | Seloken                  |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8305898       | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2011308670 |                      | 77 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Hydroxyzine          |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                  | Escitalopram Oxalate |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                  | Temazepam            |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8306814       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026095           |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Anxiety Disorder;     | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            |                      |   |      |                                  |              |
|----------------------------------------------------------------------------|----------------------|---|------|----------------------------------|--------------|
| Condition Aggravated;<br>Diarrhoea; Drug<br>Intolerance; Sleep<br>Disorder | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral | Not Reported |
|----------------------------------------------------------------------------|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8322117       | EXPEDITED (15-DAY) | Y                  | DE              | US-PAR<br>PHARMACEUTICAL,<br>INC-2011SCPR003635 |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide; Death | Alprazolam           |              |            | S           | Oral         | Unk, Unknown       |                 | Par          |
|                                                        | Carbamazepine        |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                                        | Escitalopram Oxalate |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                                                        | Lamotrigine          |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8322966       | EXPEDITED (15-DAY) | Y                  | DE              | US-JNJFOC-<br>20111212473 |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                          | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardio-Respiratory Arrest;<br>Completed Suicide;<br>Toxicity To Various Agents | Paracetamol                |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                                                                                | Paracetamol                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                | Unspecified Ingredient     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                | Propoxyphene Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                | Escitalopram Oxalate       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8323359       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20120100839 |                      | 88 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State; Drug<br>Interaction; Facial Bones<br>Fracture; Hallucination,<br>Visual | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         |                    | 8 DAY           | Not Reported |
|                                                                                            | Tahor                                       |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |         |              |
|----------------------|---|---------|--------------|
| Innohep              | C | Unknown | Not Reported |
| Movicol              | C | Unknown | Not Reported |
| Amlodipine Besylate  | C | Unknown | Not Reported |
| Calcium Carbonate    | C | Unknown | Not Reported |
| Allopurinol          | C | Unknown | Not Reported |
| Singulair            | C | Unknown | Not Reported |
| Seretide             | C | Unknown | Not Reported |
| Coumadin             | C | Unknown | Not Reported |
| Escitalopram Oxalate | S | Oral    | Not Reported |

| <u>FDA Received Date</u>                                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Jan-2012                                                          | 8323921        | NON-EXPEDITED    | N                  |                 | US-ABBOTT-11P-163-0705117-00 |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alopecia; Anxiety;<br>Dyspnoea; Fatigue;<br>Hypothyroidism; Insomnia | Synthroid      |                  |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                      | Synthroid      |                  |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                      | Lexapro        |                  |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                      | Lorazepam      |                  |                    | C               |                              |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                            | <u>Case #</u>                                                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------|-----------------|--------------|----------------|
| 05-Jan-2012                                                                                                                         | 8336158                                                                         | EXPEDITED (15-DAY) | Y                  | DE              | 1000026593           |                                                   | 90 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                               | <u>Product</u>                                                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebrovascular Accident;<br>General Physical Health<br>Deterioration;<br>Haematoma; International<br>Normalised Ratio<br>Increased | Escitalopram Oxalate                                                            |                    |                    | S               | Oral                 | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                     | Fluindione                                                                      |                    |                    | S               | Oral                 | Daily Dose Accroding To<br>Inr, Oral              |                 | Not Reported |                |
|                                                                                                                                     | Fosamax (Alendronate Sodium)<br>(10 Milligram, Tablets)<br>(Alendronate Sodium) |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
|                                                                                                                                     | Sterogyl (Ergocalciferol) (Drops)<br>(Ergocalciferol)                           |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
|                                                                                                                                     | Cacit (Calcium Carbonate,                                                       |                    |                    | C               |                      |                                                   |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholecalciferol (500 Milligram)  
(Calcium Carbonate,  
Cholecalciferol)  
Aricept (Donepezil  
Hydrochloride) (5 Milligram,  
Tablets) (Donepezil  
Hydrochloride)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Jan-2012              | 8336213       | EXPEDITED (15-DAY) | Y                  | DE              | 1000026594           |                      | 88 YR      | Male       | DNK            |

| <u>Preferred Term</u>                      | <u>Product</u>                                                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------|--------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Aphasia; Clonus;<br>Hyponatraemia; Seizure | Escitalopram Oxalate                                                                       |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                            | Lasix                                                                                      |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                            | Kardegic (Acetylsalicylate<br>Lysine)                                                      |              |            | C           |              |                                  |                 | Not Reported |
|                                            | Inexium (Esomeprazole<br>Magnesium) (40 Milligram,<br>Tablets) (Esomeprazole<br>Magnesium) |              |            | C           |              |                                  |                 | Not Reported |
|                                            | Levothyrox (Levothyroxine<br>Sodium) (25 Microgram, Tablets)<br>(Levothyroxine Sodium)     |              |            | C           |              |                                  |                 | Not Reported |
|                                            | Coversyl (Perindopril Erbumine)<br>(5 Milligram, Tablets)<br>(Perindopril Erbumine)        |              |            | C           |              |                                  |                 | Not Reported |
|                                            | Kaleorid (Potassium Chloride)<br>(600 Milligram, Tablets)<br>(Potassium Chloride)          |              |            | C           |              |                                  |                 | Not Reported |
|                                            |                                                                                            |              |            |             |              |                                  |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------------------|-----------------|--------------|----------------|
| 05-Jan-2012              | 8336406              | EXPEDITED (15-DAY) | Y                  | DS              | 1000026566           |                                                      | 47 YR           | Male         | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypoacusis; Tinnitus     | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D) :<br>15 Mg (15 Mg,1 In 1 D) : |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                  |                               |                    |                    |                        |                                                 |                          |                 |                      |                |
|--------------------------------------------------|-------------------------------|--------------------|--------------------|------------------------|-------------------------------------------------|--------------------------|-----------------|----------------------|----------------|
|                                                  |                               |                    |                    | 10 Mg (10 Mg,1 In 1 D) |                                                 |                          |                 |                      |                |
|                                                  |                               |                    |                    | Viread                 | C                                               |                          |                 |                      |                |
|                                                  |                               |                    |                    | Kaletra                | C                                               |                          |                 |                      |                |
|                                                  |                               |                    |                    | Lexomil (Bromazepam)   | C                                               |                          |                 |                      |                |
|                                                  |                               |                    |                    |                        |                                                 |                          |                 | Not Reported         |                |
|                                                  |                               |                    |                    |                        |                                                 |                          |                 | Not Reported         |                |
|                                                  |                               |                    |                    |                        |                                                 |                          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>        | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Jan-2012                                      | 8324738                       | EXPEDITED (15-DAY) | N                  | HO                     | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16325938 |                          | 64 YR           | Male                 | FRA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>            | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Glomerulonephritis<br>Membranous                 | Orencia                       |                    |                    | S                      | Intravenous (not<br>otherwise specified)        | Interrupted On 17oct2011 |                 | Bristol Myers Squibb |                |
|                                                  | Atenolol                      |                    |                    | S                      | Oral                                            |                          |                 | Sandoz               |                |
|                                                  | Ezetrol                       |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Lansoprazole                  |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Acetaminophen                 |                    |                    | S                      |                                                 |                          |                 | Not Reported         |                |
|                                                  | Escitalopram Oxalate          |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Tanakan                       |                    |                    | C                      |                                                 |                          |                 | Not Reported         |                |
|                                                  | Naftazone                     |                    |                    | C                      |                                                 |                          |                 | Not Reported         |                |
|                                                  | Domperidone                   |                    |                    | C                      |                                                 |                          |                 | Not Reported         |                |
|                                                  | Legalon                       |                    |                    | C                      |                                                 |                          |                 | Not Reported         |                |
|                                                  | Methotrexate                  |                    |                    | C                      |                                                 | Resumed On 04aug2011     |                 | Not Reported         |                |
|                                                  | Folic Acid                    |                    |                    | C                      |                                                 | Resumed On 04aug2011     |                 | Not Reported         |                |
|                                                  | Alprazolam                    |                    |                    | C                      |                                                 |                          |                 | Not Reported         |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>        | <u>Mfr Control #</u>                            | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 06-Jan-2012                                      | 8324786                       | EXPEDITED (15-DAY) | Y                  | DE                     | US-JNJFOC-<br>20111212597                       |                          | 49 YR           | Female               | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>            | <u>Route</u>                                    | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>           |                |
| Completed Suicide;<br>Toxicity To Various Agents | Cyclobenzaprine Hydrochloride |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Amitriptyline                 |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Escitalopram Oxalate          |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |
|                                                  | Salicylates Nos               |                    |                    | S                      | Oral                                            |                          |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| Unspecified Ingredient                                                                                                                              |                                                        |                    | S                  | Oral            |                              |                                            | Not Reported    |              |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|--------------------------------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Jan-2012                                                                                                                                         | 8325637                                                | EXPEDITED (15-DAY) | Y                  | DE              | US-ABBOTT-11P-163-0888246-00 |                                            | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                                                               | Acetaminophen\Hydrocodone Bitartrate                   |                    |                    | S               |                              | Ingestion                                  |                 | Not Reported |                |
|                                                                                                                                                     | Escitalopram Oxalate                                   |                    |                    | S               |                              | Ingestion                                  |                 | Not Reported |                |
|                                                                                                                                                     | Buprenorphine Hydrochloride And Naloxone Hydrochloride |                    |                    | S               | Sublingual                   |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Jan-2012                                                                                                                                         | 8272276                                                | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000024042                   |                                            | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar I Disorder; Overdose; Pain; Psychotic Behaviour; Weight Increased | Lexapro                                                |                    |                    | S               | Oral                         | 20 Mg (20 Mg,1 In 1 D), Oral               |                 | Not Reported |                |
|                                                                                                                                                     | Seroquel                                               |                    |                    | S               |                              | 300 Mg (300 Mg,Qhs) : 100 Mg (100 Mg, Qam) |                 | Not Reported |                |
|                                                                                                                                                     | Zyprexa                                                |                    |                    | S               |                              |                                            |                 | Not Reported |                |
|                                                                                                                                                     | Chantix                                                |                    |                    | C               |                              |                                            |                 | Not Reported |                |
|                                                                                                                                                     | Abilify                                                |                    |                    | C               |                              |                                            |                 | Not Reported |                |
|                                                                                                                                                     | Saphris                                                |                    |                    | C               |                              |                                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                            | <u>Case #</u>                                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-Jan-2012                                                                                                                                         | 7063060                                                | EXPEDITED (15-DAY) | Y                  | DE              | US-PFIZER INC-2009245932     |                                            | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                               | <u>Product</u>                                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide; Toxicity To Various Agents                                                                                                       | Trazodone Hydrochloride                                |                    |                    | S               | Unknown                      |                                            |                 | Unknown      |                |
|                                                                                                                                                     | Citalopram                                             |                    |                    | S               | Unknown                      |                                            |                 | Not Reported |                |
|                                                                                                                                                     | Dilantin                                               |                    |                    | S               | Unknown                      |                                            |                 | Pfizer       |                |
|                                                                                                                                                     | Zyprexa                                                |                    |                    | S               | Unknown                      | 10 Mg, 1x/Day                              |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |          |   |         |  |  |  |  |  |              |
|--|----------|---|---------|--|--|--|--|--|--------------|
|  | Benadryl | S | Unknown |  |  |  |  |  | Not Reported |
|  | Seroquel | S | Unknown |  |  |  |  |  | Not Reported |
|  | Lexapro  | S |         |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8314195       | EXPEDITED (15-DAY) | Y                  | HO, LT          | DK-TEVA-314897ISR    |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Coma; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt | Mirtazapine          |              |            | S           |              |                    |                 | Teva         |
|                                                                                                              | Baclofen             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                              | Baclofen             |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                              | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8319323       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2011-05958   |                      | 22 YR      | Female     |                |

| <u>Preferred Term</u>                                                           | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Anxiety; Disease Recurrence; Disturbance In Social Behaviour; Oculogyric Crisis | Risperidone (Risperidone) |              |            | S           | Oral         | (1.5 Mg), Oral                |                 | Not Reported |
|                                                                                 | Cipralex                  |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                 | Orphenadrine Citrate      |              |            | C           |              |                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8328666       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000026580           |                      | 23 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>                                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Affective Disorder; Delusion Of Reference; Depression; Dysarthria; Dyskinesia; Epilepsy; Hyporeflexia; Loss Of Consciousness; Muscular Weakness; | Escitalopram Oxalate                                     |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |
|                                                                                                                                                  | Olanzapine                                               |              |            | C           |              |                             |                 | Not Reported |
|                                                                                                                                                  | Oxcarbazepine (Oxcarbazepine) (Tablets) (Oxcarbameipine) |              |            | C           |              |                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neurodegenerative  
Disorder; Regressive  
Behaviour;  
Schizophreniform  
Disorder; Suicide Attempt;  
Syncope; Tardive  
Dyskinesia; Tongue Biting

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8328793       | DIRECT           | Y                  | LT              |                      |                      | 26 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abnormal Behaviour;<br>Agitation; Apathy;<br>Decreased Appetite;<br>Decreased Interest;<br>Depressed Mood;<br>Educational Problem;<br>Fatigue; Feelings Of<br>Worthlessness;<br>Hypersomnia; Suicidal<br>Ideation | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8329202       | EXPEDITED (15-DAY) | Y                  | LT              | BE-<br>GLAXOSMITHKLINE-<br>B0774379A |                      |            | Female     | BEL            |

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Bulimia Nervosa;<br>Depression; Fatigue;<br>Somnolence | Wellbutrin           |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |
|                                                        | Escitalopram Oxalate |              |            | S           | Unknown      |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8329700       | EXPEDITED (15-DAY) | Y                  | LT              | FR-PFIZER INC-<br>2012004088 |                      | 25 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Circulatory Collapse; | Xanax          |              |            | S           | Oral         | 7.5 Mg             |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                         |                      |   |      |               |              |
|-------------------------------------------------------------------------|----------------------|---|------|---------------|--------------|
| Coma; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents | Xanax                | S | Oral | 7.5 Mg        | Pfizer       |
|                                                                         | Propranolol          | S | Oral | 20 Mg, 1x/Day | Not Reported |
|                                                                         | Propranolol          | S | Oral | 2 G           | Not Reported |
|                                                                         | Oxazepam             | S | Oral | 50 Mg, 4x/Day | Not Reported |
|                                                                         | Oxazepam             | S | Oral | 1 G           | Not Reported |
|                                                                         | Escitalopram Oxalate | S | Oral | 10 Mg, 1x/Day | Not Reported |
|                                                                         | Escitalopram Oxalate | S | Oral | 140 Mg        | Not Reported |
|                                                                         | Prazepam             | C |      | Unk           | Not Reported |
|                                                                         | Loprazolam Mesilate  | C |      | 1x/Day        | Not Reported |
|                                                                         | Topiramate           | C |      | 50 Mg, 1x/Day | Not Reported |
|                                                                         | Atarax               | C |      | 3x/Day        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8330206       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026586           |                      | 63 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Affective Disorder; Cerebellar Atrophy; Cerebral Ischaemia; Dyskinesia; Gait Disturbance; Hypoaesthesia; Hyporeflexia; Sensory Loss; Slow Speech; Spur Cell Anaemia; Thinking Abnormal; Torticollis | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                     | Mirtazapine          |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Jan-2012              | 8348985       | EXPEDITED (15-DAY) | N                  | DS, HO          | 1000026716           |                      | 32 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Gait Inability; Neuralgia; Pain; Pain In Extremity; Somatic Symptom | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1 D),Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Weight  
Decreased

| <u>FDA Received Date</u> | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|--------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2012              | 7469255                  | EXPEDITED (15-DAY) | Y                  | OT              | GB-PFIZER INC-2010082072 |                      | 26 YR           | Female       | GBR            |
| <u>Preferred Term</u>    | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Death             | Sertraline Hydrochloride |                    |                    | S               |                          | 100 Mg, Daily        |                 | Pfizer       |                |
|                          | Ciprallex                |                    |                    | S               |                          | 20 Mg, Daily         |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| 11-Jan-2012                                                                                                                     | 8277482              | EXPEDITED (15-DAY) | Y                  | CA              | 1000025765           |                                          |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Pulmonary<br>Hypertension; Maternal<br>Drugs Affecting Foetus;<br>Ventricular Septal Defect | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 5 Mg (5 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                     | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-Jan-2012                                                                  | 8326358                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012002742 |                      | 57 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                        | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Accident; Drug Ineffective;<br>Hypertension; Joint Injury;<br>Sleep Disorder | Pristiq Extended Release |                  |                    | S               |                          | 50 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                              | Pristiq Extended Release |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                              | Lipitor                  |                  |                    | S               | Oral                     | 20 Mg, 1x/Day        |                 | Pfizer       |                |
|                                                                              | Lorazepam                |                  |                    | S               |                          | 1mg Daily            |                 | Pfizer       |                |
|                                                                              | Lorazepam                |                  |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                                              | Lexapro                  |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                                              | Lunesta                  |                  |                    | S               |                          | 3mg Daily            |                 | Not Reported |                |
|                                                                              | Synthroid                |                  |                    | S               |                          | 0.125 Mg, 1x/Day     |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 11-Jan-2012                                                            | 8345680              | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00366_2012       |                                    | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Atenolol             |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Citalopram           |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Lamotrigine          |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Venlafaxine          |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Hydroxyzine          |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
|                                                                        | Alcohol              |                    |                    | S               | Oral                 | Df Oral                            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Jan-2012                                                            | 8353240              | EXPEDITED (15-DAY) | Y                  | DE              | VAL_00679_2012       |                                    | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Carbamazepine        |                    |                    | S               | Oral                 | (Df Oral)                          |                 | Not Reported |                |
|                                                                        | Alprazolam           |                    |                    | S               | Oral                 | (Df Oral)                          |                 | Not Reported |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | (Df Oral)                          |                 | Not Reported |                |
|                                                                        | Lamotrigine          |                    |                    | S               | Oral                 | (Df Oral)                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                                            | 8065721              | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000022183           |                                    | 49 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Transient<br>Ischaemic Attack                        | Lexapro              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral   |                 | Not Reported |                |
|                                                                        | Ritonavir            |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                        | Truvada (Tenofovir,  |                    |                    | C               |                      |                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                               |                |                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------|
| Emtricitabine) (Tablets)<br>(Tenofovir, Emtricitabine)<br>Reyataz (Atazanavir Sulfate)<br>(Capsules) (Atazanavir Sulfate)<br>Alprazolam (Alprazolam) (0.5<br>Milligram, Tablets) (Alprazolam) | C<br><br><br>C | Not Reported<br><br><br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8286718       | EXPEDITED (15-DAY) | Y                  | DE              | 1000025960           |                      | < 1 DAY    | Unknown    | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|--------------------------------------------|--------------|------------|-------------|----------------|--------------------------------------------|-----------------|--------------|
| Death Neonatal; Maternal<br>Drugs Affecting Foetus | Lexapro                                    |              |            | S           | Transplacental | 30 Mg (30 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |
|                                                    | Ondansetron                                |              |            | C           |                |                                            |                 | Not Reported |
|                                                    | Phenergan (Promethazine)<br>(Promethazine) |              |            | C           |                |                                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8309038       | EXPEDITED (15-DAY) | Y                  | DE, OT          | US-PFIZER INC-<br>2011310288 |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                      | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory<br>Arrest; Toxicity To Various<br>Agents | Venlafaxine Hydrochloride |              |            | S           | Oral         | Unk                |                 | Pfizer       |
|                                                                                            | Atenolol                  |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Escitalopram Oxalate      |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Citalopram                |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Lamotrigine               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Hydroxyzine               |              |            | S           | Oral         | Unk                |                 | Not Reported |
|                                                                                            | Alcohol                   |              |            | S           | Oral         | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8334272       | EXPEDITED (15-DAY) | Y                  | DE              | US-UCBSA-049095      |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |                      |   |      |              |
|-------------------|----------------------|---|------|--------------|
| Completed Suicide | Alprazolam           | S | Oral | Not Reported |
|                   | Carbamazepine        | S | Oral | Not Reported |
|                   | Escitalopram Oxalate | S | Oral | Not Reported |
|                   | Lamotrigine          | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8334654       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2011FR34636      |                      | 84 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                                                                                                                                   | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Vestibular Syndrome;<br>Arteriosclerosis;<br>Dizziness; Dyskinesia;<br>Epilepsy; Fall; Loss Of Consciousness; Malaise;<br>Nystagmus; Urine Output Decreased; Vertigo;<br>Vomiting | Exelon Patch              |              |            | S           | Transdermal  | 4.6 Mg/24h         | 3 DAY           | Novartis     |
|                                                                                                                                                                                         | Escitalopram Oxalate      |              |            | S           |              | 5 Mg, Unk          | 3 DAY           | Not Reported |
|                                                                                                                                                                                         | Aprovel                   |              |            | C           |              | 75 Mg, Daily       |                 | Not Reported |
|                                                                                                                                                                                         | Vastarel                  |              |            | C           |              | 20 Mg, Bid         |                 | Not Reported |
|                                                                                                                                                                                         | Betahistine Hydrochloride |              |            | C           |              | 24 Mg, Bid         |                 | Not Reported |
|                                                                                                                                                                                         | Tanakan                   |              |            | C           |              | 40 Mg, Bid         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8349280       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05520_2012       |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|---------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Metformin Hydrochloride               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Unspecified Ingredient                |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Acetaminophen                         |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Metoprolol Succinate Extended-Release |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Escitalopram Oxalate                  |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Esomeprazole                          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8350524       | EXPEDITED (15-DAY) | Y                  | DE              | SAN_00012_2012       |                      | 31 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Completed Suicide;<br>Toxicity To Various Agents | Metformin Hydrochloride   |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Unspecified Ingredient    |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Acetaminophen\Opium       |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Alkaloids, Hydrochlorides |                    |                    |                 |                      |                      |                 |              |                |
|                                                  | Metoprolol                |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate      |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Esomeprazole              |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                      | 8350898                   | EXPEDITED (15-DAY) | Y                  | DE              | NSR_00383_2012       |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning                  | Hydroxyzine               |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Temazepam                 |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate      |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                      | 8351900                   | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05586_2012       |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Poisoning                  | Bupropion                 |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |
|                                                  | Heroin                    |                    |                    | S               |                      | (Df Unknown)         |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate      |                    |                    | S               |                      | (Df Unknown)         |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                      | 8351911                   | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05554_2012       |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Poisoning; | Bupropion Hydrochloride   |                    |                    | S               | Oral                 | (Df Oral)            |                 | Not Reported |                |

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|                    |                         |   |      |           |              |
|--------------------|-------------------------|---|------|-----------|--------------|
| Respiratory Arrest | Trazodone Hydrochloride | S | Oral | (Df Oral) | Not Reported |
|                    | Escitalopram Oxalate    | S | Oral | (Df Oral) | Not Reported |
|                    | Clonazepam              | S | Oral | (Df Oral) | Not Reported |
|                    | Lorazepam               | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8351942       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05550_2012       |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Bupropion Hydrochloride |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Oxcarbazepine           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Lorazepam               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Escitalopram Oxalate    |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Zolpidem                |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Quetiapine              |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8353099       | EXPEDITED (15-DAY) | Y                  | DE              | IMP_05661_2012       |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Alprazolam           |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Carbamazepine        |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Escitalopram Oxalate |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                                                        | Lamotrigine          |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8353841       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_48787_2012       |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed | Bupropion      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                      |   |      |           |              |
|-------------------------------------------|----------------------|---|------|-----------|--------------|
| Suicide; Poisoning;<br>Respiratory Arrest | Oxcarbazepine        | S | Oral | (Df Oral) | Not Reported |
|                                           | Lorazepam            | S | Oral | (Df Oral) | Not Reported |
|                                           | Escitalopram Oxalate | S | Oral | (Df Oral) | Not Reported |
|                                           | Zolpidem             | S | Oral | (Df Oral) | Not Reported |
|                                           | Quetiapine           | S | Oral | (Df Oral) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8354491       | EXPEDITED (15-DAY) | Y                  | DE              | 1000026792           |                      | 60 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                               | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Cardiac Arrest; Colitis<br>Ulcerative;<br>Electrocardiogram Qt<br>Prolonged; Sepsis | Lexapro                                  |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                     | Ciprofloxacin                            |              |            | S           |              | (600 Mg)                         |                 | Not Reported |
|                                                                                     | Fluconazole                              |              |            | S           |              | (200 Mg)                         |                 | Not Reported |
|                                                                                     | Piperacillin Sodium\Tazobactam<br>Sodium |              |            | S           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8354798       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_48670_2011       |                      | 46 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Poisoning;<br>Respiratory Arrest | Lorazepam            |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                        | Escitalopram Oxalate |              |            | S           | Oral         | Df Oral            |                 | Not Reported |
|                                                                        | Alcohol              |              |            | S           | Oral         | Df Oral            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Jan-2012              | 8355046       | EXPEDITED (15-DAY) | Y                  | DE              | DSA_48803_2012       |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Poisoning | Bupropion      |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
|                                 | Heroin         |              |            | S           |              | (Df Unknown)       |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                  |                                          |                    |                    |                 |                          |                      |                 |              |                |
|------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Escitalopram Oxalate                                             |                                          |                    | S                  |                 | (Df Unknown)             |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                                      | 8355404                                  | EXPEDITED (15-DAY) | Y                  | DE              | DSA_48778_2012           |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Poisoning; Respiratory Arrest | Bupropion                                |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
|                                                                  | Trazodone Hydrochloride                  |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
|                                                                  | Escitalopram Oxalate                     |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
|                                                                  | Clonazepam                               |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
|                                                                  | Lorazepam                                |                    |                    | S               | Oral                     | (Df Oral)            |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                                      | 8357704                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000026774               |                      | 83 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Loss Of Consciousness; Postictal State            | Escitalopram Oxalate                     |                    |                    | S               |                          | Reduced Dose         |                 | Not Reported |                |
|                                                                  | Reminyl                                  |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Jan-2012                                                      | 8358256                                  | EXPEDITED (15-DAY) | Y                  | DE              | 1000026906               |                      | 48 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                            | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                            | Escitalopram Oxalate                     |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                  | Hydrocodone Bitartrate And Acetaminophen |                    |                    | S               |                          |                      |                 | Not Reported |                |
|                                                                  | Buprenorphine Hydrochloride              |                    |                    | S               | Sublingual               | Sublingual           |                 | Not Reported |                |
|                                                                  | And Naloxone Hydrochloride               |                    |                    |                 |                          |                      |                 |              |                |
| <u>FDA Received Date</u>                                         | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2012                                                      | 6933684                                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-K200900063 |                      | 49 YR           | Female       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                    | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Blood<br>Pressure Increased;<br>Dyspepsia; Oedema<br>Peripheral | Altace                          |              |            | S           | Oral         | 5 Mg, Unk          |                 | Pfizer       |
|                                                                                                          | Xyrem                           |              |            | S           | Oral         | 2 G, 2x/Day        |                 | Not Reported |
|                                                                                                          | Escitalopram Oxalate            |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                          | Duloxetine Hydrochloride        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                          | Simvastatin                     |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                          | Pregabalin                      |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                          | Atenolol                        |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                          | Hydrochlorothiazide\Triamterene |              |            | C           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 13-Jan-2012              | 8335849       | EXPEDITED (15-DAY) | N                  | HO              | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2012-<br>BP-00 |                      | 75 YR      | Female     | USA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Fall; Hallucination; Joint<br>Injury | Mirapex        |              |            | S           |              |                    |                 | Boehringer Ingelheim |
|                                      | Viibryd        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |
|                                      | Lexapro        |              |            | S           | Oral         | 2.5 Mg             | 2 WEEK          | Not Reported         |
|                                      | Lexapro        |              |            | S           | Oral         | 5 Mg               | 2 WEEK          | Not Reported         |
|                                      | Lexapro        |              |            | S           |              | 7.5 Mg             | 2 WEEK          | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2012              | 8354435       | EXPEDITED (15-DAY) | Y                  | DE              | 1000027035           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                    | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Escitalopram Oxalate        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                          | Acetaminophen (Paracetamol) |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                          | Unspecified Ingredient      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                          | Unspecified Ingredient      |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Jan-2012                                      | 8354752                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000027037           |                      | 24 YR           | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Poisoning;<br>Respiratory Arrest | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Trazodone Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Bupropion Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Clonazepam              |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Lorazepam               |                    |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2012                                      | 8354771                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000027042           |                      | 67 YR           | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Respiratory Arrest            | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Metoprolol Tartrate     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Amphetamine             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Dextroamphetamine       |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Clozapine               |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Solifenacin             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Simvastatin             |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Memantine Hydrochloride |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2012                                      | 8354779                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000027045           |                      | 35 YR           | Female       | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                            | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Quetiapine Fumarate     |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |
|                                                  | Gabapentin (Gabapentin) |                    |                    | S               | Oral                 | Oral                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------|-----------------|--------------|----------------|
| 13-Jan-2012                                                                                                                                      | 8354788                 | EXPEDITED (15-DAY) | Y                  | DE              | 1000027018           |                                                        | 62 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                                                                                                | Escitalopram Oxalate    |                    |                    | S               | Oral                 | Oral                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Diltiazem Hydrochloride |                    |                    | S               | Oral                 | Oral                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Carvedilol (Carvedilol) |                    |                    | S               | Oral                 | Oral                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Lisinopril (Lisinopril) |                    |                    | S               | Oral                 | Oral                                                   |                 | Not Reported |                |
|                                                                                                                                                  | Diazepam (Diazepam)     |                    |                    | S               | Oral                 | Oral                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2012                                                                                                                                      | 8355783                 | EXPEDITED (15-DAY) | Y                  | DE              | 09-AUR-09644         |                                                        | 32 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents                                                                                                 | Citalopram Hydrobromide |                    |                    | S               |                      | 10 Mg (10 Mg, 1 In 1 D),                               |                 | Not Reported |                |
|                                                                                                                                                  | Zyprexa                 |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                  | Seroquel                |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                  | Benadryl                |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                  | Dilantin                |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                  | Trazodone Hydrochloride |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
|                                                                                                                                                  | Lexapro                 |                    |                    | S               |                      |                                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Jan-2012                                                                                                                                      | 8355890                 | EXPEDITED (15-DAY) | Y                  | LT              | 1000026898           |                                                        | 25 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                     | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrioventricular Block;<br>Circulatory Collapse;<br>Coma; Heart Rate<br>Decreased; Oxygen<br>Saturation Decreased;<br>Toxicity To Various Agents | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral; (140 Mg, Once), Oral |                 | Not Reported |                |
|                                                                                                                                                  | Propranolol             |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral; (2 Gm, Once), Oral   |                 | Not Reported |                |
|                                                                                                                                                  | Oxazepam                |                    |                    | S               | Oral                 | 200 Mg (200 Mg, 1 In 1 D),<br>Oral; (1 Gm, Once), Oral |                 | Not Reported |                |



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|                               |   |      |                                                        |              |
|-------------------------------|---|------|--------------------------------------------------------|--------------|
|                               |   | Oral | 200 Mg (200 Mg, 1 In 1 D),<br>Oral; (1 Gm, Once), Oral |              |
| Xanax                         | S | Oral | (7.5 Mg, Once), Oral                                   | Not Reported |
| Atarax                        | C |      |                                                        | Not Reported |
| Prazepam                      | C |      |                                                        | Not Reported |
| Topiramate                    | C |      |                                                        | Not Reported |
| Havlane (Loprazolam Mesilate) | C |      |                                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2012              | 8357262       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026955           |                      | 65 YR      | Male       | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------------------|--------------|------------|-------------|------------------------------------------|------------------------------------------|-----------------|--------------|
| Arthralgia;              | Escitalopram Oxalate       |              |            | S           | Oral                                     | Oral                                     |                 | Not Reported |
| Glomerulonephritis       | Orencia                    |              |            | S           | Intravenous (not<br>otherwise specified) | Intravenous (Not<br>Otherwise Specified) |                 | Not Reported |
| Membranous;              | Ezetimibe                  |              |            | S           |                                          |                                          |                 | Not Reported |
| Hypoalbuminaemia;        | Lansoprazole               |              |            | S           | Oral                                     | Oral                                     |                 | Not Reported |
| Oedema Peripheral; Renal | Caffeine\Opium             |              |            | S           | Oral                                     | Oral                                     |                 | Not Reported |
| Cyst; Tubulointerstitial | Atenolol (Atenolol)        |              |            | S           | Oral                                     | Oral                                     |                 | Not Reported |
| Nephritis                | Tanakan                    |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Etioven (Naftazone)        |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Biperidys (Domperidone)    |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Legalon (Silybum Marianum) |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Methotrexate               |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Speciafoldine (Folic Acid) |              |            | C           |                                          |                                          |                 | Not Reported |
|                          | Alprazolam                 |              |            | C           |                                          |                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Jan-2012              | 8357273       | EXPEDITED (15-DAY) | Y                  | HO              | LTI2012A00005        |                      | 62 YR      | Male       | FRA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|------------------------------------------|--------------------------|-----------------|--------------|
| Diverticulum             | Lansoprazole   |              |            | S           | Oral                                     | Oral (15 Mg,As Required) |                 | Not Reported |
| Oesophageal; Duodenitis; | Orencia        |              |            | S           | Intravenous (not<br>otherwise specified) | 750 Mg Intravenous       | 3 YR            | Not Reported |
| Gastritis;               |                |              |            |             |                                          |                          |                 |              |
| Glomerulonephritis       |                |              |            |             |                                          |                          |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                    |                                    |   |      |      |              |
|----------------------------------------------------|------------------------------------|---|------|------|--------------|
| Membranous;<br>Oesophageal Disorder;<br>Renal Cyst | Ezetimibe                          | S | Oral | Oral | Not Reported |
|                                                    | Acetaminophen\Atropa               | S | Oral | Oral | Not Reported |
|                                                    | Belladonna\Caffeic Acid\Papaverine |   |      |      |              |
|                                                    | Atenolol (Atenolol)                | S | Oral | Oral | Not Reported |
|                                                    | Escitalopram Oxalate               | S | Oral | Oral | Not Reported |
|                                                    |                                    |   | Oral | Oral |              |
|                                                    | Alprazolam                         | C |      |      | Not Reported |
|                                                    | Tanakan                            | C |      |      | Not Reported |
|                                                    | Etioven(Naftazone)                 | C |      |      | Not Reported |
|                                                    | Biperidys(Domperidone)             | C |      |      | Not Reported |
|                                                    | Legalon(Silybum Marianum)          | C |      |      | Not Reported |
|                                                    | Speciafoldine(Folic Acid)          | C |      |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8339347       | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-11P-163-0841251-00 |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Drug Interaction; Transient<br>Ischaemic Attack | Norvir         |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                 | Lexapro        |              |            | S           | Oral         |                        |                 | Not Reported |
|                                                 | Lexapro        |              |            | S           |              |                        |                 | Not Reported |
|                                                 | Truvada        |              |            | C           | Oral         |                        |                 | Not Reported |
|                                                 | Reyataz        |              |            | C           | Oral         |                        |                 | Not Reported |
|                                                 | Alprazolam     |              |            | C           | Oral         | Twice A Day, As Needed |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8340009       | DIRECT           | Y                  | HO, LT          |                      |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Psychosis;<br>Agitation; Conversion<br>Disorder; Dyskinesia;<br>General Physical Health<br>Deterioration;<br>Hallucinations, Mixed; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                           | Depakote       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                           | Topamax        |              |            | C           |              |                    |                 | Not Reported |
|                                                                                                                                           | Levothyroxine  |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Insomnia; Refusal Of  
Treatment By Patient;  
Tremor

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8357635       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026789           |                      | 88 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>                                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------------------|-----------------|--------------|
| Confusional State; Drug<br>Interaction; Epistaxis;<br>Facial Bones Fracture;<br>Haematoma;<br>Hallucination, Visual | Escitalopram Oxalate                               |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral                  |                 | Not Reported |
|                                                                                                                     | Acetaminophen\Tramadol                             |              |            | S           | Oral         | 2 To 3 Tablets (362.5 Mg,<br>1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                     | Seretide (Seretide) (Seretide)                     |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Singular                                           |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Atorvastatin Calcium                               |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Innohep (Tinzaparin Sodium)<br>(Tinzaparin Sodium) |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Warfarin Sodium                                    |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Amlodipine Besylate                                |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Cacit D3 (Lekovit Ca) (Lekovit<br>Ca)              |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Allopurinol                                        |              |            | C           |              |                                              |                 | Not Reported |
|                                                                                                                     | Movicol                                            |              |            | C           |              |                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8358151       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-00302   |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                     | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed<br>Suicide; Intentional<br>Product Misuse;<br>Respiratory Arrest;<br>Toxicity To Various Agents | Zolpidem                      |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Oxcarbazepine (Oxcarbazepine) |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Bupropion Hydrochloride       |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Lorazepam                     |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Escitalopram Oxalate          |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                           | Quetiapine Fumarate           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8359966       | EXPEDITED (15-DAY) | Y                  | DE              | 1000027070           |                      | 56 YR      | Unknown    | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                 | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Citalopram                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Atenolol (Atenolol)       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Lamotrigine (Lamotrigine) |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Venlafaxine               |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Hydroxyzine               |              |            | S           |              | Oral               |                 | Not Reported |
|                                                       | Alcohol                   |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8360012       | EXPEDITED (15-DAY) | Y                  | DE              | 1000027048           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate          |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Oxcarbazepine (Oxcarbazepine) |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Bupropion Hydrochloride       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Lorazepam                     |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Zolpidem                      |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Quetiapine Fumarate           |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Jan-2012              | 8360032       | EXPEDITED (15-DAY) | Y                  | DE              | 1000027040           |                      | 46 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Lorazepam            |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                       | Alcohol              |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------------------|-----------------|--------------|----------------|
| 17-Jan-2012                                                                           | 8360078                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000026942           |                                                   | 49 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Arthropathy;<br>Musculoskeletal Pain;<br>Tendonitis                       | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2012                                                                           | 8360129                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000026948           |                                                   | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Aortic Arteriosclerosis;                                                              | Escitalopram Oxalate              |                    |                    | S               |                      |                                                   |                 | Not Reported |                |
| Atrial Fibrillation; Condition                                                        | Exelon                            |                    |                    | S               |                      |                                                   |                 | Not Reported |                |
| Aggravated; Dizziness;                                                                | Betaserc (Betahistine) (24        |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
| Epilepsy; Fall; Loss Of                                                               | Milligram, Tablets) (Betahistine) |                    |                    |                 |                      |                                                   |                 |              |                |
| Consciousness; Malaise;                                                               | Aprovel (Irbesartan) (75          |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
| Nystagmus; Vomiting                                                                   | Milligram) (Irbesartan)           |                    |                    |                 |                      |                                                   |                 |              |                |
|                                                                                       | Vastarel                          |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
|                                                                                       | Tanakan                           |                    |                    | C               |                      |                                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2012                                                                           | 8360160                           | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026950           |                                                   | 26 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Missed; Foetal<br>Death; Maternal Exposure<br>During Pregnancy;<br>Pregnancy | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2012                                                                           | 8360194                           | EXPEDITED (15-DAY) | Y                  | LT              | DSA_48824_2012       |                                                   | 18 YR           | Female       | BEL            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                               |                      |   |  |  |                                                  |              |
|-------------------------------------------------------------------------------|----------------------|---|--|--|--------------------------------------------------|--------------|
| Bulimia Nervosa;<br>Depression; Disease<br>Recurrence; Fatigue;<br>Somnolence | Wellbutrin           | S |  |  | Df, One Tablet Every Two<br>Days, Dosage Unknown | Not Reported |
|                                                                               | Escitalopram Oxalate | S |  |  | Df                                               | Not Reported |

| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2012                                      | 8362971                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-00230   |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Carvedilol (Carvedilol) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Lisinopril (Lisinopril) |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Diltiazem               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Diazepam (Diazepam)     |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2012                                       | 8377596                   | EXPEDITED (15-DAY) | Y                  | DE, HO          | AUR-APL-2012-00125   |                      | 56 YR           | Female       | USA            |
| <u>Preferred Term</u>                             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Intentional | Atenolol (Atenolol)       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Product Misuse;                                   | Citalopram Hydrobromide   |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Respiratory Arrest;                               | Lamotrigine (Lamotrigine) |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Toxicity To Various Agents                        | Venlafaxine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Escitalopram Oxalate      |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Hydroxyzine               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                   | Alcohol                   |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-----------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 17-Jan-2012                                      | 8382858                                 | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-00101   |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide;<br>Toxicity To Various Agents | Metformin Hydrochloride                 |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Unspecified Ingredient                  |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Acetaminophen\Unspecified<br>Ingredient |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Metoprolol Tartrate                     |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                  | Escitalopram Oxalate                    |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                |                                                               |                    |                    |                 |                            |                                             |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------------------------|-----------------|--------------|----------------|
| Esomeprazole (Esomeprazole)                                                                                                    |                                                               |                    |                    | S               |                            |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Jan-2012                                                                                                                    | 8389226                                                       | EXPEDITED (15-DAY) | Y                  | DE              | 1000027240                 |                                             | 25 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest;<br>Completed Suicide                                                                                | Escitalopram Oxalate                                          |                    |                    | S               | Oral                       | Oral                                        |                 | Not Reported |                |
|                                                                                                                                | Alprazolam (Alprazolam)                                       |                    |                    | S               | Oral                       | Oral                                        |                 | Not Reported |                |
|                                                                                                                                | Carbamazepine                                                 |                    |                    | S               | Oral                       | Oral                                        |                 | Not Reported |                |
|                                                                                                                                | Lamotrigine (Lamotrigine)                                     |                    |                    | S               | Oral                       | Oral                                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2012                                                                                                                    | 8281085                                                       | EXPEDITED (15-DAY) | Y                  | HO, OT          | US-ASTRAZENECA-2011SE72130 |                                             | 58 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bipolar I Disorder; Overdose; Pain; Weight Increased | Seroquel                                                      |                    |                    | S               | Oral                       |                                             |                 | Not Reported |                |
|                                                                                                                                | Seroquel                                                      |                    |                    | S               | Oral                       | 100 Mg Every Morning,<br>300 Mg Every Night |                 | Not Reported |                |
|                                                                                                                                | Lexapro                                                       |                    |                    | S               | Oral                       |                                             |                 | Not Reported |                |
|                                                                                                                                | Zyprexa                                                       |                    |                    | S               |                            |                                             |                 | Not Reported |                |
|                                                                                                                                | Chantix                                                       |                    |                    | C               |                            |                                             |                 | Not Reported |                |
|                                                                                                                                | Abilify                                                       |                    |                    | C               |                            |                                             |                 | Not Reported |                |
|                                                                                                                                | Saphris                                                       |                    |                    | C               |                            |                                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                       | <u>Case #</u>                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Jan-2012                                                                                                                    | 8328980                                                       | EXPEDITED (15-DAY) | Y                  | DE, RI, OT      | 1000026528                 |                                             | 86 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                          | <u>Product</u>                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Delusion; Hyponatraemia; Pneumonia                                                                                 | Escitalopram Oxalate                                          |                    |                    | S               | Oral                       | 5 Mg (5 Mg,1 In 1 D),Oral                   |                 | Not Reported |                |
|                                                                                                                                | Haloperidol (Haloperidol) (Drops(For Oral Use)) (Haloperidol) |                    |                    | C               |                            |                                             |                 | Not Reported |                |
|                                                                                                                                | Furosemid (Furosemide)                                        |                    |                    | C               |                            |                                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                       |                         |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------|
| (Tablets) (Furosemide)<br>Amiodaron Hydrochloride<br>(Amiodarone Hydrochloride)<br>(Tablets) (Amiodarone<br>Hydrochloride)<br>Digoxin<br>Potassium Chloride (Potassium<br>Chloride) (Tablets) (Potassium<br>Chloride) | C<br><br><br><br>C<br>C | Not Reported<br><br><br><br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2012              | 8357734       | EXPEDITED (15-DAY) | N                  | OT              | DSA_48839_2012       |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                    | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|------------------------------|
| Abortion Spontaneous;<br>Condition Aggravated;<br>Depressed Mood;<br>Depression; Disturbance<br>In Attention; Drug<br>Ineffective; Drug Level<br>Decreased; Hypersomnia;<br>Impaired Work Ability;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Maternal<br>Exposure During<br>Pregnancy; Movement<br>Disorder; Overdose;<br>Pregnancy; Stress At<br>Work | Wellbutrin                               |              |            | S           | Oral         | Df Oral                                    |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Lamictal                                 |              |            | S           | Oral         | 300 Mg, Frequency<br>Unknown Oral, Df Oral |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          |                                          |              |            |             | Oral         | 300 Mg, Frequency<br>Unknown Oral, Df Oral |                 |                              |
|                                                                                                                                                                                                                                                                                                                                                                          | Lamotrigine                              |              |            | S           |              | 300 Mg Or 400 Mg A Day                     |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Microgestin 1/20                         |              |            | S           |              | Df                                         |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Geodon                                   |              |            | S           |              | Df                                         |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Effexor                                  |              |            | S           |              | Df                                         |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Lexapro                                  |              |            | S           |              | Df                                         |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Lipitor                                  |              |            | C           |              |                                            |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Trileptal                                |              |            | C           |              |                                            |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Nortriptyline Hydrochloride              |              |            | C           |              |                                            |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Folplex                                  |              |            | C           |              |                                            |                 | Not Reported                 |
|                                                                                                                                                                                                                                                                                                                                                                          | Prenatal Vitamins /01549301/<br>Fish Oil |              |            | C<br>C      |              |                                            |                 | Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Jan-2012              | 8382039       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027109           |                      | 62 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |                      |   |      |                                |              |
|---------------------------------------------------|----------------------|---|------|--------------------------------|--------------|
| Fall; Fatigue; Monoplegia;<br>Somnolence; Vertigo | Escitalopram Oxalate | S | Oral | 10 Mg (10 Mg,1 In 1<br>D),Oral | Not Reported |
|---------------------------------------------------|----------------------|---|------|--------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2012              | 7254482       | EXPEDITED (15-DAY) | Y                  | HO              | 1000011010           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                              | <u>Product</u>                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------|--------------------------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Cerebrovascular Accident;<br>Hemianopia Homonymous | Escitalopram Oxalate                                                           |              |            | S           | Oral         | 20 Mg (20 Mg,1 In 1<br>D),Oral                       |                 | Not Reported |
|                                                    | Derinox (Naphazoline<br>Nitrate\Prednisolone)                                  |              |            | S           | Nasal        | 3 Dosage Forms (1<br>Dosage Forms,3 In 1<br>D),Nasal |                 | Not Reported |
|                                                    | Relpax                                                                         |              |            | S           | Oral         | (40 Mg,As Required),Oral                             |                 | Not Reported |
|                                                    | Flurbiprofen                                                                   |              |            | S           | Oral         | (200 Mg,5 Days Per<br>Month),Oral                    |                 | Not Reported |
|                                                    | Euphon (Codeine, Erysimum)<br>(Syrup) (Codeine, Erysimum)                      |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Cefuroxime                                                                     |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Paracetamol (Paracetamol)<br>(Capsules) (Paracetamol)                          |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Topalgic [Tramadol<br>Hydrochloride]                                           |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Seresta (Oxazepam) (Tablets)<br>(Oxazepam)                                     |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Havlane (Loprazolam Mesilate)<br>(Tablets) (Loprazolam Mesilate)               |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Propranolol (Propranolol)<br>(Capsules) (Propranolol)                          |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Depakote (Valproate<br>Semisodium) (Tablets)<br>(Valproate Semisodium)         |              |            | C           |              |                                                      |                 | Not Reported |
|                                                    | Citalopram (Citalopram<br>Hydrobromide) (Tablets)<br>(Citalopram Hydrobromide) |              |            | C           |              |                                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 19-Jan-2012              | 8116486       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2011197848 |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Agitation;<br>Anger; Anxiety; Breast<br>Enlargement; Condition<br>Aggravated; Constipation;<br>Deafness; Dependence;<br>Disturbance In Attention;<br>Drug Ineffective; Ear<br>Disorder; Erection<br>Increased; Fatigue;<br>Feeling Abnormal; Gastric<br>Ulcer; Influenza Like<br>Illness; Insomnia; Memory<br>Impairment; Mood Swings;<br>Muscle Spasms; Pain;<br>Rash; Rectal<br>Haemorrhage;<br>Somnolence; Suicidal<br>Ideation; Therapeutic<br>Product Effect Increased;<br>Unevaluable Event;<br>Weight Increased | Zoloft                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Skelaxin                |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Mirtazapine             |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Effexor                 |              |            | S           |              | 37.5 Mg, Unk       |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Effexor Xr              |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Celebrex                |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Geodon                  |              |            | S           |              | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Depakote                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Zomig                   |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Imitrex                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Soma                    |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lithium                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Risperdal               |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Seroquel                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Zyprexa                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lexapro                 |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Lamictal                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tegretol                |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Wellbutrin              |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Buspar                  |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Valium                  |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Valium                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Valium                  |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Paxil                   |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cymbalta                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cymbalta                |              |            | S           |              |                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Elavil                  |              |            | S           |              | Unk                |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Klonopin                |              |            | S           |              | Unk                |                 | Not Reported |

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| Ritalin                                                                                                                                                                                                                                   |                    | S                  |                    | Not Reported    |                                |                         |                 |            |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|--------------------------------|-------------------------|-----------------|------------|----------------|
| Pamelor                                                                                                                                                                                                                                   |                    | S                  |                    | Not Reported    |                                |                         |                 |            |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jan-2012                                                                                                                                                                                                                               | 8343926            | EXPEDITED (15-DAY) | N                  |                 | US-SANOFI-AVENTIS-2011SA002287 |                         | 90 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Dizziness; Insomnia                                                                                                                                                                                                              | Lasix              |                    |                    | S               | Unknown                        |                         |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Lexapro            |                    |                    | S               | Unknown                        |                         |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Doxazosin Mesylate |                    |                    | S               | Unknown                        |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jan-2012                                                                                                                                                                                                                               | 8353403            | DIRECT             | Y                  | HO, LT          |                                |                         | 25 YR           | Female     | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Acute Psychosis; Agitation; Conversion Disorder; Diet Refusal; Dyskinesia; General Physical Health Deterioration; Hallucinations, Mixed; Hypersomnia; Insomnia; Refusal Of Treatment By Patient; Regressive Behaviour; Stereotypy; Tremor | Lexapro            |                    |                    | S               | Oral                           | 10mg Daily Oral         |                 |            | Forest         |
|                                                                                                                                                                                                                                           | Depakote           |                    |                    | C               |                                |                         |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Topamax            |                    |                    | C               |                                |                         |                 |            | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                                                                                                                  | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jan-2012                                                                                                                                                                                                                               | 8354452            | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026818                     |                         | 65 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                     | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper; Angina Pectoris; Chest Discomfort; Gait Inability;                                                                                                                                                                  | Lexapro            |                    |                    | S               |                                | 5 Mg (5 Mg, 1 In 1 D)   |                 |            | Not Reported   |
|                                                                                                                                                                                                                                           | Lexapro            |                    |                    | S               |                                | 10 Mg (10 Mg, 1 In 1 D) |                 |            | Not Reported   |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                        |                                                                |   |  |  |  |  |  |  |              |
|------------------------------------------------------------------------|----------------------------------------------------------------|---|--|--|--|--|--|--|--------------|
| Hypoglycaemia; Nausea;<br>Pain In Extremity;<br>Restlessness; Vomiting | Trazolan (Trazodone<br>Hydrochloride)<br>Omeprazol (Omeprazol) | C |  |  |  |  |  |  | Not Reported |
|                                                                        |                                                                | C |  |  |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2012              | 8359890       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-00257   |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Toxicity To Various Agents | Cyclobenzaprine      |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                  | Amitriptyline        |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                  | Escitalopram Oxalate |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                  | Salicylate           |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                  | Sennosides A And B   |              |            | S           |              | Unknown            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2012              | 8360175       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027110           |                      | 59 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------|-----------------|--------------|
| Thyroid Neoplasm      | Escitalopram Oxalate |              |            | S           | Oral         | 1 Df (1 Dosage Forms, 1<br>In 1 D), Oral |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Jan-2012              | 8388600       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027127           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Escitalopram Oxalate        |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Amitriptyline Hydrochloride |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Trandolapril                |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                       | Laxatives (Laxatives)       |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| 19-Jan-2012                                                                                                                                                                          | 8388721                         | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027141                   |                      | 26 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Nervousness; Peripheral Coldness; Pruritus; Skin Burning Sensation                                                                                                                   | Escitalopram Oxalate            |                    |                    | S               | Oral                         | Oral                 |                 | Not Reported    |                |
|                                                                                                                                                                                      | Contraceptives (Contraceptives) |                    |                    | C               |                              |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 19-Jan-2012                                                                                                                                                                          | 8390830                         | EXPEDITED (15-DAY) | N                  | LT              | 1000027130                   |                      | 36 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Abnormal Dreams; Aggression; Confusional State; Decreased Appetite; Disturbance In Attention; Fatigue; Nervous System Disorder; Pollakiuria; Somnolence; Suicidal Ideation; Tinnitus | Escitalopram Oxalate            |                    |                    | S               | Oral                         | 20 Mg, Oral          |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                             | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 20-Jan-2012                                                                                                                                                                          | 8346737                         | EXPEDITED (15-DAY) | Y                  | HO              | FR-GLAXOSMITHKLINE-B0708151A |                      | 63 YR           | Male            | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Haematuria; Thrombocytopenia                                                                                                                                                         | Arixtra                         |                    |                    | S               | Subcutaneous                 | 2.5mg Per Day        | 28 DAY          | Glaxosmithkline |                |
|                                                                                                                                                                                      | Escitalopram Oxalate            |                    |                    | S               | Oral                         | 10mg Per Day         | 30 DAY          | Unknown         |                |
|                                                                                                                                                                                      | Ketoprofen                      |                    |                    | S               | Oral                         |                      | 30 DAY          | Unknown         |                |
|                                                                                                                                                                                      | Sufentanyl                      |                    |                    | C               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                      | Hypnovel                        |                    |                    | C               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                      | Inexium                         |                    |                    | C               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                                                                                                                                      | Solu-Medrol                     |                    |                    | C               | Unknown                      |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chlorpromazine Hydrochloride

C

Unknown

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8349131       | EXPEDITED (15-DAY) | Y                  | DE              | US-MERCK-1201USA02191 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                             | <u>Product</u>                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------|----------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Adverse Event; Cardiac Arrest; Respiratory Arrest | Zocor                                                                            |              |            | S           | Oral         |                    |                 | Merck        |
|                                                   | Solifenacin Succinate                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Memantine                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Clozapine                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Dextroamphet Saccharat, Amphet Aspartate, Dextroamphet Sulfate And Amphet Sulfat |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Escitalopram Oxalate                                                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                   | Metoprolol                                                                       |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8349141       | EXPEDITED (15-DAY) | Y                  | DE              | US-MERCK-1201USA02206 |                      | 62 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide; Overdose | Prinivil                |              |            | S           | Oral         |                    |                 | Merck        |
|                             | Carvedilol              |              |            | S           | Oral         |                    |                 | Not Reported |
|                             | Diltiazem Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                             | Escitalopram Oxalate    |              |            | S           | Oral         |                    |                 | Not Reported |
|                             | Diazepam                |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8360154       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026944           |                      | 2 DAY      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                        |                             |   |                |                                                                                                                  |              |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---|----------------|------------------------------------------------------------------------------------------------------------------|--------------|
| Agitation Neonatal;<br>Dystonia; Flatulence;<br>Hypertonia Neonatal;<br>Maternal Drugs Affecting<br>Foetus; Regurgitation;<br>Retching | Escitalopram Oxalate        | S | Transplacental | Transplacental                                                                                                   | Not Reported |
|                                                                                                                                        | Amitriptyline Hydrochloride | S | Transplacental | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),<br>Transplacental                                                   | Not Reported |
|                                                                                                                                        | Chlorpromazine              | S | Transplacental | 75 Mg Daily Before Third<br>Quarter Of Pregnancy (75<br>Mg, 1 In 1 D),<br>Transplacental, Daily Dose<br>Decrease | Not Reported |
|                                                                                                                                        |                             |   | Transplacental | 75 Mg Daily Before Third<br>Quarter Of Pregnancy (75<br>Mg, 1 In 1 D),<br>Transplacental, Daily Dose<br>Decrease |              |
|                                                                                                                                        | Oxazepam                    | S | Transplacental | 20 Mg (20 Mg, 1 In 1 D),<br>Transplacental                                                                       | Not Reported |
|                                                                                                                                        | Prazepam                    | S | Transplacental | Switched To Oxazepam At<br>The Third Quarter,<br>Transplacental                                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8390171       | EXPEDITED (15-DAY) | N                  | CA              | 1000027180           |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Congenital Torticollis;<br>Maternal Drugs Affecting<br>Foetus | Lexapro        |              |            | S           |              | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8390177       | EXPEDITED (15-DAY) | N                  | CA              | 1000027181           |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Atrial Septal Defect;<br>Maternal Drugs Affecting<br>Foetus; Ventricular Septal | Lexapro        |              |            | S           |              | Transplacental     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Defect

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8391062       | EXPEDITED (15-DAY) | N                  | CA              | 1000027144           |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>                                                                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Fallot'S Tetralogy;<br>Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect | Lexapro        |              |            | S           | Transplacental | Transplacental     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Jan-2012              | 8391724       | EXPEDITED (15-DAY) | Y                  | LT              | 1000027206           |                      | 85 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Anxiety; Dizziness;<br>Dyspnoea; Oedema<br>Mouth; Oropharyngeal<br>Pain; Swollen Tongue | Escitalopram Oxalate                                  |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                         | Irbesartan (Irbesartan)                               |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                         | Hydrochlorotiazida<br>(Hydrochlorothiazide) (Tablets) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                         | Lorazepam (Lorazepam)<br>(Tablets) (Lorazepam)        |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 6899368       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-<br>2009161616 |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Blood<br>Pressure Increased;<br>Dyspepsia; Oedema<br>Peripheral | Lyrica         |              |            | S           |              | 225 Mg             |                 | Pfizer       |
|                                                                                                          | Atenolol       |              |            | S           |              | 25 Mg, Unk         |                 | Pfizer       |
|                                                                                                          | Altace         |              |            | S           | Oral         | 5 Mg, Unk          |                 | Pfizer       |
|                                                                                                          | Simvastatin    |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                                                                                                          | Lexapro        |              |            | S           |              | 20 Mg, Unk         |                 | Not Reported |





# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                     |   |      |             |              |
|-------------------------------------|---|------|-------------|--------------|
| Xyrem                               | S | Oral | 2 G, 2x/Day | Not Reported |
| Cymbalta                            | S |      | 60 Mg       | Not Reported |
| Triamterene And Hydrochlorothiazide | C |      | Unk         | Not Reported |

| <u>FDA Received Date</u>                                                                                                   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| 24-Jan-2012                                                                                                                | 8188669                   | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | 2011SP046144         |                       | 37 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                      | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Lactic Acid Increased; Coma; Continuous                                                                              | Mirtazapine (Mirtazapine) |                    |                    | S               |                      | 230 Mg;               |                 | Not Reported |                |
| Haemodiafiltration; Intentional Overdose; Muscle Spasms; Respiratory Acidosis; Seizure; Sinus Bradycardia; Suicide Attempt | Baclofen                  |                    |                    | S               |                      | 1859 Mg;;Po, 2500 Mg; |                 | Not Reported |                |
|                                                                                                                            | Escitalopram Oxalate      |                    |                    | S               |                      | 160 Mg;               |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 24-Jan-2012                                                                                                                                                                                           | 8305816              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026059           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 15 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Haemorrhage;<br>Condition Aggravated;<br>Cushingoid; Eosinophilic<br>Granulomatosis With<br>Polyangiitis; Epistaxis;<br>Nasal Congestion;<br>Overweight; Rash<br>Papular; Rash Pruritic;<br>Scab | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral, 15 Mg (15 Mg, 1<br>In 1 D), Oral, 20 Mg (20<br>5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral, 15 Mg (15 Mg, 1<br>In 1 D), Oral, 20 Mg (20<br>5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral, 15 Mg (15 Mg, 1<br>In 1 D), Oral, 20 Mg (20<br>5 Mg (5 Mg, 1 In 1 D),<br>Oral, 10 Mg (10 Mg, 1 In 1<br>D), Oral, 15 Mg (15 Mg, 1<br>In 1 D), Oral, 20 Mg (20<br>5 Mg (5 Mg, 1 In 1 D), |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                         |   |                                                                               |              |
|-----------------------------------------------------------------------------------------|---|-------------------------------------------------------------------------------|--------------|
|                                                                                         |   | Oral, 10 Mg (10 Mg, 1 In 1 D), Oral, 15 Mg (15 Mg, 1 In 1 D), Oral, 20 Mg (20 |              |
| Nexium (Esomeprazole Magnesium) (Tablets)                                               | C |                                                                               | Not Reported |
| (Esomeprazole Magnesium) Kalcipos (Calcium Carbonate) (Tablets) (Calcium Carbonate)     | C |                                                                               | Not Reported |
| Niferex (Ferroglycine Sulfate)                                                          | C |                                                                               | Not Reported |
| Folacin (Folic Acid) (Tablets) (Folic Acid)                                             | C |                                                                               | Not Reported |
| Methotrexat (Methotrexate) (Tablets) (Methotrexate)                                     | C |                                                                               | Not Reported |
| Prednisolon (Prednisolone) (Tablets) (Prednisolone)                                     | C |                                                                               | Not Reported |
| Melatonin (Melatonin) (3 Milligram, Tablets) (Melatonin)                                | C |                                                                               | Not Reported |
| Theralen (Alimemazine Tartrate) (Tablets) (Alimemazine Tartrate)                        | C |                                                                               | Not Reported |
| Symbicort (Budesonide, Formoterol Fumarate) (Tablets) (Budesonide, Formoterol Fumarate) | C |                                                                               | Not Reported |
| Pulmicort (Budesonide, Formoterol Fumarate) (Tablets) (Budesonide, Formoterol Fumarate) | C |                                                                               | Not Reported |
| Singulair                                                                               | C |                                                                               | Not Reported |
| Pulmozyme (Dornase Alfa) (Dornase Alfa)                                                 | C |                                                                               | Not Reported |
| Aerius (Ebastine) (Ebastine)                                                            | C |                                                                               | Not Reported |
| Tradolan (Tramadol Hydrochloride) (Tramadol Hydrochloride)                              | C |                                                                               | Not Reported |
| Stesolid (Diazepam) (Tablets) (Diazepam)                                                | C |                                                                               | Not Reported |
| Propavan (Propiomazine Maleate) (Tablets) (Propiomazine Maleate)                        | C |                                                                               | Not Reported |
| Importal (Lactitol) (Lactitol)                                                          | C |                                                                               | Not Reported |
| Tavegyl (Clemastine Fumarate) (Clemastine Fumurate)                                     | C |                                                                               | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 8336334       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026336           |                      | 51 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------|-----------------|--------------|
| Aspartate Amino transferase Increased; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Creatine Phosphokinase Increased; Blood Uric Acid Increased; Decreased Appetite; Dehydration; Feeling Abnormal; Insomnia; Lymphocyte Percentage Decreased; Seizure; Tremor; White Blood Cell Count Decreased | Lexapro                     |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                        | Amoxan (Amoxapine)          |              |            | C           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral, 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                        | Depas (Etizolam) (Etizolam) |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                        | Zolpidem Tartrate           |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                        | Rohypnol (Flunitrazepam)    |              |            | C           |              |                                                              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                        | (Flunitrazepam)             |              |            |             |              |                                                              |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 8350477       | EXPEDITED (15-DAY) | Y                  | DE              | US-SHIRE-ALL1-2012-00264 |                      | 25 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Carbamazepine        |              |            | S           | Oral         | Unk, Unknown       |                 | Shire        |
|                       | Alprazolam           |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Lamotrigine          |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 8351853       | EXPEDITED (15-DAY) | N                  | DS, OT          | US-TEVA-318288USA    |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                             |   |      |              |
|----------------------------|-----------------------------|---|------|--------------|
| Abortion Spontaneous;      | Lamotrigine                 | S | Oral | Teva         |
| Bedridden; Depressed       | Lamictal                    | S | Oral | Not Reported |
| Mood; Depression;          | Microgestin 1.5/30          | S |      | Not Reported |
| Disability; Disturbance In | Ziprasidone Hydrochloride   | S |      | Not Reported |
| Attention; Drug Level      | Bupropion                   | S | Oral | Not Reported |
| Decreased; Hypersomnia;    | Venlafaxine                 | S |      | Not Reported |
| Loss Of Personal           | Escitalopram Oxalate        | S |      | Not Reported |
| Independence In Daily      | Atorvastatin Calcium        | C |      | Not Reported |
| Activities; Maternal       | Oxcarbazepine               | C |      | Not Reported |
| Exposure During            | Nortriptyline Hydrochloride | C |      | Not Reported |
| Pregnancy; Overdose;       | Folplex                     | C |      | Not Reported |
| Stress                     | Prenatal Vitamins           | C |      | Not Reported |
|                            | Fish Oil                    | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 8392061       | EXPEDITED (15-DAY) | Y                  | DE, HO          | 1000027245           |                      | 68 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Bronchial Disorder;      | Escitalopram Oxalate           |              |            | S           | Oral         | 2 Dosage Form (2 Dosage |                 | Not Reported |
| Cachexia; General        |                                |              |            |             |              | Forms, 1 In 1 D), Oral  |                 |              |
| Physical Health          | Dihydroergotamine Mesylate     |              |            | S           | Oral         | Oral                    |                 | Not Reported |
| Deterioration;           | Levothyroxine Sodium           |              |            | C           |              |                         |                 | Not Reported |
| Lymphadenopathy          | Un-Alfa (Alfacalcidol)         |              |            | C           |              |                         |                 | Not Reported |
| Mediastinal; Psychomotor | (Alfacalcidol)                 |              |            |             |              |                         |                 |              |
| Retardation; Pulmonary   | Tenormin                       |              |            | C           |              |                         |                 | Not Reported |
| Fibrosis; Tuberculosis   | Fortimel (Protein Supplements) |              |            | C           |              |                         |                 | Not Reported |
|                          | (Protein Supplements)          |              |            |             |              |                         |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Jan-2012              | 8392156       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027319           |                      |            | Female     | DNK            |

| <u>Preferred Term</u>     | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Anxiety; Apallic Syndrome | Escitalopram Oxalate           |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), |                 | Not Reported |
|                           |                                |              |            |             |              | Oral                     |                 |              |
|                           | Zolpidem (Zolpidem) (Zolpidem) |              |            | C           |              |                          |                 | Not Reported |
|                           | Spifen (Ibuprofen) (Ibuprofen) |              |            | C           |              |                          |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                                  |   |              |
|--|----------------------------------|---|--------------|
|  | Dafalgan (Paracetamol)           | C | Not Reported |
|  | (Paracetamol)                    |   |              |
|  | Derinox (Amoxicillin Trihydrate) | C | Not Reported |
|  | Pinaverium (Pinaverium)          | C | Not Reported |
|  | (Pinaverium)                     |   |              |

| <u>FDA Received Date</u>                                                                                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------------------|-----------------|--------------|----------------|
| 25-Jan-2012                                                                                                                             | 7140416              | EXPEDITED (15-DAY) | Y                  | DS              | 1000008839           |                                  | 44 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated;<br>Dyskinesia; Dysphagia;<br>Dystonia; Mastication<br>Disorder; Pain In Jaw;<br>Speech Disorder; Tongue<br>Biting | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
|                                                                                                                                         | Tamoxifen Citrate    |                    |                    | C               |                      |                                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                             | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------|---------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------|-----------------|--------------|----------------|
| 25-Jan-2012                                                          | 8274535                   | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000025715           |                                            |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Induced;<br>Anencephaly; Maternal<br>Drugs Affecting Foetus | Escitalopram Oxalate      |                    |                    | S               | Transplacental       | 10 Mg (10 Mg, 1 In 1 D),<br>Transplacental |                 | Not Reported |                |
|                                                                      | Kenacutan                 |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                      | Acetaminophen             |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                      | Vitamin (Vitamins Nos)    |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                      | Gravitamin (Vitamins Nos) |                    |                    | C               |                      |                                            |                 | Not Reported |                |
|                                                                      | Haemoglobin Iron (Iron)   |                    |                    | C               |                      |                                            |                 | Not Reported |                |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------|-----------------|--------------|----------------|
| 25-Jan-2012                                                            | 8353028        | EXPEDITED (15-DAY) | N                  | HO, LT, OT      | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16360927 |                        | 47 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Increased;<br>Dizziness; Drug<br>Ineffective; Dry Mouth; | Abilify        |                    |                    | S               | Oral                                            | Restarted In Jul,Dec11 |                 | Not Reported |                |
|                                                                        | Abilify        |                    |                    | S               | Oral                                            | Restarted In Jul,Dec11 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |             |   |              |
|-----------------------------|-------------|---|--------------|
| Headache; Major             | Lexapro     | S | Not Reported |
| Depression; Medication      | Lexapro     | S | Not Reported |
| Error; Overdose;            | Wellbutrin  | S | Not Reported |
| Paranoia; Suicidal Ideation | Wellbutrin  | S | Not Reported |
|                             | Prozac      | S | Not Reported |
|                             | Prozac      | S | Not Reported |
|                             | Seroquel    | C | Not Reported |
|                             | Neurontin   | C | Not Reported |
|                             | Topamax     | C | Not Reported |
|                             | Misoprostol | C | Not Reported |
|                             | Actos       | C | Not Reported |
|                             | Prilosec    | C | Not Reported |
|                             | Diovan      | C | Not Reported |
|                             | Glimepiride | C | Not Reported |
|                             | Welchol     | C | Not Reported |
|                             | Celebrex    | C | Not Reported |
|                             | Vesicare    | C | Not Reported |
|                             | Singular    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2012              | 8353701       | DIRECT           | Y                  | OT              |                      |                      | 28 YR      | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Deafness;<br>Insomnia; Tinnitus | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jan-2012              | 8392940       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027368           |                      | 19 YR      | Female     | DNK            |

| <u>Preferred Term</u>    | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|--------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------|-----------------|--------------|
| Blood Potassium          | Escitalopram Oxalate                             |              |            | S           | Oral         | (0.5 Dosage Forms), Oral           |                 | Not Reported |
| Increased; Eye Swelling; | Escitalopram Oxalate                             |              |            | S           | Oral         | (1 Dosage Forms), Oral             |                 | Not Reported |
| Generalised Erythema;    | Macrobid                                         |              |            | S           | Oral         | 200 Mg (100 Mg, 2 In 1 D),<br>Oral |                 | Not Reported |
| Pruritus Generalised;    |                                                  |              |            |             |              |                                    |                 |              |
| Urticaria; Visual        |                                                  |              |            |             |              |                                    |                 |              |
| Impairment; White Blood  | Tramadol Hydrochloride                           |              |            | C           |              |                                    |                 | Not Reported |
| Cell Count Increased     | (Tramadol Hydrochloride)<br>(Unknown) (Tramadol) |              |            |             |              |                                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrochloride)  
Marvelon (Marvelon) (Tablets)  
(Marvelon)

C

Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Jan-2012              | 8336082       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000026582           |                      |            | Male       | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|---------------------------------------------|-----------------|--------------|
| Blood Lactic Acid Increased; Coma; Continuous Haemodiafiltration; Intentional Overdose; Miosis; Muscle Spasms; Poisoning; Respiratory Acidosis; Seizure; Sinus Bradycardia; Snoring; Suicide Attempt | Lexapro                   |              |            | S           |              | Overdose: Unclear If 160mg Or 100 Mg (Once) |                 | Not Reported |
|                                                                                                                                                                                                      | Mirtazapine (Mirtazapine) |              |            | S           |              | Overdose 230 Mg (Once)                      |                 | Not Reported |
|                                                                                                                                                                                                      | Baclofen                  |              |            | S           |              | Overdose 1850 Mg (Once)                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2012              | 8355189       | EXPEDITED (15-DAY) | Y                  | DE              | US-SHIRE-ALL1-2012-00257 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Dextroamphetamine     |              |            | S           | Oral         | Unk, Unknown       |                 | Shire        |
|                       | Metoprolol            |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Escitalopram Oxalate  |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Clozapine             |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Memantine             |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Solifenacin Succinate |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |
|                       | Simvastatin           |              |            | S           | Oral         | Unk, Unknown       |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Jan-2012              | 8355689       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012015409 |                      | 32 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| Abortion Spontaneous;<br>Bedridden; Depressed<br>Mood; Depression;<br>Disability; Disturbance In<br>Attention; Drug Level<br>Decreased; Hypersomnia;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Overdose;<br>Stress | Effexor            |                    |                    | S               |                      | Unk                             |                 | Pfizer       |                |
|                                                                                                                                                                                                                                      | Geodon             |                    |                    | S               |                      | Unk                             |                 | Pfizer       |                |
|                                                                                                                                                                                                                                      | Lamictal           |                    |                    | S               | Oral                 | 300 Mg, Unk                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lamotrigine        |                    |                    | S               | Oral                 | 300 Mg, Unk                     |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Microgestin 1.5/30 |                    |                    | S               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Wellbutrin         |                    |                    | S               | Oral                 | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro            |                    |                    | S               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lipitor            |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Trileptal          |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Nortriptyline      |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Multivitamins      |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Prenatal Vitamins  |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Fish Oil           |                    |                    | C               |                      | Unk                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2012                                                                                                                                                                                                                          | 8356098            | DIRECT             | N                  | HO, OT          |                      |                                 | 27 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Blindness; Mental<br>Impairment; Migraine;<br>Speech Disorder; Tremor                                                                                                                                                                | Lexapro            |                    |                    | S               | Oral                 | 1 Tab                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                             | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Jan-2012                                                                                                                                                                                                                          | 8382052            | EXPEDITED (15-DAY) | Y                  | LT, RI, OT      | 1000026517           |                                 | 35 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Amnesia; Asthenia;<br>Bradycardia; Cough; Fall;<br>Headache; Loss Of<br>Consciousness; Parosmia;<br>Tic                                                                                                                              | Lexapro            |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                      | Lexapro            |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                  |   |              |
|--------------------------------------------------|---|--------------|
| Drug For Headache (Drug For Headache)            | C | Not Reported |
| Dogmatyl (Sulpiride) (Sulpiride)                 | C | Not Reported |
| Wypax (Lorazepam) (Lorazepam)                    | C | Not Reported |
| Zolpidem Tartrate                                | C | Not Reported |
| Depas (Etizolam) (Etizolam)                      | C | Not Reported |
| Lexotan (Bromazepam) (Bromazepam)                | C | Not Reported |
| Asmedin (Cimetidine) (Dimetidine)                | C | Not Reported |
| Kipres (Montelukast Sodium) (Montelukast Sodium) | C | Not Reported |
| Lansoprazole                                     | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 26-Jan-2012              | 8394307              | EXPEDITED (15-DAY) | Y                  | OT              | 2012MA000915         |                      | 21 YR           | Female       | DNK            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oculogyric Crisis        | Risperidone          |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                          | Cipralex             |                    |                    | S               | Oral                 | 20 Mg;Qd;Po          |                 | Not Reported |                |
|                          | Orphenadrine Citrate |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------|-----------------|--------------|----------------|
| 27-Jan-2012                             | 7870817                 | EXPEDITED (15-DAY) | Y                  | HO              | 1000019020           |                           | 25 YR           | Male         | DNK            |
| <u>Preferred Term</u>                   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Encephalopathy; Hepatitis Toxic | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg (10 Mg,1 In 1 D)    |                 | Not Reported |                |
|                                         | Clozapine               |                    |                    | S               |                      | 400 Mg (400 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                         | Risperidone             |                    |                    | S               | Intramuscular        | (50 Mg), Intramuscular    |                 | Not Reported |                |
|                                         | Topiramate              |                    |                    | S               |                      | 400 Mg (400 Mg,1 In 1 D)  |                 | Not Reported |                |
|                                         | Omeprazole              |                    |                    | S               |                      | 20 Mg (20 Mg,1 In 1 D)    |                 | Not Reported |                |
|                                         | Biperiden Hydrochloride |                    |                    | S               |                      | 4 Mg (4 Mg)               |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|--------------------------|------------------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|-----------------|----------------|
| 27-Jan-2012              | 8357867                      | NON-EXPEDITED      | N                  |                 | US-GLAXOSMITHKLINE-A0914299A          |                      | 55 YR           | Male            | USA            |
| <u>Preferred Term</u>    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Erectile Dysfunction     | Wellbutrin XI                |                    |                    | S               | Oral                                  | 300mg Per Day        |                 | Glaxosmithkline |                |
|                          | Lexapro                      |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012              | 8357909                      | NON-EXPEDITED      | Y                  |                 | US-GLAXOSMITHKLINE-A0928630A          |                      | 58 YR           | Female          | USA            |
| <u>Preferred Term</u>    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Back Pain; Dyspepsia;    | Wellbutrin                   |                    |                    | S               | Oral                                  | 160mg Per Day        | 28 DAY          | Glaxosmithkline |                |
| Gastroesophageal Reflux  | Lexapro                      |                    |                    | S               | Oral                                  | 10mg Per Day         | 26 DAY          | Not Reported    |                |
| Disease; Sensation Of    | Lexapro                      |                    |                    | S               | Oral                                  | 5mg Per Day          | 4 DAY           | Not Reported    |                |
| Foreign Body             |                              |                    |                    |                 |                                       |                      |                 |                 |                |
| <u>FDA Received Date</u> | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012              | 8358491                      | EXPEDITED (15-DAY) | Y                  | HO              | FR-MERCK-1201USA02794                 |                      | 64 YR           | Male            | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Glomerulonephritis       | Zetia                        |                    |                    | S               | Oral                                  |                      |                 | Merck           |                |
| Membranous               | Orencia                      |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Not Reported    |                |
|                          | Lansoprazole                 |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Acetaminophen\Caffeine\Opium |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Atenolol                     |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Escitalopram Oxalate         |                    |                    | S               | Oral                                  |                      |                 | Not Reported    |                |
|                          | Alprazolam                   |                    |                    | C               | Unknown                               |                      |                 | Not Reported    |                |
|                          | Tanakan                      |                    |                    | C               | Unknown                               |                      |                 | Not Reported    |                |
|                          | Naftazone                    |                    |                    | C               | Unknown                               |                      |                 | Not Reported    |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                            | Domperidone    |                    | C                  | Unknown         |                              |                                        |                 | Not Reported    |                |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------------------------|-----------------|-----------------|----------------|
|                                                                            | Legalon        |                    | C                  | Unknown         |                              |                                        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012                                                                | 8360108        | NON-EXPEDITED      | Y                  | OT              | US-GLAXOSMITHKLINE-A0903029A |                                        | 65 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>      |                |
| Inappropriate Schedule Of Product Administration; Mania; Oedema Peripheral | Wellbutrin     |                    |                    | S               | Unknown                      |                                        |                 | Glaxosmithkline |                |
|                                                                            | Saphris        |                    |                    | S               | Sublingual                   | 20mg At Night                          |                 | Not Reported    |                |
|                                                                            | Lexapro        |                    |                    | S               | Unknown                      |                                        |                 | Not Reported    |                |
|                                                                            | Alprazolam     |                    |                    | C               |                              | 4mg At Night                           |                 | Glaxosmithkline |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012                                                                | 8394695        | EXPEDITED (15-DAY) | Y                  | CA, DE          | 1000027276                   |                                        |                 | Unknown         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>      |                |
| Abortion Induced; Maternal Drugs Affecting Foetus; Spina Bifida            | Lexapro        |                    |                    | S               | Transplacental               | 20 Mg (20 Mg,1 In 1 D), Transplacental |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012                                                                | 8394696        | EXPEDITED (15-DAY) | N                  | CA              | 1000027413                   |                                        | < 1 DAY         | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>      |                |
| Craniosynostosis; Maternal Drugs Affecting Foetus                          | Lexapro        |                    |                    | S               | Transplacental               | Transplacental                         |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 27-Jan-2012                                                                | 8396430        | EXPEDITED (15-DAY) | Y                  | HO              | 1000027402                   |                                        | < 1 DAY         | Female          | DNK            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>      |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                                  |   |                |                                        |              |
|-----------------------------------------------------------------|----------------------------------|---|----------------|----------------------------------------|--------------|
| Maternal Drugs Affecting Fetus; Neonatal Respiratory Depression | Lexapro                          | S | Transplacental | 20 Mg (20 Mg,1 In 1 D), Transplacental | Not Reported |
|                                                                 | Ferrofumaraat (Ferrous Fumarate) | C |                |                                        | Not Reported |
|                                                                 | Omeprazole                       | C |                |                                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 29-Jan-2012              | 8378738       | NON-EXPEDITED    | N                  |                 | US-ABBOTT-11P-163-0860738-00 |                      | 44 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Alopecia              | Humira         |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | 20 Mg Tablet Daily |                 | Not Reported |
|                       | Simvastatin    |              |            | C           |              |                    |                 | Not Reported |
|                       | Fenofibrate    |              |            | C           |              |                    |                 | Not Reported |
|                       | Levothyroxine  |              |            | C           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | C           |              |                    |                 | Not Reported |
|                       | Neocon         |              |            | C           |              | 0.5-35-28 Daily    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 7841882       | EXPEDITED (15-DAY) | Y                  | HO              | ES-ABBOTT-11P-144-0707957-00 |                      | 25 YR      | Male       | ESP            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|--------------|
| Hepatic Encephalopathy; Hepatitis Toxic | Biperiden            |              |            | S           |               |                    |                 | Not Reported |
|                                         | Escitalopram Oxalate |              |            | S           |               |                    |                 | Not Reported |
|                                         | Clozapine            |              |            | S           |               |                    |                 | Not Reported |
|                                         | Risperidone          |              |            | S           | Intramuscular |                    |                 | Not Reported |
|                                         | Topiramate           |              |            | S           |               |                    |                 | Not Reported |
|                                         | Omeprazole           |              |            | S           |               |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 8324463       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2012002012 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Dizziness; Drug       | Neurontin      |              |            | S           | Oral         | 300 Mg, 1x/Day     | 11 DAY          | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |         |   |     |              |
|--------------------------|---------|---|-----|--------------|
| Hypersensitivity; Nausea | Lexapro | S | Unk | Not Reported |
|                          | Versed  | S | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 8339776       | EXPEDITED (15-DAY) |                    | OT              | PHHY2012US002247     |                      | 78 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatitis; Liver Injury | Diclofenac     |              |            | S           |              | Unk Unk, Unk       |                 | Novartis     |
|                         | Nitrofurantoin |              |            | S           |              | Unk Unk, Unk       |                 | Not Reported |
|                         | Lexapro        |              |            | S           |              | 10 Mg, Qd          |                 | Not Reported |
|                         | Lexapro        |              |            | S           |              | 20 Mg, Qd          |                 | Not Reported |
|                         | Lisinopril     |              |            | C           |              | Unk Unk, Unk       |                 | Not Reported |
|                         | Furosemide     |              |            | C           |              | Unk Unk, Unk       |                 | Not Reported |
|                         | Loratadine     |              |            | C           |              | Unk Unk, Unk       |                 | Not Reported |
|                         | Cymbalta       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 8347928       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2012013038 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Ineffective      | Pristiq Extended Release |              |            | S           |              | 50 Mg, 1x/Day      |                 | Pfizer       |
|                       | Lorazepam                |              |            | S           |              | 0.5 Mg, 2x/Day     |                 | Pfizer       |
|                       | Prozac                   |              |            | S           |              | 30 Mg, Unk         | 91 DAY          | Not Reported |
|                       | Lexapro                  |              |            | S           |              | 20 Mg, Unk         | 91 DAY          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 8382074       | EXPEDITED (15-DAY) | Y                  | HO, LT          | 1000027054           |                      | 94 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Atrial Fibrillation; Atrial Flutter; Chest Pain; Drug | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                             |                         |   |      |                                  |              |
|---------------------------------------------------------------------------------------------|-------------------------|---|------|----------------------------------|--------------|
| Interaction; Dyspnoea;<br>Electrocardiogram Qt<br>Prolonged; Hypotension;<br>Terminal State | Trazodone Hydrochloride | S | Oral | 50 Mg (50 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                                                                             | Furosemide              | C |      |                                  | Not Reported |
|                                                                                             | Memantine Hydrochloride | C |      |                                  | Not Reported |
|                                                                                             | Tramadol Hydrochloride  | C |      |                                  | Not Reported |
|                                                                                             | Paracetamol             | C |      |                                  | Not Reported |
|                                                                                             | Nitrofurantoin          | C |      |                                  | Not Reported |
|                                                                                             | Losartan Potassium      | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Jan-2012              | 8396425       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027441           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------|-----------------|--------------|
| Extrasystoles; Malaise | Escitalopram Oxalate |              |            | S           | Oral         | 0.5 Dosage Form (0.5<br>Dosage Forms, 1 In 1 D),<br>Oral |                 | Not Reported |
|                        | Prednisone           |              |            | S           |              | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D)              |                 | Not Reported |
|                        | Plaquenil            |              |            | C           |              |                                                          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8242789       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025018           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                            | <u>Product</u>                    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|-----------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain; Amylase<br>Increased; Biliary<br>Dilatation; Lipase<br>Increased | Escitalopram Oxalate              |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                  | Truvada                           |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                  | Isentress                         |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                  | Cyamemazine                       |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                                                                  | Approvel(Irbesartan) (Irbesartan) |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8329447       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026545           |                      | 90 YR      | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                                                                                                  |   |      |                                  |              |
|---------------------------------------|--------------------------------------------------------------------------------------------------|---|------|----------------------------------|--------------|
| Delirium; Drug Interaction;<br>Tremor | Memantine Hydrochloride                                                                          | S | Oral | 20 Mg (20 Mg, 1 In 1 D),<br>Oral | Not Reported |
|                                       | Escitalopram Oxalate                                                                             | S | Oral | 15 Mg (15 Mg,1 In 1<br>D),Oral   | Not Reported |
|                                       | Mepyramine Hydrochloride                                                                         | S | Oral | 30 MI (30 MI, 1 In 1<br>D),Oral  | Not Reported |
|                                       | Mepyramine Hydrochloride                                                                         | S |      |                                  | Not Reported |
|                                       | Tebetane Compuesto(Alanine,<br>Glutamic Acid, Glycine Prunus<br>Africana)(Capsules)              | C |      | 33 Df (3 Dosage Forms, 1<br>In 1 | Not Reported |
|                                       | Bonviva(Ibandronic Acid)(150<br>Milligram, Tablets)(Ibandronic<br>Acid)                          | C |      |                                  | Not Reported |
|                                       | Lekovit Ca(Calcium Carbonate,<br>Colecalciferol)(Tablets)(Calcium<br>Carbonate, Colecalciferoli) | C |      |                                  | Not Reported |
|                                       | Pariet (Rabeprazole<br>Sodium)(Tablets)(Rabeprazole<br>Sodium)                                   | C |      |                                  | Not Reported |
|                                       | Pritor<br>(Telmisartan)(Tablets)(Telmisart<br>an)                                                | C |      |                                  | Not Reported |
|                                       | Sutril Neo<br>(Torasemide)(Tablets)(Torasemi<br>de)                                              | C |      |                                  | Not Reported |
|                                       | Tardyferon (Ferrous<br>Sulfate)(Ferrous Sulfate)                                                 | C |      |                                  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8373108       | NON-EXPEDITED    | Y                  | OT              | US-PFIZER INC-<br>2012021057 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Disorientation; Serotonin<br>Syndrome | Zyvox          |              |            | S           |              | Unk                |                 | Pfizer       |
|                                       | Lexapro        |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8374498       | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-<br>20120112411 |                      | 93 YR      | Female     | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>     | <u>Product</u>                           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Seizure | Tramadol Hydrochloride And Acetaminophen |              |            | S           | Unknown      | As Needed          |                 | Not Reported |
|                           | Levothyrox                               |              |            | C           |              |                    |                 | Not Reported |
|                           | Fortimel                                 |              |            | C           |              |                    |                 | Not Reported |
|                           | Tareg                                    |              |            | C           |              |                    |                 | Not Reported |
|                           | Escitalopram Oxalate                     |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8391211       | EXPEDITED (15-DAY) | N                  | OT              | AUR-APL-2012-00505   |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Abdominal Distension;<br>Abdominal Pain; Blood Pressure Increased;<br>Dyspepsia; Joint Swelling;<br>Oedema Peripheral | Atenolol (Atenolol) |              |            | S           |              | (25 Mg), Unknown            |                 | Not Reported |
|                                                                                                                       | Simvastatin         |              |            | S           |              | (20 Mg), Unknown            |                 | Not Reported |
|                                                                                                                       | Lyrica              |              |            | S           |              | (225 Mg), Unknown           |                 | Not Reported |
|                                                                                                                       | Altace              |              |            | S           | Oral         | (5 Mg), Oral                |                 | Not Reported |
|                                                                                                                       | Lexapro             |              |            | S           |              | (20 Mg), Unknown            |                 | Not Reported |
|                                                                                                                       | Xyrem               |              |            | S           | Oral         | 4 Gm (2 Gm, 2 In 1 D), Oral |                 | Not Reported |
|                                                                                                                       | Cymbalta            |              |            | S           |              | (60 Mg), Unknown            |                 | Not Reported |
|                                                                                                                       | Dyazide             |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 31-Jan-2012              | 8399412       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027365           |                      | 56 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Asthenia; Blood Albumin Decreased; C-Reactive Protein Increased;<br>Hyponatraemia; Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                   | Remeron              |              |            | S           | Oral         | 45 Mg (45 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                   | Seroquel             |              |            | S           | Oral         | 50 Mg (50 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                                   | Lorazepam            |              |            | C           |              |                               |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                        |                                               |                    |                    |                 |                          |                                                          |                 |              |                |
|--------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------------------------------|-----------------|--------------|----------------|
| Zolpidem Tartrate                                                                                      |                                               |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 31-Jan-2012                                                                                            | 8400039                                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027504               |                                                          |                 | Male         | DEU            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Petit Mal<br>Epilepsy                                                                   | Escitalopram Oxalate                          |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                         |                 | Not Reported |                |
|                                                                                                        | Furosemide                                    |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2012                                                                                            | 7995993                                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000021144               |                                                          | 21 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Disease<br>Recurrence; Disturbance<br>In Social Behaviour;<br>Oculogyric Crisis               | Escitalopram Oxalate                          |                    |                    | S               | Oral                     | 10 Mg (10 Mg, 1 In 1 D),<br>Oral                         |                 | Not Reported |                |
|                                                                                                        | Escitalopram Oxalate                          |                    |                    | S               | Oral                     | 20 Mg (10 Mg, 2 In 1 D),<br>Oral                         |                 | Not Reported |                |
|                                                                                                        | Risperidone (Risperidone)                     |                    |                    | S               | Oral                     | Variable Doses Between<br>0.25mg And 1 Mg Daily,<br>Oral |                 | Not Reported |                |
|                                                                                                        | Risperidone (Risperidone)                     |                    |                    | S               | Oral                     | 1.5 Mg (1.5 Mg, 1 In 1 D),<br>Oral                       |                 | Not Reported |                |
|                                                                                                        | Orphenadrine (Orphanedrine)<br>(Orphenadrine) |                    |                    | C               |                          |                                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                               | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 01-Feb-2012                                                                                            | 8382506                                       | EXPEDITED (15-DAY) | N                  | OT              | US-WATSON-2012-<br>00582 |                                                          | 32 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                  | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;<br>Bedridden; Depression;<br>Disability; Disturbance In<br>Attention; Drug Level | Microgestin Fe 1.5/30                         |                    |                    | S               | Unknown                  | Unk                                                      |                 | Watson       |                |
|                                                                                                        | Lamictal                                      |                    |                    | S               | Oral                     | 300 Mg                                                   |                 | Not Reported |                |
|                                                                                                        | Lamotrigine                                   |                    |                    | S               | Oral                     | 300 Mg                                                   |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                   |                                                       |   |         |     |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|---|---------|-----|--------------|
| Decreased; Hypersomnia;<br>Loss Of Personal<br>Independence In Daily<br>Activities; Maternal<br>Exposure During<br>Pregnancy; Overdose;<br>Stress | Ziprasidone Hydrochloride                             | S | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Wellbutrin XI                                         | S | Oral    | Unk | Not Reported |
|                                                                                                                                                   | Venlafaxine                                           | S | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Lexapro                                               | S | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Atorvastatin Calcium                                  | C | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Oxcarbazepine                                         | C | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Nortriptyline Hydrochloride                           | C | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Cyanocobalamin\Folic<br>Acid\Pyridoxine Hydrochloride | C | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Ascorbic<br>Acid\Biotin\Retinol\Tocopherol            | C | Unknown | Unk | Not Reported |
|                                                                                                                                                   | Fish Oil                                              | C | Unknown | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8382680       | EXPEDITED (15-DAY) | Y                  | HO              | DE-PFIZER INC-DE-<br>WYE-G05122209 |                      | 38 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Intentional<br>Overdose; Somnolence;<br>Suicide Attempt | Tavor (Lorazepam)       |              |            | S           | Oral         | Unk                | 1 DAY           | Pfizer       |
|                                                                      | Ramipril                |              |            | S           | Oral         | 25 Mg, Unk         | 1 DAY           | Pfizer       |
|                                                                      | Abilify                 |              |            | S           | Oral         | 25 Mg, Unk         | 1 DAY           | Not Reported |
|                                                                      | Cipralex                |              |            | S           | Oral         | 50 Mg, Unk         | 1 DAY           | Not Reported |
|                                                                      | Pipamperone             |              |            | S           | Oral         | 100 Mg, Unk        | 1 DAY           | Not Reported |
|                                                                      | Levothyroxine Sodium    |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |
|                                                                      | Metformin Hydrochloride |              |            | S           | Oral         | Unk                | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8383724       | EXPEDITED (15-DAY) | Y                  | HO              | ES-ASTRAZENECA-<br>2012SE05050 |                      | 58 YR      | Male       | ESP            |

| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia | Atacand Hct    |              |            | S           | Oral         | 32+25 Mg, 1 Df Daily |                 | Astrazeneca  |
|                                    | Atenolol       |              |            | C           | Oral         |                      |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |                                                                      |              |
|----------------------|---|--------------|----------------------------------------------------------------------|--------------|
| Atorvastatin         | C | Oral         |                                                                      | Not Reported |
| Clopidogrel          | C | Oral         |                                                                      | Not Reported |
| Anagasta             | C | Oral         |                                                                      | Not Reported |
| Levemir              | C | Subcutaneous | 100u/MI , 5 Prefilled Pens,<br>3 MI Innolet , 24 lu Daily            | Not Reported |
| Insulin Aspart       | C | Subcutaneous | 100u/MI Injectable<br>Solution In A Prefilled Pen<br>5, 24 lu Daily. | Not Reported |
| Agomelatine          | C | Oral         |                                                                      | Not Reported |
| Indapamide           | C | Oral         |                                                                      | Not Reported |
| Venlafaxine          | C |              |                                                                      | Not Reported |
| Escitalopram Oxalate | S | Oral         |                                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8392019       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027243           |                      | 69 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Blood Creatine Phosphokinase Increased;<br>Chronic Obstructive Pulmonary Disease;<br>Infection | Escitalopram Oxalate                                       |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                | Surmontil (Trimipramine) (4 Percent, Drops) (Trimipramine) |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                | Axotide                                                    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                | Foradil Hfa (Formoterol Fumarate) (Formoterol Fumarate)    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                | Spiriva                                                    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                | Ventolin (Salbutamol)                                      |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                | (Salbutamol)                                               |              |            |             |              |                                  |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8399982       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000027356           |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Dyspnoea; Heart Rate  | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                                       |   |      |              |
|--------------------------------------|---------------------------------------|---|------|--------------|
| Increased; Migraine;<br>Palpitations | Fentanyl                              | C | Oral | Not Reported |
|                                      | Soma                                  | C |      | Not Reported |
|                                      | Norco (Hydrocodone,<br>Acetaminophen) | C |      | Not Reported |
|                                      | Trazodone Hydrochloride               | C |      | Not Reported |
|                                      | Gabapentin                            | C |      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8401367       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027494           |                      | 27 YR      | Female     | DNK            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Blood Prolactin Increased;<br>Galactorrhoea | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                             | Risperdal            |              |            | S           | Oral         | 1 Mg (1 Mg, 1 In 1 D), Oral      |                 | Not Reported |
|                                             | Zyprexa              |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Feb-2012              | 8402393       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027458           |                      | 93 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                             | <u>Product</u>                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------|--------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Amnesia; Chronic Kidney<br>Disease; Confusional<br>State; Hemianopia                              | Escitalopram Oxalate           |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
| Homonymous; Malaise;<br>Refusal Of Treatment By<br>Patient; Speech Disorder;<br>Unevaluable Event | Acetaminophen\Tramadol         |              |            | S           | Oral         | (If Necessary), Oral             |                 | Not Reported |
|                                                                                                   | Tareg (Valsartan) (Valsartan)  |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                   | Levothyroxine Sodium           |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                                   | Fortimel (Fortimel) (Fortimel) |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2012              | 7522497       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000015081           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Flushing;<br>Headache; Hypotension; | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                     |                                     |   |      |                               |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---|------|-------------------------------|--------------|
| Loss Of Consciousness;<br>Malaise; Pallor;<br>Palpitations;<br>Phaeochromocytoma;<br>Photopsia; Syncope;<br>Tachycardia; Vertigo;<br>Vision Blurred | Escitalopram Oxalate                | S | Oral | 20 Mg (20 Mg, 1 In 1 D), Oral | Not Reported |
|                                                                                                                                                     | Atarax                              | C |      |                               | Not Reported |
|                                                                                                                                                     | Effortil (Etilefrine Hydrochloride) | C |      |                               | Not Reported |
|                                                                                                                                                     | (Etilefrine Hydrochloride)          |   |      |                               |              |
|                                                                                                                                                     | Imigrane (Sumatriptan)              | C |      |                               | Not Reported |
|                                                                                                                                                     | (Sumatriptan)                       |   |      |                               |              |
|                                                                                                                                                     | Levonogestrel W/                    | C |      |                               | Not Reported |
|                                                                                                                                                     | Ethinylestradiol (Levonorgestrel    |   |      |                               |              |
|                                                                                                                                                     | Ethinyl Estradiol)                  |   |      |                               |              |
|                                                                                                                                                     | (Levonorgestrel, Ethinyl Estrad     |   |      |                               |              |
|                                                                                                                                                     | Tardyferon (Tardyferon)             | C |      |                               | Not Reported |
|                                                                                                                                                     | (Tardyferon)                        |   |      |                               |              |
|                                                                                                                                                     | Tanganil (Acetylleucine)            | C |      |                               | Not Reported |
|                                                                                                                                                     | (Acetylleucine)                     |   |      |                               |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2012              | 8328330       | EXPEDITED (15-DAY) | Y                  | HO              | 1000026561           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                 | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------|-----------------|--------------|
| Apathy; Asthenia;<br>Atrioventricular Block First<br>Degree; Cardiac Disorder;<br>Cardiac Ventricular<br>Disorder; Chest<br>Discomfort; Dyspnoea;<br>Electrocardiogram Normal;<br>Electrocardiogram Qt<br>Prolonged; Fatigue;<br>Headache; Nightmare;<br>Palpitations | Escitalopram Oxalate             |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                       |                                  |              |            |             | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral<br>10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 |              |
|                                                                                                                                                                                                                                                                       | Escitalopram Oxalate             |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                       | Escitalopram Oxalate             |              |            | S           | Oral         | 15 Mg (15 Mg, 1 In 1 D),<br>Oral                                |                 | Not Reported |
|                                                                                                                                                                                                                                                                       | Mirzaten (Mirtazapine) (Tablets) |              |            | C           |              |                                                                 |                 | Not Reported |
|                                                                                                                                                                                                                                                                       | (Mirtazapine)                    |              |            |             |              |                                                                 |                 |              |
|                                                                                                                                                                                                                                                                       | Helex (Alprazolam) (Tablets)     |              |            | C           |              |                                                                 |                 | Not Reported |
|                                                                                                                                                                                                                                                                       | (Alprazolam)                     |              |            |             |              |                                                                 |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2012              | 8405537       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000027466           |                      |            | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------------------------------|-----------------|--------------|
| Anxiety Disorder;<br>Condition Aggravated;<br>Depressed Mood; Drug<br>Interaction; Feeling<br>Abnormal; Gastrointestinal<br>Infection; Serotonin<br>Syndrome; Stress At Work | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D)<br>Tapered Down From 20<br>Mg To 5 Mg In Steps Of<br>2.5 Mg |                 | Not Reported |
|                                                                                                                                                                              | Escitalopram Oxalate |              |            | S           |              | 15 Mg (15 Mg, 1 In 1 D)                                                             |                 | Not Reported |
|                                                                                                                                                                              | Escitalopram Oxalate |              |            | S           |              | 20 Mg (20 Mg, 1 In 1 D) 15<br>Mg (15 Mg, 1 In 1 D)                                  |                 | Not Reported |
|                                                                                                                                                                              | Nystatin             |              |            | S           |              |                                                                                     | 2 WEEK          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2012              | 8405642       | EXPEDITED (15-DAY) | Y                  | HO, OT          | UCM201201-000003     |                      | 60 YR      | Male       | IRL            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                   | <u>Product</u>                                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------------------------------|
| Aggression; Agitation;<br>Amnesia; Blood Pressure<br>Increased; C-Reactive<br>Protein Increased;<br>Homicidal Ideation;<br>Irritability; Leukocytosis;<br>Major Depression;<br>Neutrophil Count<br>Decreased; Physical<br>Assault; Rash; Rash<br>Erythematous;<br>Somnolence; Speech<br>Disorder; Stress At Work;<br>Suicidal Ideation; Thermal<br>Burn | Meloxicam<br>Escitalopram Oxalate<br>Zolpidem |              |            | S<br>S<br>S |              |                    |                 | Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Feb-2012              | 8405964       | EXPEDITED (15-DAY) | Y                  | DE              | 2012MA001183         |                      | 64 YR      | Female     | ITA            |

| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Completed Suicide;<br>Incorrect Dose | Mirtazapine    |              |            | S           |              | 30 Mg              |                 | Purepac    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                          |                      |   |        |                |
|------------------------------------------|----------------------|---|--------|----------------|
| Administered; Toxicity To Various Agents | Mirtazapine          | S | 30 Mg  | Actavis Totowa |
|                                          | Escitalopram Oxalate | S | 10 Mg  | Not Reported   |
|                                          | Depakin Chrono       | S | 300 Mg | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2012              | 7055163       | EXPEDITED (15-DAY) | Y                  | HO              | 1000007206           |                      | 58 YR      | Female     | DNK            |

| <u>Preferred Term</u>                 | <u>Product</u>                                                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|-----------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Gastric Ulcer<br>Haemorrhage | Escitalopram Oxalate                                                  |              |            | S           | Oral         | Oral               |                 | Not Reported |
|                                       | Voltaren                                                              |              |            | S           | Oral         | (50 Mg), Oral      |                 | Not Reported |
|                                       | Dafalgan (Paracetamol)<br>(Tablets) (Paracetamol)                     |              |            | C           |              |                    |                 | Not Reported |
|                                       | Blopress (Candesartan Cilexetil)<br>(Tablets) (Candesartan Cilexetil) |              |            | C           |              |                    |                 | Not Reported |
|                                       | Inderal (Propranolol) (Tablets)<br>(Propranolol)                      |              |            | C           |              |                    |                 | Not Reported |
|                                       | Imigran (Sumatriptan) (Tablets)<br>(Sumatriptan)                      |              |            | C           |              |                    |                 | Not Reported |
|                                       | Xanax (Alprazolam) (Tablets)<br>(Alprazolam)                          |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-Feb-2012              | 8286741       | EXPEDITED (15-DAY) | Y                  | HO              | 1000025868           |                      | 59 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                              | <u>Product</u>                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------|-----------------|--------------|
| Anaemia; Asthenia;<br>Gastric Ulcer;<br>Oesophageal<br>Haemorrhage | Escitalopram Oxalate                                                            |              |            | S           | Oral         | Oral                              |                 | Not Reported |
|                                                                    | Voltaren                                                                        |              |            | S           | Oral         | 150 Mg (50 Mg, 3 In 1 D),<br>Oral |                 | Not Reported |
|                                                                    | Xanax (Alprazolam) (Tablets)<br>(Alprazolam)                                    |              |            | C           |              |                                   |                 | Not Reported |
|                                                                    | Inderal (Propranolol<br>Hydrochloride) (Tablets)<br>(Propranolol Hydrochloride) |              |            | C           |              |                                   |                 | Not Reported |
|                                                                    | Imigran (Sumatriptan) (Tablets)<br>(Sumatriptan)                                |              |            | C           |              |                                   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                          |                         |                    |                    |                 |                                      |                                 |                 |                 |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------------|---------------------------------|-----------------|-----------------|----------------|
| Dafalgan (Paracetamol)<br>(Tablets) (Paracetamol)                                                                                                        |                         | C                  |                    |                 |                                      |                                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Feb-2012                                                                                                                                              | 8314830                 | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000026217                           |                                 | 56 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Condition Aggravated;<br>Neoplasm Malignant                                                                                                              | Lexapro                 |                    |                    | S               | Oral                                 | 20 Mg (20 Mg,1 In 1 D),Oral     |                 | Not Reported    |                |
|                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                                 | 20 Mg (20 Mg,1 In 1 D),Oral     |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Feb-2012                                                                                                                                              | 8388007                 | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0903725A |                                 | 65 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Blood Pressure Increased;<br>Diarrhoea; Dizziness;<br>Drug Interaction; Flushing;<br>Headache; Malaise;<br>Nausea                                        | Lamictal                |                    |                    | S               | Oral                                 |                                 |                 | Glaxosmithkline |                |
|                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                                 | 5mg Per Day                     |                 | Not Reported    |                |
|                                                                                                                                                          | Imodium                 |                    |                    | S               | Oral                                 |                                 |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                 | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Feb-2012                                                                                                                                              | 8394899                 | DIRECT             | N                  | DS, HO          |                                      |                                 |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                    | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>      |                |
| Akathisia; Disturbance In<br>Attention; Dyskinesia;<br>Inappropriate Affect;<br>Logorrhoea; Memory<br>Impairment; Mental Status<br>Changes; Panic Attack | Citalopram Hydrobromide |                    |                    | S               | Oral                                 | Citalopram 20 Mg Daily By Mouth |                 | Not Reported    |                |
|                                                                                                                                                          | Lexapro                 |                    |                    | S               | Oral                                 | Lexapro 10 Mg Daily By Mouth    |                 | Forest          |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------------|-----------------|--------------|----------------|
| 03-Feb-2012                               | 8395431                           | DIRECT             | Y                  |                 |                      |                                          | 19 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Trismus                                   | Lexapro                           |                    |                    | S               | Oral                 | Lexapro 5mg 1 Up To 2qd Po Starting Dose |                 | Forest       |                |
|                                           | Lexapro                           |                    |                    | S               | Oral                 | Lexapro 20mg 1qd Po                      |                 | Forest       |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2012                               | 8403973                           | EXPEDITED (15-DAY) | Y                  | OT              | 2012AP000194         |                                          | 78 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Fibrosis; Hepatitis; Liver Injury | Loratadine                        |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                           | Lisinopril                        |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                           | Diclofenac                        |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                           | Nitrofurantoin                    |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                           | Furosemide                        |                    |                    | S               |                      |                                          |                 | Not Reported |                |
|                                           | Escitalopram Oxalate              |                    |                    | S               |                      | 10 Mg;Qd, 20 Mg;Qd                       |                 | Not Reported |                |
|                                           | Cymbalta                          |                    |                    | S               |                      |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2012                               | 8406467                           | EXPEDITED (15-DAY) | Y                  | OT              | 1000027417           |                                          | 69 YR           | Female       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Eye Haemorrhage                           | Lexapro                           |                    |                    | S               | Oral                 | 15 Mg (15 Mg,1 In 1 D),Oral              |                 | Not Reported |                |
|                                           | Dilantin                          |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                           | Neurontin                         |                    |                    | C               |                      |                                          |                 | Not Reported |                |
|                                           | Avalide (Karvea Hct) (Karvea Hct) |                    |                    | C               |                      |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Feb-2012                               | 8406480                           | EXPEDITED (15-DAY) | N                  | CA              | 1000027562           |                                          | < 1 DAY         | Male         | USA            |

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| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|----------------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------------------------------------------|--------------------------|---------------------|-------------------------|
| Congenital Aortic Stenosis; Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                                            |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Feb-2012                                                                                  | 8406555                 | EXPEDITED (15-DAY)        | Y                           |                          | 1000027384                    |                                                           |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anorgasmia                                                                                   | Lexapro                 |                           |                             | S                        |                               |                                                           |                          | Not Reported        |                         |
|                                                                                              | Adderall                |                           |                             | S                        |                               |                                                           |                          | Not Reported        |                         |
|                                                                                              | Dexilant                |                           |                             | S                        |                               |                                                           |                          | Not Reported        |                         |
|                                                                                              | Zetia (Ezetimibe)       |                           |                             | S                        |                               |                                                           |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Feb-2012                                                                                  | 8200520                 | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000024586                    |                                                           |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Caesarean Section; Maternal Drugs Affecting Foetus; Supraventricular Extrasystoles           | Lexapro                 |                           |                             | S                        |                               | 20 Mg (20 Mg, 1 In 1),                                    |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a>                             | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Feb-2012                                                                                  | 8410448                 | EXPEDITED (15-DAY)        | N                           | RI, OT                   | 1000027376                    |                                                           | 13 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>                               | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Off Label Use; Suicidal Ideation; Treatment Noncompliance                                    | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 15 Mg (15 Mg,1 In 1 D),Oral                               |                          | Not Reported        |                         |
|                                                                                              | Escitalopram Oxalate    |                           |                             | S                        | Oral                          | 20 Mg (20 Mg,1 In 1 D),Oral : 15 Mg (15 Mg,1 In 1 D),Oral |                          | Not Reported        |                         |
|                                                                                              |                         |                           |                             |                          | Oral                          | 20 Mg (20 Mg,1 In 1 D),Oral : 15 Mg (15 Mg,1              |                          |                     |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

In 1 D),Oral

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 07-Feb-2012                          | 8393837        | DIRECT           | N                  | DS              |                      |                      | 43 YR           | Male       | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Akathisia; Quality Of Life Decreased | Prozac         |                  |                    | S               | Oral                 | 1-2 Per Day          |                 |            | Not Reported   |
|                                      | Lexapro        |                  |                    | S               | Oral                 |                      |                 |            | Not Reported   |

| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------|----------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|------------|----------------|
| 07-Feb-2012                | 8412485                                | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027592           |                               | 57 YR           | Female     | DNK            |
| <u>Preferred Term</u>      | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u> |                |
| Confusional State; Syncope | Lexapro                                |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 |            | Not Reported   |
|                            | Lexapro                                |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                            | Thyrox (Levothyroxine Sodium)          |                    |                    | C               |                      |                               |                 |            | Not Reported   |
|                            | Anastrozol (Anastrozole) (Anastrozole) |                    |                    | C               |                      |                               |                 |            | Not Reported   |

| <u>FDA Received Date</u>                                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|------------|----------------|
| 08-Feb-2012                                                                            | 7508598              | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000015043           |                             | 88 YR           | Female     | DNK            |
| <u>Preferred Term</u>                                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Blood Sodium Decreased; Drug Interaction; Serotonin Syndrome | Escitalopram Oxalate |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral |                 |            | Not Reported   |
|                                                                                        | Miconazole           |                    |                    | S               |                      | 50 Mg (50 Mg, 1 In 1 D),    |                 |            | Not Reported   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Feb-2012              | 8356822       | EXPEDITED (15-DAY) | Y                  | HO              | JP-ABBOTT-12P-087-0897995-00 |                      | 77 YR      | Female     | JPN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------------------|-----------------|--------------|----------------|
| Confusional State;<br>Hallucination, Visual;<br>Hyponatraemia; Urinary<br>Retention | Biperiden               |                    |                    | S               | Oral                                                | (3 Milligrams)                   |                 | Not Reported |                |
|                                                                                     | Lexapro                 |                    |                    | S               |                                                     | (10 Milligrams)                  |                 | Not Reported |                |
|                                                                                     | Antihypertensives       |                    |                    | C               |                                                     |                                  |                 | Not Reported |                |
|                                                                                     | Hypnotics And Sedatives |                    |                    | C               |                                                     |                                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2012                                                                         | 8394038                 | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027379                                          |                                  | 30 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Seizure                                                                             | Escitalopram Oxalate    |                    |                    | S               | Oral                                                | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2012                                                                         | 8395356                 | DIRECT             | N                  | LT              |                                                     |                                  | 57 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Panic Reaction;<br>Serotonin Syndrome                                    | Lexapro                 |                    |                    | S               | Oral                                                | 10 Mg                            | 4 DAY           | Forest       |                |
| <u>FDA Received Date</u>                                                            | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Feb-2012                                                                         | 8395582                 | EXPEDITED (15-DAY) | Y                  | OT              | IN-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-00595RO |                                  | 45 YR           | Male         | IND            |
| <u>Preferred Term</u>                                                               | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Delirium; Drug Ineffective;<br>Drug Withdrawal<br>Syndrome; Medication<br>Error     | Zolpidem                |                    |                    | S               |                                                     | 10 Mg                            |                 | Roxane       |                |
|                                                                                     | Zolpidem                |                    |                    | S               |                                                     | 15 Mg                            |                 | Roxane       |                |
|                                                                                     | Zolpidem                |                    |                    | S               |                                                     | 20 Mg                            |                 | Roxane       |                |
|                                                                                     | Zolpidem                |                    |                    | S               |                                                     | 20 Mg                            |                 | Roxane       |                |
|                                                                                     | Zolpidem                |                    |                    | S               |                                                     | 45 Mg                            |                 | Roxane       |                |
|                                                                                     | Zolpidem                |                    |                    | S               |                                                     | 7.5 Mg                           |                 | Roxane       |                |
|                                                                                     | Lorazepam               |                    |                    | S               |                                                     | 8 Mg                             |                 | Roxane       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |        |              |
|--|----------------------|---|--------|--------------|
|  | Escitalopram Oxalate | S | 20 Mg  | Not Reported |
|  | Propranolol          | S | 40 Mg  | Not Reported |
|  | Propranolol          | S | 80 Mg  | Not Reported |
|  | Propranolol          | S | 120 Mg | Not Reported |
|  | Mirtazapine          | S | 7.5 Mg | Not Reported |

| <u>FDA Received Date</u>                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 08-Feb-2012                                                               | 8396219              | EXPEDITED (15-DAY) | Y                  | OT              | ZA-PFIZER INC-2012028757 |                      | 50 YR           | Female       | ZAF            |
| <u>Preferred Term</u>                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia;<br>Depersonalisation/Derealisation Disorder; Drug Interaction | Lyrica               |                    |                    | S               | Oral                     | 75 Mg, 2x/Day        |                 | Pfizer       |                |
|                                                                           | Escitalopram Oxalate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 08-Feb-2012              | 8396517        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012030008 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Ineffective         | Zoloft         |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Effexor Xr     |                  |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                          | Prozac         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Celexa         |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Lexapro        |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Wellbutrin     |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                          | Cymbalta       |                  |                    | S               |                          | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-Feb-2012              | 8402410        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027508           |                      | 88 YR           | Female     | DNK            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                    |                      |   |                         |              |
|--------------------------------------------------------------------|----------------------|---|-------------------------|--------------|
| Blood Sodium Decreased;<br>Drug Interaction;<br>Serotonin Syndrome | Escitalopram Oxalate | S | 5 Mg (5 Mg, 1 In 1 D)   | Not Reported |
|                                                                    | Miconazole           | S | 50 Mg (50 Mg, 1 In 1 D) | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2012              | 8418953       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027666           |                      | 88 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------------------------------------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Atrial Flutter        | Escitalopram Oxalate                                           |              |            | S           | Oral         | 1 Dosage Form (1 Dosage Forms, 1 In 1 D), Oral |                 | Not Reported |
|                       | Micardis (Telmisartan) (40)                                    |              |            | C           |              |                                                |                 | Not Reported |
|                       | Levothyrox (Levothyroxine Sodium) (25) (Levothyroxine Sodium)  |              |            | C           |              |                                                |                 | Not Reported |
|                       | Inexium (Esomeprazole Magnesium) (20) (Esomeprazole Magnesium) |              |            | C           |              |                                                |                 | Not Reported |
|                       | Voltarene (Diclofenac Sodium)                                  |              |            | C           |              |                                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Feb-2012              | 8419225       | EXPEDITED (15-DAY) | Y                  | OT              | ZOLP20120002         |                      | 45 YR      | Male       | IND            |

| <u>Preferred Term</u>                                                                                                                                                                              | <u>Product</u>                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|------------|-------------|--------------|---------------------------------|-----------------|--------------|
| Abnormal Behaviour;<br>Agitation; Blood Pressure Fluctuation; Delirium;<br>Disorientation;<br>Incontinence; Initial<br>Insomnia; Overdose;<br>Refusal Of Treatment By Patient; Withdrawal Syndrome | Zolpidem Tartrate                      |              |            | S           |              | 10-25 Mg Daily From Days 13-35, |                 | Not Reported |
|                                                                                                                                                                                                    | Escitalopram Oxalate                   |              |            | S           |              |                                 |                 | Not Reported |
|                                                                                                                                                                                                    | Lorazepam                              |              |            | C           |              |                                 |                 | Not Reported |
|                                                                                                                                                                                                    | Mirtazapine                            |              |            | C           |              |                                 |                 | Not Reported |
|                                                                                                                                                                                                    | Propranolol (Propanolol) (Propranolol) |              |            | C           |              |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2012              | 8397790       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-NAPPMUNDI-DEU-2012-0008587 |                      |            | Male       | DEU            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                     | <u>Product</u>                        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------|---------------------------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Drug Withdrawal Syndrome Neonatal; Neonatal Respiratory Distress Syndrome | Oxycodone Hydrochloride               |              |            | S           | Transplacental | 70 Mg, Daily       | 270 DAY         | Purdue       |
|                                                                           | Oxycodone Hydrochloride               |              |            | S           | Transplacental | 10 Mg, See Text    |                 | Purdue       |
|                                                                           | Morphine Sulfate                      |              |            | S           | Transplacental | Unk, See Text      | 40 DAY          | Purdue       |
|                                                                           | Sertraline Hydrochloride              |              |            | S           | Transplacental | 50 Mg, Daily       | 228 DAY         | Not Reported |
|                                                                           | Amitriptyline Hydrochloride           |              |            | S           | Transplacental | 150 Mg, Daily      | 40 DAY          | Not Reported |
|                                                                           | Cymbalta                              |              |            | S           | Transplacental | 30 Mg, Bid         | 40 DAY          | Not Reported |
|                                                                           | Cipralex                              |              |            | S           | Transplacental | 30 Mg, Daily       | 40 DAY          | Not Reported |
|                                                                           | Chlorprothixene                       |              |            | S           | Transplacental | 50 Mg, Daily       | 40 DAY          | Not Reported |
|                                                                           | Dimenhydrinate                        |              |            | S           | Transplacental | 50 Mg, Tid         | 68 DAY          | Not Reported |
|                                                                           | Ferrous Succinate\Magnesium Hydroxide |              |            | S           | Transplacental | 0.4 Mg, Daily      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Feb-2012              | 7234096       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-K200901600 |                      | 38 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                          | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hypotension; Intentional Overdose; Somnolence; Suicide Attempt | Altace                    |              |            | S           | Oral         | 25 Mg, Single      | 1 DAY           | Pfizer       |
|                                                                | Levoxyl                   |              |            | S           | Oral         | 5 Df, Single       | 1 DAY           | Pfizer       |
|                                                                | Metformin                 |              |            | S           | Oral         | 5 Df, Single       | 1 DAY           | Not Reported |
|                                                                | Abilify                   |              |            | S           | Oral         | 25 Mg, Single      | 1 DAY           | Not Reported |
|                                                                | Escitalopram Oxalate      |              |            | S           | Oral         | 50 Mg, Single      | 1 DAY           | Not Reported |
|                                                                | Pipamperone Hydrochloride |              |            | S           | Oral         | 100 Mg, Single     | 1 DAY           | Not Reported |
|                                                                | Tavor (Lorazepam)         |              |            | S           | Oral         | 30 Mg, Single      | 1 DAY           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Feb-2012              | 8235527       | EXPEDITED (15-DAY) | Y                  | HO, OT          | PHFR2011GB06215      |                      | 50 YR      | Male       | GBR            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Adrenal Disorder;     | Ritalin        |              |            | S           | Oral         | Unk Unk, Unk       |                 | Novartis   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                  |                |                    |                    |                 |                                      |                                             |                 |                 |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------------|---------------------------------------------|-----------------|-----------------|----------------|
| Adrenomegaly                                                                                                                                                                                                     | Ciprallex      |                    | S                  | Oral            | 20 Mg, Per Day                       |                                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2012                                                                                                                                                                                                      | 8399749        | NON-EXPEDITED      | N                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0945641A |                                             |                 | Male            | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| Abdominal Pain Upper;<br>Attention Deficit/Hyperactivity<br>Disorder; Hyperhidrosis;<br>Libido Decreased; Loss Of<br>Libido; Middle Insomnia;<br>Night Sweats; Post-<br>Traumatic Stress Disorder;<br>Somnolence | Paxil          |                    |                    | S               | Unknown                              | 40mg Per Day                                |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Unknown                              |                                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2012                                                                                                                                                                                                      | 8399843        | NON-EXPEDITED      | Y                  |                 | US-<br>GLAXOSMITHKLINE-<br>A0957158A |                                             |                 | Female          | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Cortisol<br>Increased; Gastritis<br>Erosive; Insomnia;<br>Palpitations; Tremor;<br>Withdrawal Syndrome                                                                                                  | Paxil Cr       |                    |                    | S               | Oral                                 | 12.5mg Per Day                              |                 | Glaxosmithkline |                |
|                                                                                                                                                                                                                  | Lexapro        |                    |                    | S               | Oral                                 |                                             |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                                                                                                                                                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 10-Feb-2012                                                                                                                                                                                                      | 8422602        | EXPEDITED (15-DAY) | Y                  | DS              | 1000028049                           |                                             | 21 YR           | Female          | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u>      |                |
| Atonic Urinary Bladder;<br>Overdose; Urinary<br>Retention                                                                                                                                                        | Lexapro        |                    |                    | S               | Oral                                 | Overdose: 10 - 30 Mg A<br>Day (10 Mg), Oral |                 | Not Reported    |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-------------------------------------------------------------------------------------------|----------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 10-Feb-2012                                                                               | 8422684                                | EXPEDITED (15-DAY)        | Y                           | CA                       | 1000027920                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypoplastic Left Heart Syndrome; Maternal Drugs Affecting Foetus                          | Lexapro                                |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Feb-2012                                                                               | 8422708                                | EXPEDITED (15-DAY)        | N                           | CA                       | 1000027890                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fallot'S Tetralogy; Maternal Drugs Affecting Foetus                                       | Lexapro                                |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Feb-2012                                                                               | 8423089                                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000028052                    |                               | 84 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Confusional State; Delirium; Depression; Sudden Onset Of Sleep; Weight Decreased | Escitalopram Oxalate                   |                           |                             | S                        | Oral                          | See Image                     |                          | Not Reported        |                         |
|                                                                                           | Escitalopram Oxalate                   |                           |                             | S                        | Oral                          | 40 Mg (40 Mg,1 In 1 D),Oral   |                          | Not Reported        |                         |
|                                                                                           | Escitalopram Oxalate                   |                           |                             | S                        | Oral                          | 10 Mg (10 Mg,1 In 1 D),Oral   |                          | Not Reported        |                         |
|                                                                                           | Bipreterax (Perindopril) (Perindopril) |                           |                             | C                        |                               |                               |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                         | <a href="#">Case #</a>                 | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Feb-2012                                                                               | 8323254                                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000026337                    |                               | 72 YR                    | Female              | DNK                     |
| <a href="#">Preferred Term</a>                                                            | <a href="#">Product</a>                | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                       |                                                                               |   |      |                                 |              |
|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|---|------|---------------------------------|--------------|
| Arthralgia; Gastrointestinal<br>Haemorrhage; Muscle<br>Contracture; Oedema<br>Peripheral; Torticollis | Escitalopram Oxalate                                                          | S | Oral | 10 Mg (10 Mg, 1 In 1<br>D),Oral | Not Reported |
|                                                                                                       | Topalgic [Tramadol<br>Hydrochloride]                                          | C |      |                                 | Not Reported |
|                                                                                                       | Lexomil (Bromazepam) (Tablets)<br>(Bromazepam)                                | C |      |                                 | Not Reported |
|                                                                                                       | Piascledine (Piascledine<br>/01305801/) (Tablets)<br>(Piascledine /01305801/) | C |      |                                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2012              | 8402522              | EXPEDITED (15-DAY) | Y                  | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T20120009 |                      | 77 YR           | Male         | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide        | Restoril             |                    |                    | S               | Oral                                                      |                      |                 | Tyco         |                |
|                          | Hydroxyzine          |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |
|                          | Escitalopram Oxalate |                    |                    | S               | Oral                                                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------|-----------------|--------------|----------------|
| 13-Feb-2012                                                                                           | 8403309                       | EXPEDITED (15-DAY) | Y                  | HO              | PHHY2012FR010607     |                                      | 77 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bundle Branch Block;<br>Chest Pain; Oxygen<br>Saturation Decreased;<br>Pulmonary Embolism;<br>Vertigo | Hydrochlorothiazide/Valsartan |                    |                    | S               | Oral                 | 1 Df, Daily                          |                 | Novartis     |                |
|                                                                                                       | Ebixa                         |                    |                    | S               | Oral                 | 20 Mg, Unk                           |                 | Not Reported |                |
|                                                                                                       | Galantamine Hydrobromide      |                    |                    | S               | Oral                 | 16 Mg, Unk                           |                 | Not Reported |                |
|                                                                                                       | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 5 Mg, Unk                            |                 | Not Reported |                |
|                                                                                                       | Atarax                        |                    |                    | S               | Oral                 | 25 Mg, Unk                           |                 | Not Reported |                |
|                                                                                                       | Caduet                        |                    |                    | S               | Oral                 | 1 Df, (5 Mg Amlod/ 10 Mg<br>Atorvas) |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Feb-2012              | 8422365       | EXPEDITED (15-DAY) | N                  | CA              | 1000028169           |                      | < 1 DAY    | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Atrial Septal Defect;<br>Coarctation Of The Aorta;<br>Maternal Drugs Affecting<br>Foetus; Ventricular Septal<br>Defect                                                                      | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2012                                                                                                                                                                                 | 8422417        | EXPEDITED (15-DAY) | N                  | CA              | 1000028153           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari<br>Malformation; Cerebral<br>Ventricle Dilatation;<br>Congenital<br>Hydrocephalus; Maternal<br>Drugs Affecting Foetus;<br>Microcephaly; Spina Bifida                          | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2012                                                                                                                                                                                 | 8422429        | EXPEDITED (15-DAY) | N                  | CA              | 1000028145           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Congenital Tricuspid Valve<br>Atresia; Foetal Exposure<br>During Pregnancy;<br>Pulmonary Artery Stenosis<br>Congenital; Transposition<br>Of The Great Vessels;<br>Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Feb-2012                                                                                                                                                                                 | 8422438        | EXPEDITED (15-DAY) | N                  | CA              | 1000028143           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                           |         |   |                |                |              |
|-------------------------------------------------------------------------------------------|---------|---|----------------|----------------|--------------|
| Double Outlet Right Ventricle; Maternal Drugs Affecting Foetus; Ventricular Septal Defect | Lexapro | S | Transplacental | Transplacental | Not Reported |
|-------------------------------------------------------------------------------------------|---------|---|----------------|----------------|--------------|

| <u>FDA Received Date</u>                                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2012                                                                | 8422449        | EXPEDITED (15-DAY) | N                  | CA              | 1000028138           |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari Malformation; Foetal Exposure During Pregnancy; Spina Bifida | Lexapro        |                    |                    | S               | Transplacental       | Transplacental       |                 | Not Reported |                |

| <u>FDA Received Date</u>                                   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2012                                                | 8422458        | EXPEDITED (15-DAY) | N                  | CA              | 1000028126           |                      | < 1 DAY         | Female       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting Foetus; Ventricular Septal Defect | Lexapro        |                    |                    | S               | Transplacental       | Translacental        |                 | Not Reported |                |

| <u>FDA Received Date</u>                         | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Feb-2012                                      | 8424625                 | EXPEDITED (15-DAY) | Y                  | OT              | 2012MA001568         |                      | 92 YR           | Male         | DNK            |
| <u>Preferred Term</u>                            | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Disease Recurrence; Drug Ineffective | Citalopram Hydrobromide |                    |                    | S               |                      | 20 Mg                |                 | Purepac      |                |
|                                                  | Escitalopram Oxalate    |                    |                    | S               |                      | 10 Mg                |                 | Not Reported |                |
|                                                  | Ciprallex               |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Feb-2012              | 8451364        | NON-EXPEDITED    | N                  |                 | 1000026361           |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                               |         |   |      |                                      |              |
|-----------------------------------------------------------------------------------------------|---------|---|------|--------------------------------------|--------------|
| Abnormal Dreams; Crying;<br>Drug Ineffective; Energy<br>Increased; Insomnia; Off<br>Label Use | Savella | S | Oral | 12.5 Mg (12.5 Mg, 1 In 1<br>D), Oral | Not Reported |
|                                                                                               | Lexapro | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral     | Not Reported |
|                                                                                               | Lexapro | S | Oral | 5 Mg (5 Mg, 1 In 1 D), Oral          | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8273373       | EXPEDITED (15-DAY) | Y                  | DS              | FR-UCBSA-046521      |                      | 72 YR      | Female     | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Keratitis             | Neupro               |              |            | S           | Transdermal  | Daily Dose:1 Patch. |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           | Oral         | Daily Dose:1 Unit   |                 | Not Reported |
|                       | Dexamethasone        |              |            | S           | Intraocular  | Collyrium           |                 | Not Reported |
|                       | Tamoxifen Citrate    |              |            | C           |              |                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8404649       | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-JNJFOC-<br>20120205246 |                      | 80 YR      | Male       | FRA            |

| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Pulmonary Embolism;<br>Thrombocytopenia | Risperdal            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Risperdal            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Risperdal            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Ebixa                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Aricept              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Aspirin              |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Nicorandil           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Perindopril          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Xanax                |              |            | S           | Oral         |                    |                 | Not Reported |
|                                         | Lovenox              |              |            | C           | Unknown      |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8405197       | EXPEDITED (15-DAY) |                    | HO, OT          | DE-PFIZER INC-2012021189 |                      |            | Male       | DEU            |

| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                                             | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|----------------|----------------------------------------------------------------|-----------------|--------------|
| Agitation; Body Temperature Increased; Drug Withdrawal Syndrome Neonatal; Hyperhidrosis; Maternal Exposure Timing Unspecified; Neonatal Respiratory Distress Syndrome; Tachycardia; Tremor | Sertraline Hcl                       |              |            | S           | Transplacental | 50 Mg, 1x/Day, From Gw 6 To 38.3                               |                 | Pfizer       |
|                                                                                                                                                                                            | Oxycodone Hydrochloride              |              |            | S           | Transplacental | 70 Mg/D (30-10-30)                                             |                 | Pfizer       |
|                                                                                                                                                                                            | Oxycodone Hydrochloride              |              |            | S           | Transplacental | 10 Mg/D                                                        |                 | Pfizer       |
|                                                                                                                                                                                            | Sevredol                             |              |            | S           | Transplacental | 40 Mg/D 3 To 4 Times Per Week, 2x 20mg/D Max, From Gw 0 To 5.4 |                 | Pfizer       |
|                                                                                                                                                                                            | Saroten                              |              |            | S           | Transplacental | 150 Mg/D From Gw 0 To 5.4                                      |                 | Not Reported |
|                                                                                                                                                                                            | Cymbalta                             |              |            | S           | Transplacental | 30 Mg, 2x/Day From Gw 0 To 5.4                                 |                 | Not Reported |
|                                                                                                                                                                                            | Cipralext                            |              |            | S           | Transplacental | 30 Mg, 1x/Day                                                  |                 | Not Reported |
|                                                                                                                                                                                            | Truxal                               |              |            | S           | Transplacental | 50 Mg, 1x/Day From Gw 0 To 5.4                                 |                 | Not Reported |
|                                                                                                                                                                                            | Vomex A                              |              |            | S           | Transplacental | 50 Mg, 3x/Day, From Gw 6 To 15.4                               |                 | Not Reported |
|                                                                                                                                                                                            | Femibion [Minerals Nos;Vitamins Nos] |              |            | S           | Transplacental | 0.4 Mg, 1x/Day From Gw 5.4 To 12                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8427029       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028167           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                       | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Chills; Dry Mouth; Feeling Abnormal; Nausea; Vision Blurred | Escitalopram Oxalate             |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                             | Inexium (Esomeprazole Magnesium) |              |            | C           |              |                               |                 | Not Reported |
|                                                             | Crestor                          |              |            | C           |              |                               |                 | Not Reported |
|                                                             | Stilnox (Zolpidem Tartrate)      |              |            | C           |              |                               |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                   |  |  |  |   |  |  |  |  |              |
|-----------------------------------|--|--|--|---|--|--|--|--|--------------|
| (Zolpidem Tartrate)               |  |  |  |   |  |  |  |  |              |
| Lexomil (Bromazepam)              |  |  |  | C |  |  |  |  | Not Reported |
| (Bromazepam)                      |  |  |  |   |  |  |  |  |              |
| Oestrogel (Estradiol) (Estradiol) |  |  |  | C |  |  |  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8431624       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028150           |                      | 50 YR      | Male       | DNK            |

| <u>Preferred Term</u>           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Thrombosis;<br>Malaise | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Feb-2012              | 8431639       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028151           |                      | 79 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                | <u>Product</u>                                                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|-----------------------------------------------|-----------------|--------------|
| Abdominal Distension;<br>Abnormal Behaviour;<br>Aggression;<br>Gastrointestinal Pain | Escitalopram Oxalate                                                                |              |            | S           | Oral         | 1 Dosage Form (1 Dosage Forms,1 In 1 D), Oral |                 | Not Reported |
|                                                                                      | Oxazepam                                                                            |              |            | S           | Oral         | 50 Mg (50 Mg, 1 In 1 D), Oral                 |                 | Not Reported |
|                                                                                      | Xanax                                                                               |              |            | S           |              |                                               |                 | Not Reported |
|                                                                                      | Tiaprider                                                                           |              |            | S           |              |                                               |                 | Not Reported |
|                                                                                      | Efferalgan (Paracetamol) (Paracetamol)                                              |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Inexium (Esomeprazole Magnesium)                                                    |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Fosavance (Alendronate Sodium, Colecalciferol) (Alendronate Sodium, Colecalciferol) |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Aranesp (Darbepoetin Alfa) (Darbepoetin Alfa)                                       |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Kardegic (Acetylsalicylate Lysine) (Acetylsalicylate Lysine)                        |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Lantus (Insulin Glargine) (Insulin Glargine)                                        |              |            | C           |              |                                               |                 | Not Reported |
|                                                                                      | Apidra (Insulin Glulisine) (Insulin Glulisine)                                      |              |            | C           |              |                                               |                 | Not Reported |

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| Lactulose (Lactulose)(Lactulose)                                                                    |                                                                     |                    | C                  |                    | Not Reported         |                                                                                          |                      |              |                |                |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|--------------------|--------------------|----------------------|------------------------------------------------------------------------------------------|----------------------|--------------|----------------|----------------|
| Eductyl                                                                                             |                                                                     |                    | C                  |                    | Not Reported         |                                                                                          |                      |              |                |                |
| <u>FDA Received Date</u>                                                                            | <u>Case #</u>                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>    | <u>Mfr Control #</u> | <u>503B Facility</u>                                                                     | <u>Age</u>           | <u>Sex</u>   | <u>Country</u> |                |
| 14-Feb-2012                                                                                         | 8431655                                                             | EXPEDITED (15-DAY) | Y                  | LT, RI, OT         | 1000028093           |                                                                                          | < 1 DAY              | Female       | DNK            |                |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>                                                                       | <u>Duration</u>      | <u>Mfr</u>   |                |                |
| Caesarean Section;<br>Maternal Drugs Affecting<br>Foetus; Neonatal<br>Asphyxia; Neonatal<br>Seizure | Lexapro                                                             |                    |                    | S                  |                      | 10 Mg (10 Mg, 1 In 1<br>D),Transplacental ; 20 Mg<br>(20 Mg, 1 In 1<br>D),Transplacental |                      | Not Reported |                |                |
|                                                                                                     | Zoloft (Sertraline Hydrochloride)<br>(Setraline Hydrochloride)      |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Reflex (Mirtazapine)<br>(Mirtazapine)                               |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Halrack (Triazolam) (Triazolam)                                     |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Silece (Flunitrazepam)<br>(Flunitrazepam)                           |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Levotomin (Levomepromazine<br>Maleate) (Levomepromazine<br>Maleate) |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Solanax (Alprazolam)<br>(Alprazolam)                                |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Lexotan (Bromazepam)<br>(Bromazepam)                                |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Risperidone                                                         |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Lekrica (Chlorphenamine<br>Maleate) (Chlorphenamine<br>Maleate)     |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | Goodmin (Brotizolam)<br>(Brotizolam)                                |                    |                    | C                  |                      |                                                                                          |                      | Not Reported |                |                |
|                                                                                                     | <u>FDA Received Date</u>                                            | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>      | <u>Mfr Control #</u>                                                                     | <u>503B Facility</u> | <u>Age</u>   | <u>Sex</u>     | <u>Country</u> |
|                                                                                                     | 15-Feb-2012                                                         | 8406640            | EXPEDITED (15-DAY) | Y                  | HO                   | FR-JNJFOC-<br>20120204674                                                                |                      | 77 YR        | Female         | FRA            |
| <u>Preferred Term</u>                                                                               | <u>Product</u>                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>        | <u>Route</u>         | <u>Dosage Text</u>                                                                       | <u>Duration</u>      | <u>Mfr</u>   |                |                |
| Pulmonary Embolism                                                                                  | Galantamine Hydrobromide                                            |                    |                    | S                  | Oral                 | During Several Years                                                                     |                      | Not Reported |                |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                               |   |         |               |              |
|-------------------------------|---|---------|---------------|--------------|
| Ebixa                         | S | Oral    |               | Not Reported |
| Escitalopram Oxalate          | S | Unknown |               | Not Reported |
| Atarax                        | S | Unknown |               | Not Reported |
| Hydrochlorothiazide\Valsartan | S | Oral    | 80 Mg/12.5 Mg | Not Reported |
| Caduet                        | S | Oral    | 5 Mg/10 Mg    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------------|----------------------|------------|------------|----------------|
| 15-Feb-2012              | 8407589       | EXPEDITED (15-DAY) | Y                  | DE              | US-COVIDIEN/TYCO<br>HEALTHCARE/MALLIN<br>CKRODT-T20120034 |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Acetaminophen\Hydrocodone<br>Bitartrate                   |              |            | S           | Oral         |                    |                 | Tyco         |
|                       | Buprenorphine Hydrochloride<br>And Naloxone Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate                                      |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2012              | 8292684       | EXPEDITED (15-DAY) | Y                  | DS              | 1000025970           |                      | 72 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Keratitis             | Escitalopram Oxalate         |              |            | S           | Oral         | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D), Oral           |                 | Not Reported |
|                       | Rotigotine                   |              |            | S           | Transdermal  | 1 Dosage Form (1 Dosage<br>Forms, 1 In 1 D),<br>Transdermal |                 | Not Reported |
|                       | Dexamethasone Sodium Sulfate |              |            | S           | Intraocular  | Intraocular                                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2012              | 8429458       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028374           |                      | 26 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|--------------|
| Blood Creatine        | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg (40 Mg, 1 In 1 D), |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Phosphokinase Increased;  
Overdose

Oral

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Feb-2012              | 8430836       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028301           |                      | 50 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                             | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                                                                                                                                                                                           | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| Cardiac Arrest;<br>Haemorrhoids; Malaise;<br>Orthostatic Hypotension;<br>Paraesthesia; Procedural<br>Complication | Escitalopram Oxalate  |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D) 20<br>Mg (20 Mg, 1 In 1 D) 5 Mg<br>(10 Mg, 1 In 2 D)<br>10 Mg (10 Mg, 1 In 1 D) 20<br>Mg (20 Mg, 1 In 1 D) 5 Mg<br>(10 Mg, 1 In 2 D)<br>10 Mg (10 Mg, 1 In 1 D) 20<br>Mg (20 Mg, 1 In 1 D) 5 Mg<br>(10 Mg, 1 In 2 D) |                 | Not Reported |
|                                                                                                                   | Lexomil (Bromazepam)  |              |            | C           |              |                                                                                                                                                                                                                                              |                 | Not Reported |
|                                                                                                                   | Prazepam              |              |            | C           |              |                                                                                                                                                                                                                                              |                 | Not Reported |
|                                                                                                                   | Magnesium (Magnesium) |              |            | C           |              |                                                                                                                                                                                                                                              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2012              | 8286481       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025959           |                      | 33 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Maternal Exposure During<br>Pregnancy; Overdose;<br>Pregnancy; Premature<br>Delivery | Lexapro        |              |            | S           | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |
|                                                                                      | Ondansetron    |              |            | C           |              |                                  |                 | Not Reported |
|                                                                                      | Phenergan      |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Feb-2012              | 8402564       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027473           |                      | 24 YR      | Male       | DNK            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                        |                                |   |      |                                  |  |              |
|--------------------------------------------------------------------------------------------------------|--------------------------------|---|------|----------------------------------|--|--------------|
| Activation Syndrome;<br>Depression Suicidal;<br>Nausea; Pyrexia; Suicidal<br>Ideation; Suicide Attempt | Lexapro                        | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral |  | Not Reported |
|                                                                                                        | Risperidone (Risperidone)      | C |      |                                  |  | Not Reported |
|                                                                                                        | Tefmetin (Trimebutine Maleate) | C |      |                                  |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-Feb-2012              | 8410860       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012039637 |                      | 32 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Chest Discomfort; Drug<br>Interaction; Dry Mouth;<br>Dyspnoea; Feeling<br>Abnormal; Myocardial<br>Infarction; Nausea; Oral<br>Discomfort; Pruritus<br>Generalised; Seizure;<br>Throat Tightness; Tremor | Dilantin-125          |              |            | S           |                | Unk                |                 | Pfizer       |
|                                                                                                                                                                                                         | Sumatriptan Succinate |              |            | S           | Intrameningeal | 6 Mg, Unk          |                 | Not Reported |
|                                                                                                                                                                                                         | Lexapro               |              |            | S           | Oral           | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                                                                                                                                                                         | Sumatriptan           |              |            | S           |                | 50 Mg, Unk         |                 | Not Reported |
|                                                                                                                                                                                                         | Zonegran              |              |            | C           |                | Unk                |                 | Not Reported |
|                                                                                                                                                                                                         | Neurontin             |              |            | C           |                | Unk                |                 | Not Reported |
|                                                                                                                                                                                                         | Temazepam             |              |            | C           |                | Unk                |                 | Not Reported |
|                                                                                                                                                                                                         | Famotidine            |              |            | C           |                | Unk                |                 | Not Reported |
|                                                                                                                                                                                                         | Multivitamins         |              |            | C           |                | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 17-Feb-2012              | 8411312       | EXPEDITED (15-DAY) | N                  | DS, OT          | US-JNJFOC-<br>20120205160 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------------------------------------------|-----------------|--------------|
| Balance Disorder; Drug<br>Ineffective; Drug<br>Interaction; Epilepsy;<br>Somnolence; Tremor | Topamax        |              |            | S           | Oral         | 100 Mg 1 Tablet In The<br>Morning And 2 Tablets At<br>Night |                 | Not Reported |
|                                                                                             | Provera        |              |            | S           | Oral         |                                                             |                 | Not Reported |
|                                                                                             | Premarin       |              |            | S           | Oral         |                                                             |                 | Not Reported |
|                                                                                             | Lamictal       |              |            | S           | Oral         |                                                             |                 | Not Reported |
|                                                                                             | Vimpat         |              |            | S           | Unknown      |                                                             |                 | Not Reported |
|                                                                                             | Lexapro        |              |            | S           | Unknown      |                                                             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|----------------------|-----------------------------|-----------------|--------------|----------------|
| 17-Feb-2012                                                                                                                                                                   | 8412649                           | EXPEDITED (15-DAY) | Y                  | OT              | DK-WATSON-2012-02600 |                             | 27 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Maternal Exposure During Pregnancy; Morbid Thoughts; Psychotic Disorder                                                                                           | Citalopram Hydrobromide           |                    |                    | S               | Oral                 | 20 Mg Daily                 |                 | Watson       |                |
|                                                                                                                                                                               | Risperidone                       |                    |                    | S               | Oral                 | 4 Mg Daily                  |                 | Watson       |                |
|                                                                                                                                                                               | Escitalopram Oxalate              |                    |                    | S               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Aripiprazole                      |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2012                                                                                                                                                                   | 8435587                           | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000028376           |                             |                 | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Eating Disorder; Malaise; Off Label Use; Suicidal Ideation; Visual Impairment                                                                                                 | Escitalopram Oxalate              |                    |                    | S               |                      |                             |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                      | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 17-Feb-2012                                                                                                                                                                   | 8441669                           | EXPEDITED (15-DAY) | Y                  | HO              | 1000028421           |                             | 58 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                         | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Blood Glucose Increased; Blood Sodium Decreased; Depressed Level Of Consciousness; Diarrhoea; Dizziness; Drug Interaction; Hyponatraemia; Vision Blurred | Escitalopram Oxalate              |                    |                    | S               | Oral                 | 20 Mg (20 Mg, 1 In 1d) Oral |                 | Not Reported |                |
|                                                                                                                                                                               | Atacand Hct                       |                    |                    | S               | Oral                 | 32 Mg/25 Mg (3 In 1 D) Oral |                 | Not Reported |                |
|                                                                                                                                                                               | Atenolol (Atenolol)               |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Atorvastatin (Atorvastatin)       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Clopidogrel                       |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Pantoprazole                      |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Insulin Detemir (Insulin Detemir) |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Insulin Aspart (Insulin Aspart)   |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Valdoxan (Agomelatine)            |                    |                    | C               |                      |                             |                 | Not Reported |                |
|                                                                                                                                                                               | Indapamide                        |                    |                    | C               |                      |                             |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                          |                                                 |                    |                    |                 |                       |                               |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------|--------------------|-----------------|-----------------------|-------------------------------|-----------------|--------------|----------------|
| Venlafaxine                                                                                                              |                                                 |                    | C                  |                 |                       | Not Reported                  |                 |              |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Feb-2012                                                                                                              | 8413733                                         | NON-EXPEDITED      | Y                  |                 | US-ALLERGAN-1101265US |                               |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Eyelid Ptosis                                                                                                            | Botox                                           |                    |                    | S               | Intramuscular         |                               |                 | Allergan     |                |
|                                                                                                                          | Escitalopram Oxalate                            |                    |                    | S               | Oral                  | Unk                           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2012                                                                                                              | 8218697                                         | EXPEDITED (15-DAY) | Y                  | OT              | FR-MERCK-1110FRA00094 |                               | 33 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Amylase Increased; Biliary Tract Disorder; Lipase Increased; Pancreatic Disorder                                         | Isentress                                       |                    |                    | S               | Oral                  |                               |                 | Merck        |                |
|                                                                                                                          | Isentress                                       |                    |                    | S               | Oral                  |                               |                 | Merck        |                |
|                                                                                                                          | Emtricitabine And Tenofovir Disoproxil Fumarate |                    |                    | S               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                          | Emtricitabine And Tenofovir Disoproxil Fumarate |                    |                    | S               | Unknown               |                               |                 | Not Reported |                |
|                                                                                                                          | Escitalopram Oxalate                            |                    |                    | S               | Oral                  |                               | 184 DAY         | Not Reported |                |
|                                                                                                                          | Cyamemazine                                     |                    |                    | S               | Oral                  |                               |                 | Not Reported |                |
|                                                                                                                          | Irbesartan                                      |                    |                    | C               | Unknown               |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                 | <u>Case #</u>                                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 20-Feb-2012                                                                                                              | 8323221                                         | EXPEDITED (15-DAY) | Y                  | HO              | 1000026327            |                               | 19 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                    | <u>Product</u>                                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma Scale Abnormal; Depressed Level Of Consciousness; Dysarthria; Dysstasia; Extrapyrimalal Disorder; Gait Disturbance; | Escitalopram Oxalate                            |                    |                    | S               | Oral                  | 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                          | Levomepromazine                                 |                    |                    | S               | Oral                  | 30 Mg (15 Mg, 2 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                          | Seroquel                                        |                    |                    | S               | Oral                  | 50 Mg (50 Mg, 1 In 1 D),      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                            |         |  |   |      |                                          |  |              |
|----------------------------------------------------------------------------|---------|--|---|------|------------------------------------------|--|--------------|
| Nystagmus; Somnolence;<br>Suicidal Ideation; Toxicity<br>To Various Agents | Effexor |  | S | Oral | Oral<br>75 Mg (75 Mg, 1 In 1 D),<br>Oral |  | Not Reported |
|----------------------------------------------------------------------------|---------|--|---|------|------------------------------------------|--|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 21-Feb-2012              | 8168185       | EXPEDITED (15-DAY) | Y                  | HO              | FR-<br>GLAXOSMITHKLINE-<br>B0751068A |                      | 83 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>      |
|---------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|-----------------|
| Malaise; Nausea; Sleep<br>Disorder; Tremor;<br>Vomiting | Deroxat              |              |            | S           | Oral         | 20mg Unknown                  | 141 DAY         | Glaxosmithkline |
|                                                         | Modopar              |              |            | S           | Oral         | 62.5mg Three Times Per<br>Day | 141 DAY         | Unknown         |
|                                                         | Stresam              |              |            | S           | Oral         |                               | 19 DAY          | Unknown         |
|                                                         | Bromazepam           |              |            | S           | Oral         |                               | 19 DAY          | Unknown         |
|                                                         | Escitalopram Oxalate |              |            | S           | Oral         |                               | 19 DAY          | Unknown         |
|                                                         | Pariet               |              |            | C           | Unknown      |                               |                 | Unknown         |
|                                                         | Olmotec              |              |            | C           |              |                               |                 | Unknown         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2012              | 8404017       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027461           |                      | 46 YR      | Female     | DNK            |

| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------------|-----------------|--------------|
| Amnesia; Cough; Facial<br>Paralysis; Seizure | Escitalopram Oxalate |              |            | S           | Oral<br>Oral | 20 (20 Mg, 1 In1 D) Oral<br>20 (20 Mg, 1 In1 D) Oral |                 | Not Reported |
|                                              | Abilify              |              |            | S           |              | 10 Mg (10 Mg, 1 In 1 D)                              |                 | Not Reported |
|                                              | Abilify              |              |            | S           |              | 5 Mg (5 Mg, 1 In 1 D)                                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2012              | 8431115       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028375           |                      | 65 YR      | Female     | DNK            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyperthyroidism       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                    |                |                    |                    |                 |                      |                                                              |                 |              |                |
|------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|--------------------------------------------------------------|-----------------|--------------|----------------|
| Levothyroxine Sodium                                                               |                |                    | C                  |                 |                      | Not Reported                                                 |                 |              |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2012                                                                        | 8435299        | EXPEDITED (15-DAY) | N                  | DS, RI, OT      | 1000028218           |                                                              | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor | Lexapro        |                    |                    | S               |                      | 20 Mg (20 Mg, 1 In 1 D)                                      |                 | Not Reported |                |
|                                                                                    | Provera        |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral, 20 Years Ago                   |                 | Not Reported |                |
|                                                                                    | Premarin       |                    |                    | S               | Oral                 | 0.625 Mg (0.625 Mg, 1 In 1 D), Oral                          |                 | Not Reported |                |
|                                                                                    | Lamictal       |                    |                    | S               | Oral                 | 300 Mg (150 Mg, 2 In 1 D), Oral                              |                 | Not Reported |                |
|                                                                                    | Topamax        |                    |                    | S               | Oral                 | 300 Mg (100 Mg Qam And 200 Mg Qpm),Oral                      |                 | Not Reported |                |
|                                                                                    | Vimpat         |                    |                    | S               | Oral                 | 400 Mg (100 Mg, 4 In 1 D),Oral                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2012                                                                        | 8436943        | EXPEDITED (15-DAY) | N                  | CA              | 1000028280           |                                                              |                 | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Cleft Palate; Maternal Drugs Affecting Foetus                                      | Lexapro        |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral, 7.5 Mg (7.5 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                    |                |                    |                    |                 | Oral                 | 5 Mg (5 Mg, 1 In 1 D), Oral, 7.5 Mg (7.5 Mg, 1 In 1 D), Oral |                 |              |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Feb-2012                                                                        | 8438087        | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028407           |                                                              |                 | Unknown      | DNK            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                           | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                         |                      |   |      |                                  |              |
|-------------------------|----------------------|---|------|----------------------------------|--------------|
| Intentional Self-Injury | Escitalopram Oxalate | S | Oral | Daily Dose Not Reported,<br>Oral | Not Reported |
|-------------------------|----------------------|---|------|----------------------------------|--------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2012              | 8438207       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000028420           |                      | 34 YR      | Female     | DNK            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blindness; Papilloedema | Escitalopram Oxalate |              |            | S           | Oral         | Oral               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 21-Feb-2012              | 8454632       | NON-EXPEDITED    | N                  |                 | 1000025781           |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                           | <u>Product</u>                                                                                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>     | <u>Route</u> | <u>Dosage Text</u>                                              | <u>Duration</u> | <u>Mfr</u>                                       |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------|------------|-----------------|--------------|-----------------------------------------------------------------|-----------------|--------------------------------------------------|
| Contusion; Cystitis;<br>Insomnia; Off Label Use | Viibryd                                                                                         |              |            | S               | Oral         | 10 Mg (10 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported                                     |
|                                                 | Viibryd                                                                                         |              |            | S               | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 | Not Reported                                     |
|                                                 |                                                                                                 |              |            |                 | Oral         | 30 Mg (30 Mg, 1 In 1 D),<br>Oral, 20 Mg (20 Mg, 1 In 1 D), Oral |                 |                                                  |
|                                                 | Lexapro<br>Vyvanse (Lisdexamfetamine<br>Mesilate) (Lisdexamfetamine<br>Mesilate)<br>Simvastatin |              |            | S<br>C<br><br>C |              |                                                                 |                 | Not Reported<br>Not Reported<br><br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2012              | 8382082       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027107           |                      | 43 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Alanine Aminotransferase<br>Increased; Aspartate<br>Aminotransferase | Lexapro        |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D),<br>Oral |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                 |                              |   |              |
|-----------------------------------------------------------------|------------------------------|---|--------------|
| Increased; Blood Lactate Dehydrogenase                          | Reflex (Mirtazapine)         | C | Not Reported |
| Increased; Gamma-Glutamyltransferase; Hepatic Function Abnormal | Gascon (Dimeticone)          | C | Not Reported |
|                                                                 | (Dimeticone)                 | C | Not Reported |
|                                                                 | Gasmotin (Mosapride Citrate) | C | Not Reported |
|                                                                 | (Mosapride Citrate)          | C | Not Reported |
|                                                                 | Magmitt (Magnesium Oxide)    | C | Not Reported |
|                                                                 | (Magnesium Oxide)            | C | Not Reported |
|                                                                 | Lorazepam                    | C | Not Reported |
|                                                                 | Rohyphnol (Flunitrazepam)    | C | Not Reported |
|                                                                 | (Flunitrazepam)              | C | Not Reported |
|                                                                 | Risperdal                    | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2012              | 8412766       | EXPEDITED (15-DAY) | Y                  | HO              | 1000027598           |                      | 43 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                        | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------|-----------------|--------------|
| Feeling Drunk; Incorrect Dose Administered; Suicide Attempt; Toxicity To Various Agents | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg (20 Mg, 1 In 1 D), Oral Overdose: 280 Mg Once, Oral |                 | Not Reported |
|                                                                                         | Propranolol          |              |            | S           | Oral         | Overdose: 2 G Once, Oral                                  |                 | Not Reported |
|                                                                                         | Tetrazepam           |              |            | S           | Oral         | Overdose: 500 Mg Once, Oral                               |                 | Not Reported |
|                                                                                         | Bromazepam           |              |            | S           | Oral         | One Unique Intake (Unknown Dosage), Oral                  |                 | Not Reported |
|                                                                                         | Alcohol (Ethanol)    |              |            | S           |              |                                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Feb-2012              | 8420213       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027825           |                      | 91 YR      | Female     | DNK            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Hallucination; Off Label Use; Senile Dementia | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                               | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 22-Feb-2012                                                                                                                                                                                                 | 8420895                                       | DIRECT             | N                  | OT              |                      |                                 | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Anorgasmia; Depersonalisation/Derealisation Disorder; Emotional Disorder; Hypoaesthesia; Libido Decreased; Maternal Exposure Before Pregnancy; Personality Change; Pregnancy; Sexual Dysfunction | Lexapro                                       |                    |                    | S               |                      |                                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2012                                                                                                                                                                                                 | 8423103                                       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028031           |                                 | 32 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Cholesterol Increased; Blood Triglycerides Increased; Gamma-Glutamyltransferase Increased; Liver Function Test Abnormal     | Escitalopram Oxalate                          |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                             | Trazodone Hydrochloride                       |                    |                    | S               | Oral                 | 100 Mg (100 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                                             | Seroquel                                      |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D), Oral   |                 | Not Reported |                |
|                                                                                                                                                                                                             | Zyprexa (Olanzapine)                          |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                             | Tresleen (Sertraline Hydrochloride) (Tablets) |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                             | Ixel (Milnacipran) (Tablets)                  |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                                                                                                                                                                             | (Milnacipran)                                 |                    |                    |                 |                      |                                 |                 |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                                    | <u>Case #</u>                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Feb-2012                                                                                                                                                                                                 | 8427019                                       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028164           |                                 | 81 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                       | <u>Product</u>                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                                                          |   |      |                                   |              |
|------------------------------------------------------------------------|----------------------------------------------------------|---|------|-----------------------------------|--------------|
| Feeling Hot;<br>Hyperhidrosis; Loss Of<br>Consciousness;<br>Presyncope | Escitalopram Oxalate                                     | S | Oral | 10 Mg (10 Mg, 1 In 1 D),<br>Oral  | Not Reported |
|                                                                        | Betahistine Hydrochloride                                | S | Oral | 32 Mg (16 Mg, 2 In 1 D),<br>Oral  | Not Reported |
|                                                                        | Lyrica                                                   | S | Oral | 150 Mg (75 Mg, 2 In 1 D),<br>Oral | Not Reported |
|                                                                        | Lansoprazolo (Lansoprazole)<br>(Capsules) (Lansoprazole) | C |      |                                   | Not Reported |
|                                                                        | Simvastatin (Simvastatin)<br>(Tablets) (Simvastatin)     | C |      |                                   | Not Reported |

| <u>FDA Received Date</u>                                      | <u>Case #</u>                                                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------|-------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------|-----------------|--------------|----------------|
| 23-Feb-2012                                                   | 8217915                                                           | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000024734           |                                 | 74 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                         | <u>Product</u>                                                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Pain;<br>Diarrhoea Haemorrhagic;<br>Viral Infection | Escitalopram Oxalate                                              |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1<br>D),Oral |                 | Not Reported |                |
|                                                               | Stagig (Metformin Embonate)<br>(Metformin Embonate)               |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                               | Nisis (Valsartan) (Valsartan)                                     |                    |                    | C               |                      |                                 |                 | Not Reported |                |
|                                                               | Orocal D3 (Calcium<br>Colecalciferol) (Calcium<br>Colecalciferol) |                    |                    | C               |                      |                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                                                                                              | <u>Case #</u>                                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>               | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------------|-----------------|--------------|----------------|
| 23-Feb-2012                                                                                                                                                                                                                                           | 8431291                                          | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000028224           |                                    | 86 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                 | <u>Product</u>                                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                 | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Myocardial<br>Infarction; Aggression;<br>Anxiety; Atrial Fibrillation;<br>Delirium; Fatigue; Fear;<br>Gastrooesophageal Reflux<br>Disease; Haemoglobin<br>Decreased; Hallucination,<br>Gustatory; Hallucination,<br>Visual; Insomnia; Irregular | Escitalopram Oxalate                             |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral         |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Escitalopram Oxalate                             |                    |                    | S               | Oral                 | 10 Mg, (10 Mg, 1 In 1 D) ,<br>Oral |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Distraneuran (Clomethiazole)<br>(Clomethiazole)  |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Litalir (Hydroxycarbamide)<br>(Hydroxycarbamide) |                    |                    | C               |                      |                                    |                 | Not Reported |                |
|                                                                                                                                                                                                                                                       | Aspirin                                          |                    |                    | C               |                      |                                    |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                 |                                                                                                                                                                           |                  |                                                              |
|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------------------------------------------------|
| Sleep Wake Rhythm Disorder; Left Ventricular Failure; Lymphocyte Count Decreased; Restlessness; Suicide Attempt | Digoxin<br>Carvedilol (Carvedilo)<br>(Cavedilol)<br>Pantoprazole (Pantoprazole)<br>(Pantoprazole)<br>Iron (Iii)-Hydroxide (Iron (Iii)-Hydroxide) (Iron (Iii)-Hyhydroxide) | C<br>C<br>C<br>C | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------------------------------------------------|

| <u>FDA Received Date</u>                                                                | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| 23-Feb-2012                                                                             | 8431325                                  | EXPEDITED (15-DAY) | Y                  | HO              | 1000028239           |                              | 84 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                   | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Dizziness; Inappropriate Antidiuretic Hormone Secretion; Loss Of Consciousness; Seizure | Lexapro                                  |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D),Oral |                 | Not Reported |                |
|                                                                                         | Lexapro                                  |                    |                    | S               | Oral                 | 5 Mg (5 Mg, 1 In 1 D),Oral   |                 | Not Reported |                |
|                                                                                         | Rheumatrex (Methotrexate) (Methotrexate) |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                         | Remicade                                 |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                         | Durotep                                  |                    |                    | C               |                      |                              |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                                                                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|---------------------------------------|-----------------|--------------|----------------|
| 23-Feb-2012                                                                                                                                                                     | 8441123              | EXPEDITED (15-DAY) | Y                  | CA, HO, RI, OT  | 1000028438           |                                       |                 | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation Neonatal; Atrial Septal Defect; Infantile Apnoea; Maternal Drugs Affecting Foetus; Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Pyelocaliectasis | Escitalopram Oxalate |                    |                    | S               | Transplacental       | 40 Mg (40 Mg,L In 1 D),Transplacental |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2012              | 8441466       | EXPEDITED (15-DAY) | N                  | RI, OT          | 1000028475           |                      | 16 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                           | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                         | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------------------------------------------|-----------------|--------------|
| Anxiety; Drug Withdrawal Syndrome; Dyskinesia; Muscle Twitching; Off Label Use; Tongue Disorder | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral ,(15 Mg,Instead Of 10 Mg, When Required),Oral |                 | Not Reported |
|                                                                                                 |                      |              |            |             | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral ,(15 Mg,Instead Of 10 Mg, When Required),Oral |                 |              |
|                                                                                                 | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral                                               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2012              | 8443482       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028437           |                      | 30 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Gestational Diabetes; Maternal Exposure During Pregnancy; Overdose; Pregnancy | Escitalopram Oxalate |              |            | S           |              | 40 Mg (40 Mg, 1 In 1 D) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Feb-2012              | 8444571       | EXPEDITED (15-DAY) | Y                  | HO, RI, OT      | 1000028452           |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                                                                  | <u>Product</u>                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------|-------------|--------------|-------------------------------|-----------------|--------------|
| Acute Psychosis; Agitation; Conversion Disorder; Dyskinesia; Hallucination, Auditory; Insomnia; Tremor | Lexapro                              |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                                                        | Lexapro                              |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral   |                 | Not Reported |
|                                                                                                        | Depakote                             |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                        | Topamax (Topiramate)                 |              |            | C           |              |                               |                 | Not Reported |
|                                                                                                        | Levothyroxine (Levothyroxine Sodium) |              |            | C           |              |                               |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------|------------------------|--------------------|--------------------|-----------------|---------------------------------|----------------------|-----------------|--------------|----------------|
| 24-Feb-2012                        | 8407648                | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-EISAI INC-E2020-10330-SPO-FR |                      | 80 YR           | Male         | FRA            |
| <u>Preferred Term</u>              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Embolism                 | Aricept                |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Perindopril            |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Risperdal              |                    |                    | S               | Oral                            |                      | 10 DAY          | Not Reported |                |
|                                    | Risperdal              |                    |                    | S               | Oral                            |                      | 10 DAY          | Not Reported |                |
|                                    | Risperdal              |                    |                    | S               | Oral                            |                      | 10 DAY          | Not Reported |                |
|                                    | Aspirin                |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Ebixa                  |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Escitalopram Oxalate   |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Nicorandil             |                    |                    | S               | Oral                            |                      |                 | Not Reported |                |
|                                    | Xanax                  |                    |                    | S               | Oral                            |                      | 7 DAY           | Not Reported |                |
|                                    | Lovenox                |                    |                    | C               |                                 | Unknown              |                 | Not Reported |                |
| <u>FDA Received Date</u>           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2012                        | 8423864                | NON-EXPEDITED      | N                  |                 | US-MYLANLABS-2011S1026036       |                      | 42 YR           | Female       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal; Throat Tightness | Lexapro                |                    |                    | S               |                                 |                      |                 | Mylan        |                |
|                                    | Unspecified Ingredient |                    |                    | S               |                                 |                      |                 | Not Reported |                |
|                                    | Perphenazine           |                    |                    | S               |                                 |                      |                 | Not Reported |                |
|                                    | Alprazolam             |                    |                    | S               |                                 |                      |                 | Mylan        |                |
| <u>FDA Received Date</u>           | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2012                        | 8424706                | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-K201100732        |                      | 64 YR           | Male         | USA            |
| <u>Preferred Term</u>              | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Angioedema; Dizziness              | Altace                 |                    |                    | S               |                                 | Unk                  |                 | Pfizer       |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |      |               |              |
|----------------------|---|------|---------------|--------------|
| Lexapro              | S | Oral | 5 Mg, 1x/Day  | Not Reported |
| Lexapro              | S | Oral | 10 Mg, 1x/Day | Not Reported |
| Lexapro              | S | Oral | 20 Mg, 1x/Day | Not Reported |
| Beta Blocking Agents | C |      | 25 Mg, Unk    | Not Reported |
| Folic Acid           | C |      | Unk           | Not Reported |
| Niaspan              | C |      | 1 G, Unk      | Not Reported |
| Aspirin              | C |      | Unk           | Not Reported |
| Prilosec             | C |      | Unk           | Not Reported |
| B50                  | C |      | Unk           | Not Reported |
| Ubidecarenone        | C |      | 200 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2012              | 8425414       | EXPEDITED (15-DAY) | Y                  | DE              | US-UCBSA-049071      |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Acetaminophen\Hydrocodone   |              |            | S           | Oral         |                    |                 | Not Reported |
|                            | Buprenorphine Hydrochloride |              |            | S           | Sublingual   |                    |                 | Not Reported |
|                            | And Naloxone Hydrochloride  |              |            |             |              |                    |                 |              |
|                            | Escitalopram Oxalate        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2012              | 8436024       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028442           |                      | 65 YR      | Male       | DNK            |

| <u>Preferred Term</u>                     | <u>Product</u>                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------------------------|--------------|------------|-------------|--------------|----------------------------------|-----------------|--------------|
| Loss Of Consciousness;<br>Suicide Attempt | Lexapro                          |              |            | S           | Oral         | 20 Mg (10 Mg, 1 In 2 D),<br>Oral |                 | Not Reported |
|                                           | Dogmatyl (Sulpiride (Sulpiride)) |              |            | C           |              |                                  |                 | Not Reported |
|                                           | Anafranil                        |              |            | C           |              |                                  |                 | Not Reported |
|                                           | Cymbalta                         |              |            | C           |              |                                  |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2012              | 8436881       | EXPEDITED (15-DAY) | Y                  | HO              | 1000028406           |                      | 59 YR      | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------|-----------------|--------------|----------------|
| Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Condition Aggravated; Gamma-Glutamyltransferase Increased; Liver Disorder | Lexapro                             |                    |                    | S               | Oral                 | 10;20 Mg (10;20 Mg, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                            |                                     |                    |                    |                 | Oral                 | 10;20 Mg (10;20 Mg, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                            | Lexapro                             |                    |                    | S               | Oral                 | 10 Mg (10 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |
|                                                                                                                                                                                            | Risperdal                           |                    |                    | S               | Oral                 | 1;0.5 MI (1;0.5 MI, 1 In 1 D), Oral |                 | Not Reported |                |
|                                                                                                                                                                                            |                                     |                    |                    |                 | Oral                 | 1;0.5 MI (1;0.5 MI, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                            |                                     |                    |                    |                 | Oral                 | 1;0.5 MI (1;0.5 MI, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                            |                                     |                    |                    |                 | Oral                 | 1;0.5 MI (1;0.5 MI, 1 In 1 D), Oral |                 |              |                |
|                                                                                                                                                                                            | Gasmotin (Mosapride Citrate)        |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                            | Ensure Liquid (Ensure /06184901/)   |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                            | Jzoloft (Setrtraline Hydrochloride) |                    |                    | C               |                      |                                     |                 | Not Reported |                |
|                                                                                                                                                                                            | Magmitt (Magnesium Oxide)           |                    |                    | C               |                      |                                     |                 | Not Reported |                |
| Sennoside (Sennoside A+B)                                                                                                                                                                  |                                     |                    | C                  |                 |                      |                                     | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Feb-2012                                                                                                                                                                                | 8442159                             | EXPEDITED (15-DAY) | Y                  | DE              | 1000028549           |                                     | 25 YR           | Male         | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Infection; Myocardial Infarction                                                                                                                                                   | Escitalopram Oxalate                |                    |                    | S               | Oral                 | Oral                                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Feb-2012                                                                                                                                                                                | 8257329                             | EXPEDITED (15-DAY) | Y                  | DE, HO, RI, OT  | 1000025398           |                                     | 72 YR           | Female       | DNK            |
| <u>Preferred Term</u>                                                                                                                                                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                  | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiomegaly; Constipation; Fall; Hepatic                                                                                                                                                  | Escitalopram Oxalate                |                    |                    | S               | Oral                 | 30 Mg (30 Mg, 1 In 1 D), Oral       |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                           |                                           |  |  |                                                                  |  |  |                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--|--|------------------------------------------------------------------|--|--|----------------------------------------------------------------------------------------------------------------------------------------------|
| Cirrhosis; Humerus Fracture; Hypertension; Hyperventilation; Internal Fixation Of Fracture; Lactic Acidosis; Lacunar Infarction; Multiple Organ Dysfunction Syndrome; Neuroleptic Malignant Syndrome; Renal Failure; Rhabdomyolysis; Serotonin Syndrome; Urinary Tract Infection | Ziprasidone Hydrochloride<br>Lithium Citrate<br>Mirtazapine (Mirtazapine)<br>Fragmin (Dalteparin Sodium)<br>Ferro Dureter (Ferrous Sulfate)<br>Centyl Med Kaliumklorid (Bendroflumethazide, Potassium Chloride)<br>Furosemide<br>Amlodipine<br>Alprazolam | S<br>S<br>S<br>C<br>C<br>C<br>C<br>C<br>C |  |  | 80 Mg (40 Mg, 2 In 1 D)<br>Oral<br>30 Mg (30 Mg, 1 In 1 D), Oral |  |  | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--|--|------------------------------------------------------------------|--|--|----------------------------------------------------------------------------------------------------------------------------------------------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8260896       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000025428           |                      | 51 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                    | <u>Product</u>                                                                                 | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>      | <u>Route</u> | <u>Dosage Text</u>                                                | <u>Duration</u> | <u>Mfr</u>                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------|------------|------------------|--------------|-------------------------------------------------------------------|-----------------|--------------------------------------------------------------|
| Autoimmune Thyroiditis; Blood Pressure Increased; Fatigue; Malaise; Myalgia; Restlessness; Serotonin Syndrome; Terminal Insomnia; Tremor | Escitalopram Oxalate<br>Escitalopram Oxalate<br>Mirtazapine (Mirtazapine)<br>Lithium Carbonate |              |            | S<br>S<br>C<br>C | Oral<br>Oral | 20 Mg (20 Mg, 1 In 1 D), Oral<br>10; 5 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8345268       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000026666           |                      | 52 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                 | <u>Product</u>                                                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u> | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>                                                                   |
|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------|------------|-----------------------|--------------|-------------------------------|-----------------|------------------------------------------------------------------------------|
| Angina Pectoris; Blood Cholesterol Increased; Drug Ineffective; Electrocardiogram ST Segment Abnormal | Escitalopram Oxalate<br>Marevan<br>Sanval (Zolpidem Tartrate)<br>Trandolapril<br>Diazepam (Diazepam) |              |            | S<br>C<br>C<br>C<br>C | Oral         | 10 Mg (10 Mg, 1 In 1 D), Oral |                 | Not Reported<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8420247       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000027806           |                      | 18 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                                                                                                                                                                                                                                                                                                                                     | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                 | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------------------------------------------------------|-----------------|--------------|
| Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Blood Bilirubin Unconjugated Increased; C-Reactive Protein Increased; Drug Interaction; Fatigue; Gastrointestinal Disorder; Liver Injury; Nausea; Platelet Count Decreased; Treatment Noncompliance; Viral Infection | Escitalopram Oxalate                       |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Acetaminophen                              |              |            | S           | Oral         | 10 Mg (10 Mg, 1 In 1 D),Oral, 10 Mg (10 Mg, 1 In 1 D), Oral        |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Drospirenone\Ethinyl Estradiol             |              |            | S           | Oral         | 2000 Mg (500 Mg, 4 In 1 D), Oral, 2000 Mg (500 Mg, 4 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Desloratadine                              |              |            | C           |              | 2000 Mg (500 Mg, 4 In 1 D), Oral, 2000 Mg (500 Mg, 4 In 1 D), Oral |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Mometasone Furoate Monohydrate             |              |            | C           |              | 1 Df (1 Dosage Forms, 1 In 1 D), Oral                              |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Rubozinc (Zinc Gluconate) (Zinc Gluconate) |              |            | C           |              |                                                                    |                 | Not Reported |
|                                                                                                                                                                                                                                                                                                                                                                           | Amoxicillin                                |              |            | C           |              |                                                                    |                 | Not Reported |

| <u>FDA Received Date</u>                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                      | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|--------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------------------|-------------------------------------------|-----------------|----------------------|----------------|
| 27-Feb-2012                                            | 8427057        | EXPEDITED (15-DAY) | N                  | HO, OT          | FR-BRISTOL-MYERS SQUIBB COMPANY-16404576 |                                           | 91 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u>           |                |
| Arrhythmia; Haematoma; Haematuria; Haemorrhagic Stroke | Coumadin       |                    |                    | S               | Oral                                     | 1 Tablet In The Evening                   |                 | Bristol Myers Squibb |                |
|                                                        | Paracetamol    |                    |                    | S               |                                          |                                           |                 | Cadence              |                |
|                                                        | Ramipril       |                    |                    | S               |                                          | One In The Morning And One In The Evening |                 | Not Reported         |                |
|                                                        | Cordarone      |                    |                    | S               |                                          | 1df=One At Noon 5 Days/7 Days             |                 | Not Reported         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                     |   |                             |              |
|---------------------------------------------------------------------------------------------------------------------|---|-----------------------------|--------------|
| Aspirin                                                                                                             | S | At Noon                     | Not Reported |
| Tahor                                                                                                               | S | In The Evening              | Not Reported |
| Oxazepam                                                                                                            | S | In The Evening              | Not Reported |
| Escitalopram Oxalate                                                                                                | S | In The Morning              | Not Reported |
| Topalgic (France)                                                                                                   | S |                             | Not Reported |
| Zopiclone                                                                                                           | S | One At Bedtime              | Not Reported |
| Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) | S | 1df=1 Sachet In The Morning | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8428725       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ROCHE-1042038     |                      | 58 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Confusional State;<br>Somnolence | Valium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Seroquel             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Risperdal            |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8441162       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028552           |                      | 25 YR      | Female     | DNK            |

| <u>Preferred Term</u>                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------|-----------------|--------------|
| Lymphangitis;<br>Photosensitivity Reaction;<br>Purpura; Skin Injury | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg (5 Mg, 1 In 1 D), Oral |                 | Not Reported |
|                                                                     | Xanax                |              |            | C           |              |                             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Feb-2012              | 8441365       | EXPEDITED (15-DAY) | Y                  | RI, OT          | 1000028513           |                      |            | Female     | DNK            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--------------------------------------------------------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Amenorrhoea; Dizziness; Intentional Self-Injury; Memory Impairment; Weight Increased | Lexapro                 |                           |                             | S                        | Oral                          | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Feb-2012                                                                          | 8443536                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000028595                    |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Talipes                                            | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Feb-2012                                                                          | 8443550                 | EXPEDITED (15-DAY)        |                             | CA                       | 1000028598                    |                               | < 1 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Maternal Drugs Affecting Foetus; Spina Bifida                                        | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Feb-2012                                                                          | 8443556                 | EXPEDITED (15-DAY)        | N                           | CA                       | 1000028593                    |                               | < 1 DAY                  | Male                | USA                     |
| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Cleft Lip And Palate; Maternal Drugs Affecting Foetus                                | Lexapro                 |                           |                             | S                        | Transplacental                | Transplacental                |                          | Not Reported        |                         |
| <a href="#">FDA Received Date</a>                                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Feb-2012                                                                          | 8444100                 | EXPEDITED (15-DAY)        | Y                           | HO                       | 1000028576                    |                               |                          | Male                | DNK                     |
| <a href="#">Preferred Term</a>                                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hepatitis; Hepatitis Cholestatic; International                                      | Escitalopram Oxalate    |                           |                             | S                        |                               |                               |                          | Not Reported        |                         |

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|                            |                                 |   |      |                              |              |
|----------------------------|---------------------------------|---|------|------------------------------|--------------|
| Normalised Ratio Increased | Coumadin                        | S | Oral | 10 Mg (10 Mg,1 In 1 D), Oral | Not Reported |
|                            | Tenormin                        | C |      |                              | Not Reported |
|                            | Lercanidipine                   | C |      |                              | Not Reported |
|                            | Atacand (Candesartan Cilexetil) | C |      |                              | Not Reported |
|                            | Atorvastatin Calcium            | C |      |                              | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Feb-2012                       | 8445074                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000028545                    |                               | 52 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a>                                                  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------------------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-------------------------------|--------------------------|---------------------|
| Agitation; Drug Withdrawal Syndrome; Erectile Dysfunction; Paraesthesia; Tremor | Lexapro                 |                       |                     | S                    | Oral                  | 10 Mg (10 Mg, 1 In 1 D), Oral |                          | Not Reported        |
|                                                                                 | Lansoprazole            |                       |                     | C                    |                       |                               |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2012                       | 8444005                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000028582                    |                               | 33 YR               | Male                | DNK                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>                       | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>  | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-----------------------------------------------|-----------------------|---------------------|----------------------|-----------------------|------------------------------|--------------------------|---------------------|
| Blood Triglycerides Increased  | Lexapro                                       |                       |                     | S                    | Oral                  | 20 Mg (20 Mg, 1 In 1 D),Oral |                          | Not Reported        |
|                                | Meilax (Ethyl Loflazepate)(Ethyl Loflazepate) |                       |                     | C                    |                       |                              |                          | Not Reported        |
|                                | Flunitrazepam (Flunitrazepam)                 |                       |                     | C                    |                       |                              |                          | Not Reported        |
|                                | Abilify(Aripiprazole)(Aripiprazole)           |                       |                     | C                    |                       |                              |                          | Not Reported        |
|                                | Lansoprazole                                  |                       |                     | C                    |                       |                              |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Feb-2012                       | 8444267                | EXPEDITED (15-DAY)        | Y                           | RI, OT                   | 1000028492                    |                               | 24 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Intentional Overdose; Suicide Attempt | Viibryd                 |                       |                     | S                    |                       |                             |                          | Not Reported        |
|                                       | Lexapro                 |                       |                     | S                    |                       |                             |                          | Not Reported        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 29-Feb-2012                                                                                              | 8423172                | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2012042738 |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                                                                                              | Xanax                  |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                                                          | Atarax                 |                    |                    | S               | Oral                     | Unk                  |                 | Pfizer       |                |
|                                                                                                          | Escitalopram Oxalate   |                    |                    | S               | Oral                     | Unk                  |                 | Not Reported |                |
|                                                                                                          | Aerius (Desloratadine) |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                                                                                              | 8432205                | DIRECT             |                    | HO              |                          |                      | 29 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Valve Disease; Depression; Diabetes Mellitus; Nausea; Night Sweats; Nightmare; Suicidal Ideation | Lexapro                |                    |                    | S               | Oral                     | 250 Mg               |                 | Not Reported |                |
|                                                                                                          | Vitamins               |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                                                                                              | 8432666                | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20120210107    |                      | 58 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Acute Kidney Injury; Balance Disorder; Confusional State; Drug Interaction; Somnolence                   | Risperdal              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                                                                          | Bisoprolol             |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                          | Amlodipine Besylate    |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                          | Coaprovel              |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                          | Esidrex                |                    |                    | C               | Unknown                  |                      |                 | Not Reported |                |
|                                                                                                          | Quetiapine             |                    |                    | S               | Oral                     |                      | 33 DAY          | Not Reported |                |
|                                                                                                          | Quetiapine             |                    |                    | S               | Oral                     |                      | 33 DAY          | Not Reported |                |
|                                                                                                          | Quetiapine             |                    |                    | S               | Oral                     |                      | 33 DAY          | Not Reported |                |

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|                                          | Quetiapine           |                    | S                  | Oral            |                          |                      | 33 DAY          |              | Not Reported   |
|------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
|                                          | Escitalopram Oxalate |                    | S                  | Oral            |                          |                      | 33 DAY          |              | Not Reported   |
|                                          | Valium               |                    | S                  | Oral            |                          |                      |                 |              | Not Reported   |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                              | 8432741              | EXPEDITED (15-DAY) | Y                  | HO              | FR-PFIZER INC-2012052630 |                      | 83 YR           | Male         | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia                              | Eupantol             |                    |                    | S               | Oral                     | 20 Mg, Unk           | 16 DAY          | Pfizer       |                |
|                                          | Aspirin              |                    |                    | S               | Oral                     | 75 Mg, Unk           |                 | Not Reported |                |
|                                          | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg, Unk           |                 | Not Reported |                |
|                                          | Tareg                |                    |                    | S               | Oral                     | 80 Mg, Unk           |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                              | 8433172              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000026774        |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Seizure                   | Escitalopram Oxalate |                    |                    | S               | Oral                     |                      |                 | Forest       |                |
|                                          | Reminyl              |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                              | 8433188              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000028138        |                      | 33 YR           | Male         | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari Malformation; Spina Bifida | Lexapro              |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
|                                          | Folic Acid           |                    |                    | C               | Transplacental           |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Feb-2012                              | 8433928              | EXPEDITED (15-DAY) | N                  | HO              | US-FRI-1000028168        |                      | 30 YR           | Female       | USA            |
| <u>Preferred Term</u>                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

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|                        |              |   |      |       |              |
|------------------------|--------------|---|------|-------|--------------|
| Back Pain; Chest Pain; | Lexapro      | S | Oral | 10 Mg | Forest       |
| Dyspnoea;              | Lexapro      | S |      |       | Forest       |
| Electrocardiogram St   | Allegra      | C |      |       | Not Reported |
| Segment Abnormal; Limb | Buspar       | C |      |       | Not Reported |
| Discomfort; Maternal   | Skelaxin     | C |      |       | Not Reported |
| Exposure During        | Imitrex      | C |      |       | Not Reported |
| Pregnancy; Premature   | Ortho Cyclen | C |      |       | Not Reported |
| Rupture Of Membranes;  | Ativan       | C |      |       | Not Reported |
| Sinus Tachycardia      |              |   |      |       |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 29-Feb-2012              | 8434018       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2012SE12534 |                      | 58 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Balance Disorder;<br>Confusional State;<br>Somnolence | Quetiapine Fumarate  |              |            | S           | Oral         |                    | 3 DAY           | Astrazeneca  |
|                                                       | Quetiapine Fumarate  |              |            | S           | Oral         |                    | 17 DAY          | Astrazeneca  |
|                                                       | Quetiapine Fumarate  |              |            | S           | Oral         |                    | 6 DAY           | Astrazeneca  |
|                                                       | Quetiapine Fumarate  |              |            | S           | Oral         |                    | 7 DAY           | Astrazeneca  |
|                                                       | Escitalopram Oxalate |              |            | S           | Oral         |                    | 33 DAY          | Not Reported |
|                                                       | Risperdal            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Valium               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Bisoprolol           |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                       | Amlodipine Besylate  |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                       | Coaprovel            |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                       | Esidrex              |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 29-Feb-2012              | 8441366       | DIRECT           | N                  | OT              |                      |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Dizziness; Drug<br>Ineffective; Migraine;<br>Nausea; Rash; Renal<br>Pain; Tremor | Lexapro        |              |            | S           |              | 10mgs Once Daily 7 Days |                 | Forest       |
|                                                                                  | Lexapro        |              |            | S           |              |                         |                 | Not Reported |



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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 01-Mar-2012              | 8406436       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | FR-PFIZER INC-2012036442 |                      | 80 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Aggression; Anxiety; Dementia Alzheimer'S Type; Pulmonary Embolism; Thrombocytopenia | Xanax                |              |            | S           | Oral         | 0.25 Mg, 1x/Day    | 7 DAY           | Pfizer       |
|                                                                                      | Aricept              |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Pfizer       |
|                                                                                      | Risperdal            |              |            | S           | Oral         | 0.25 Mg, 2x/Day    | 2 DAY           | Not Reported |
|                                                                                      | Risperdal            |              |            | S           | Oral         | 0.5 Mg, 2x/Day     | 4 DAY           | Not Reported |
|                                                                                      | Risperdal            |              |            | S           | Oral         | 1 Mg, 2x/Day       | 4 DAY           | Not Reported |
|                                                                                      | Ebixa                |              |            | S           | Oral         | 20 Mg, 1x/Day      |                 | Not Reported |
|                                                                                      | Aspirin              |              |            | S           | Oral         | 75 Mg, 1x/Day      |                 | Not Reported |
|                                                                                      | Nicorandil           |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |
|                                                                                      | Perindopril          |              |            | S           | Oral         | 4 Mg, 1x/Day       |                 | Not Reported |
|                                                                                      | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2012              | 8434787       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000028280    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Cleft Palate          | Lexapro        |              |            | S           | Transplacental | 5 Mg               |                 | Forest     |
|                       | Lexapro        |              |            | S           | Transplacental | 7.5 Mg             |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 01-Mar-2012              | 8435106       | EXPEDITED (15-DAY) | N                  | CA, OT          | US-FRI-1000028143    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Double Outlet Right Ventricle; Pyelocaliectasis; Transposition Of The Great Vessels; Ventricular Extrasystoles; Ventricular | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                             | Prenatabs Fa   |              |            | C           | Transplacental |                    |                 | Not Reported |
|                                                                                                                             | Amoxicillin    |              |            | C           | Transplacental |                    |                 | Not Reported |

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|               |                 |   |                |              |
|---------------|-----------------|---|----------------|--------------|
| Septal Defect | Folic Acid      | C | Transplacental | Not Reported |
|               | Vitamin B12     | C | Transplacental | Not Reported |
|               | Vitamin C       | C | Transplacental | Not Reported |
|               | Ferrous Sulfate | C | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Mar-2012              | 8436357                | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-FRI-1000028676    |                      | 43 YR           | Female       | FRA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia              | Escitalopram Oxalate   |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                          | Xanax                  |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Atarax                 |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                          | Rivotril               |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                          | Aerius (Desloratadine) |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 01-Mar-2012                                                             | 8436408              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000028672    |                      | 58 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder;<br>Confusional State; Drug<br>Interaction; Somnolence | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                         | Quetiapine Fumarate  |                    |                    | S               | Oral                 | 300 Mg               | 32 DAY          | Not Reported |                |
|                                                                         | Quetiapine Fumarate  |                    |                    | S               | Oral                 | 600 Mg               | 32 DAY          | Not Reported |                |
|                                                                         | Quetiapine Fumarate  |                    |                    | S               | Oral                 | 400 Mg               | 32 DAY          | Not Reported |                |
|                                                                         | Quetiapine Fumarate  |                    |                    | S               | Oral                 | 600 Mg               | 32 DAY          | Not Reported |                |
|                                                                         | Risperdal            |                    |                    | S               | Oral                 | 8 Mg                 |                 | Not Reported |                |
|                                                                         | Valium               |                    |                    | S               | Oral                 | 10 Mg                |                 | Not Reported |                |
|                                                                         | Bisoprolol           |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Amlodipine Besylate  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Coaprovel            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                         | Esidrex              |                    |                    | C               |                      |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------------|-----------------|--------------|----------------|
| 01-Mar-2012                                                                        | 8446215                     | EXPEDITED (15-DAY) | Y                  | OT              | DKLU1066670              |                                  | 33 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Infertility Male; Sperm Analysis Abnormal                                          | Escitalopram Oxalate        |                    |                    | S               | Oral                     | 10 Mg, 1 In 1 D, Oral            |                 | Not Reported |                |
|                                                                                    | Tranxene T-Tab              |                    |                    | S               | Oral                     | 10;5 Mg, 3;2 In 1 D, Oral        |                 | Not Reported |                |
|                                                                                    | Aceprometazine\Meprobamate  |                    |                    | S               | Oral                     | 1 Df Dosage Form, 1 In 1 D, Oral |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                                                        | 8354946                     | EXPEDITED (15-DAY) | Y                  | DS, OT          | US-PFIZER INC-2012017345 |                                  |                 | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor | Provera                     |                    |                    | S               | Oral                     | 10 Mg, Daily                     |                 | Pfizer       |                |
|                                                                                    | Premarin                    |                    |                    | S               | Oral                     | 0.625 Mg, Daily                  |                 | Pfizer       |                |
|                                                                                    | Lamictal                    |                    |                    | S               | Oral                     | 150 Mg, 2x/Day                   |                 | Not Reported |                |
|                                                                                    | Topamax                     |                    |                    | S               | Oral                     | Unk,2x/Day                       |                 | Not Reported |                |
|                                                                                    | Lacosamide                  |                    |                    | S               |                          | 100 Mg, 4x/Day                   |                 | Not Reported |                |
|                                                                                    | Lexapro                     |                    |                    | S               |                          | 20 Mg, Daily                     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                           | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>             | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                                                        | 8437024                     | EXPEDITED (15-DAY) | Y                  | DE, OT          | CHPA2012US003762         |                                  | 52 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>               | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardio-Respiratory Arrest; Completed Suicide                                       | Acetaminophen (Paracetamol) |                    | Y                  | S               | Oral                     | Unk,Unk                          |                 | Novartis     |                |
|                                                                                    | Unspecified Ingredient      |                    |                    | S               | Oral                     | Unk,Unk                          |                 | Not Reported |                |
|                                                                                    | Propoxyphene Hydrochloride  |                    |                    | S               | Oral                     | Unk,Unk                          |                 | Not Reported |                |
|                                                                                    | Escitalopram Oxalate        |                    |                    | S               | Oral                     | Unk,Unk                          |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|-------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 02-Mar-2012                                             | 8437082           | EXPEDITED (15-DAY) | Y                  | OT              | DE-JNJFOC-20120210508 |                      | 24 YR           | Male         | DEU            |
| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Intentional Product Misuse; Somnolence; Suicide Attempt | Risperdal         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                         | Paracetamol       |                    | Y                  | S               | Oral                  |                      |                 | Not Reported |                |
|                                                         | Paracetamol       |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                         | Ciprallex         |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                             | 8437664           | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000027107     |                      | 43 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Function Abnormal                               | Lexapro           |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |
|                                                         | Mirtazapine       |                    |                    | C               | Oral                  | 15 Mg                |                 | Not Reported |                |
|                                                         | Gascon            |                    |                    | C               | Oral                  | 120 Mg               |                 | Not Reported |                |
|                                                         | Mosapride Citrate |                    |                    | C               | Oral                  | 15 Mg                |                 | Not Reported |                |
|                                                         | Magnesium Oxide   |                    |                    | C               | Oral                  | 750 Mg               |                 | Not Reported |                |
|                                                         | Lorazepam         |                    |                    | C               | Oral                  | 1.5 Mg               |                 | Not Reported |                |
|                                                         | Flunitrazepam     |                    |                    | C               | Oral                  | 2 Mg                 |                 | Not Reported |                |
|                                                         | Risperdal         |                    |                    | C               | Oral                  | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                             | 8438400           | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000027356     |                      | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyspnoea; Heart Rate Increased; Migraine; Palpitations  | Lexapro           |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |
|                                                         | Fentanyl          |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                         | Soma              |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                                         | Norco             |                    |                    | C               |                       |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Trazodone Hydrochloride                                                                                  |                             |                    | C                  |                 |                          |                            | Not Reported    |              |                |
|----------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|--------------|----------------|
| Gabapentin                                                                                               |                             |                    | C                  |                 |                          |                            | Not Reported    |              |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                                                                              | 8438429                     | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012052996 |                            | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Mood Swings; Paranoia; Suicidal Ideation                                                       | Pristiq Extended Release    |                    |                    | S               |                          | 50 Mg, Daily               |                 | Pfizer       |                |
|                                                                                                          | Wellbutrin                  |                    |                    | S               |                          | Unk                        |                 | Not Reported |                |
|                                                                                                          | Lexapro                     |                    |                    | S               |                          | Unk                        |                 | Not Reported |                |
|                                                                                                          | Seroquel                    |                    |                    | S               |                          | 300 Mg, Daily              |                 | Not Reported |                |
|                                                                                                          | Seroquel                    |                    |                    | S               |                          | 600 Mg Daily               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Mar-2012                                                                                              | 8438619                     | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000028633        |                            |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Dyskinesia; Fall; Feeling Abnormal; Movement Disorder; Muscle Twitching; Paraesthesia; Visual Impairment | Lexapro                     |                    |                    | S               | Oral                     | 10 Mg                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2012                                                                                              | 8436388                     | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000028689        |                            | 88 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypersensitivity Vasculitis; Vascular Purpura                                                            | Escitalopram Oxalate        |                    |                    | S               | Oral                     |                            |                 | Forest       |                |
|                                                                                                          | Influenza Virus Vaccine Nos |                    |                    | S               | Intramuscular            | Single Dose On 22-Nov-2011 |                 | Not Reported |                |
|                                                                                                          | Clamoxyl (Amoxicillin)      |                    |                    | S               | Oral                     |                            |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 05-Mar-2012                                                                                                                                                                                      | 8438632                     | EXPEDITED (15-DAY) | Y                  | OT              | DE-FRI-1000028710              |                      | 59 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Decreased Appetite;<br>Dizziness; Dysgeusia;<br>Insomnia; Nausea;<br>Nervousness; Panic<br>Attack; Restlessness;<br>Suicidal Ideation;<br>Supraventricular<br>Extrasystoles; Weight<br>Decreased | Escitalopram Oxalate        |                    |                    | S               | Oral                           | 5 Mg (5 Drops)       |                 | Forest       |                |
|                                                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               |                                |                      |                 | Forest       |                |
|                                                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               | Oral                           | 10 Mg (10 Drops)     |                 | Forest       |                |
|                                                                                                                                                                                                  | Escitalopram Oxalate        |                    |                    | S               | Oral                           | 8 Mg (8 Drops)       |                 | Forest       |                |
|                                                                                                                                                                                                  | Doxepin Hydrochloride       |                    |                    | C               | Oral                           | 15 - 80 Mg           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                         | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2012                                                                                                                                                                                      | 8441525                     | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-<br>2012SE13176 |                      | 72 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                            | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Chronic Kidney Disease;<br>Condition Aggravated;<br>Confusional State;<br>Dehydration                                                                                                            | Seroquel Xr                 |                    |                    | S               | Oral                           |                      | 5 DAY           | Astrazeneca  |                |
|                                                                                                                                                                                                  | Ciprallex                   |                    |                    | S               | Oral                           |                      | 12 DAY          | Not Reported |                |
|                                                                                                                                                                                                  | Zuclopenthixol              |                    |                    | S               | Oral                           |                      | 8 DAY           | Not Reported |                |
|                                                                                                                                                                                                  | Clomethiazole               |                    |                    | S               | Oral                           |                      | 14 DAY          | Not Reported |                |
|                                                                                                                                                                                                  | Buprenorphine Hydrochloride |                    |                    | S               | Oral                           |                      | 3 DAY           | Not Reported |                |
|                                                                                                                                                                                                  | Insulatard Nph Human        |                    |                    | C               | Subcutaneous                   |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Dafalgan                    |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Beloc-Zok                   |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Phosphonorm                 |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Levothyroxine Sodium        |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Lasix                       |                    |                    | C               | Oral                           |                      |                 | Not Reported |                |
|                                                                                                                                                                                                  | Pramipexole Dihydrochloride |                    |                    | C               |                                |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------|-----------------|--------------|----------------|
| 05-Mar-2012                                                                                        | 8441812                                                                                                       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000028301    |                        | 47 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Electrocardiogram<br>Repolarisation<br>Abnormality;<br>Paraesthesia; Presyncope | Escitalopram Oxalate                                                                                          |                    |                    | S               | Oral                 | 10 Mg                  |                 | Forest       |                |
|                                                                                                    | Escitalopram Oxalate                                                                                          |                    |                    | S               | Oral                 | 20 Mg                  |                 | Forest       |                |
|                                                                                                    | Escitalopram Oxalate                                                                                          |                    |                    | S               | Oral                 | 5 Mg                   |                 | Not Reported |                |
|                                                                                                    | Bromazepam                                                                                                    |                    |                    | C               | Oral                 | 6 Mg                   |                 | Not Reported |                |
|                                                                                                    | Prazepam                                                                                                      |                    |                    | C               |                      | Occasionally           |                 | Not Reported |                |
|                                                                                                    | Magnesium                                                                                                     |                    |                    | C               |                      | Occasionally           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Mar-2012                                                                                        | 8456634                                                                                                       | EXPEDITED (15-DAY) | Y                  | CA, OT          | GER/GER/12/0023169   |                        |                 | Female       | DEU            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Drugs Affecting<br>Foetus; Oesophageal<br>Atresia                                         | Zolpidem                                                                                                      |                    |                    | S               | Transplacental       | Transplacental         |                 | Not Reported |                |
|                                                                                                    | Mycophenolate Mofetil                                                                                         |                    |                    | S               | Transplacental       | 0.5 Gm, Transplacental |                 | Not Reported |                |
|                                                                                                    | Lorazepam                                                                                                     |                    |                    | S               | Transplacental       | Transplacental         |                 | Not Reported |                |
|                                                                                                    | Escitalopram Oxalate                                                                                          |                    |                    | S               | Transplacental       | Transplacental         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>                                                                                                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2012                                                                                        | 8359854                                                                                                       | EXPEDITED (15-DAY) | Y                  | DE              | AUR-APL-2012-00252   |                        | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>                                                                                                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest;<br>Respiratory Arrest;<br>Toxicity To Various Agents                               | Metoprolol Tartrate                                                                                           |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                    | Simvastatin                                                                                                   |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                    | Escitalopram Oxalate                                                                                          |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                    | Amphetamine Aspartate And<br>Amphetamine Sulfate And<br>Dextroamphetamine Saccharate<br>And Dextroamphetamine |                    |                    | S               |                      |                        |                 | Not Reported |                |
|                                                                                                    |                                                                                                               |                    |                    |                 |                      |                        |                 |              |                |
|                                                                                                    |                                                                                                               |                    |                    |                 |                      |                        |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clozapine  
Memantine Hydrochloride  
Solifenacin

S  
S  
S

Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2012              | 8442601       | DIRECT           | N                  | DS, OT          |                      |                      | 47 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Disease Recurrence; Economic Problem; Hostility; Mania; Unemployment | Lexapro        |              |            | S           | Oral         | 10 Mg, 1 A Day, Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 06-Mar-2012              | 8442851       | EXPEDITED (15-DAY) | Y                  | CA              | DE-SANOFI-AVENTIS-2012SA014787 |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Oesophageal Atresia; Tracheal Atresia | Zolpidem Tartrate     |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                         | Escitalopram Oxalate  |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                         | Mycophenolate Mofetil |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                                                         | Lorazepam             |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2012              | 8442885       | EXPEDITED (15-DAY) |                    | HO              | CH-FRI-1000027365    |                      |            | Female     | CHE            |

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Agitation; Anxiety; Asthenia; Hyponatraemia; Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                      | Remeron              |              |            | S           | Oral         | 45 Mg              |                 | Not Reported |
|                                                      | Remeron              |              |            | S           | Oral         | 45 Mg              |                 | Not Reported |
|                                                      | Remeron              |              |            | S           | Oral         | 30 Mg              |                 | Not Reported |
|                                                      | Seroquel             |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                      | Seroquel             |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |



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|           |   |      |         |              |
|-----------|---|------|---------|--------------|
| Seroquel  | S | Oral | 100 Mg  | Not Reported |
| Lorazepam | C | Oral | 2.5 Mg  | Not Reported |
| Lorazepam | C | Oral | 1 Mg    | Not Reported |
| Lorazepam | C | Oral | 3 Mg    | Not Reported |
| Lorazepam | C | Oral | 2 Mg    | Not Reported |
| Stilnox   | C | Oral | 12.5 Mg | Not Reported |

| <u>FDA Received Date</u>                                               | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2012                                                            | 8443101        | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16415879 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pulmonary Hypertension;<br>Wrong Technique In<br>Product Usage Process | Abilify        |                    |                    | S               |                                                 |                      | 2 MTH           | Not Reported |                |
|                                                                        | Lexapro        |                    |                    | S               |                                                 |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 06-Mar-2012                                                                                       | 8443818              | EXPEDITED (15-DAY) | Y                  | OT              | DE-FRI-1000028437    |                      | 30 YR           | Female     | DEU            |
| <u>Preferred Term</u>                                                                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Breast Feeding;<br>Gestational Diabetes;<br>Meconium In Amniotic<br>Fluid; Overdose;<br>Pregnancy | Escitalopram Oxalate |                    |                    | S               |                      | 40 Mg                |                 | Forest     |                |
|                                                                                                   | Escitalopram Oxalate |                    |                    | S               |                      | Unknown Dosage       |                 | Forest     |                |

| <u>FDA Received Date</u>                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 06-Mar-2012                                            | 8443819              | EXPEDITED (15-DAY) | Y                  | OT              | DE-FRI-1000028813    |                      |                 | Female       | DEU            |
| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Potentiating Drug<br>Interaction; Urinary<br>Retention | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                        | Pantozol             |                    |                    | C               |                      | 40 Mg                |                 | Not Reported |                |
|                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |      |        |              |
|-------------|---|------|--------|--------------|
| Seroquel Xr | S | Oral | 200 Mg | Not Reported |
| Seroquel Xr | S | Oral | 100 Mg | Not Reported |
| Seroquel Xr | S | Oral | 200 Mg | Not Reported |
| Seroquel Xr | S | Oral | 300 Mg | Not Reported |
| Remergil    | S | Oral | 30 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 06-Mar-2012              | 8443922       | EXPEDITED (15-DAY) | Y                  | HO              | CH-FRI-1000028832    |                      | 72 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                        | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Chronic Kidney Disease;<br>Confusional State;<br>Dehydration | Escitalopram Oxalate        |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                                              | Escitalopram Oxalate        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported |
|                                                              | Zuclopenthixol Acetate      |              |            | S           | Oral         | 40 Mg              |                 | Not Reported |
|                                                              | Zuclopenthixol Acetate      |              |            | S           | Oral         | 60 Mg              |                 | Not Reported |
|                                                              | Zuclopenthixol Acetate      |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                              | Seroquel Xr                 |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |
|                                                              | Seroquel Xr                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                              | Seroquel Xr                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                              | Seroquel Xr                 |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                              | Clomethiazole               |              |            | S           | Oral         | 600 Mg             |                 | Not Reported |
|                                                              | Clomethiazole               |              |            | S           |              |                    |                 | Not Reported |
|                                                              | Buprenorphine Hydrochloride |              |            | S           | Oral         | 0.1 Mg             |                 | Not Reported |
|                                                              | Dafalgan                    |              |            | C           | Oral         | 3 G                |                 | Not Reported |
|                                                              | Insulatard Nph Human        |              |            | C           | Other        | 30 Iu              |                 | Not Reported |
|                                                              | Insulatard Nph Human        |              |            | C           |              | 16 Iu              |                 | Not Reported |
|                                                              | Beloc-Zok                   |              |            | C           | Oral         | 12.5 Mg            |                 | Not Reported |
|                                                              | Phosphonorm                 |              |            | C           | Oral         | 900 Mg             |                 | Not Reported |
|                                                              | Levothyroxine Sodium        |              |            | C           | Oral         | 150 Mcg            |                 | Not Reported |
|                                                              | Lasix                       |              |            | C           | Oral         | 500 Mg             |                 | Not Reported |
|                                                              | Lasix                       |              |            | C           | Oral         | 250 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                                                     |                      |                    |                    |                 |                          |                                          |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------------------|-----------------|--------------|----------------|
| Pramipexole Dihydrochloride                                                                                                                                                                                                         |                      |                    | C                  | Oral            | 0.075 Mg                 |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Mar-2012                                                                                                                                                                                                                         | 8447947              | EXPEDITED (15-DAY) | Y                  | HO              | FR10S00054               |                                          | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Interaction; Hyperreflexia; Hypertension; Hypertonia; Hyponatraemia;                                                                                                                                        | Loramyc              |                    |                    | S               |                          | 50 Mg Milligram (S) X                    |                 | Not Reported |                |
| Overdose; Serotonin Syndrome; Somnolence; Tachycardia; Tremor                                                                                                                                                                       | Seroplex             |                    |                    | S               | Buccal                   | 5 Mg Milligram (S) X 1 1 Per Days Buccal |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Levothyroxine Sodium |                    |                    | C               |                          |                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Timolol Maleate      |                    |                    | C               |                          |                                          |                 | Not Reported |                |
|                                                                                                                                                                                                                                     | Travoprost           |                    |                    | C               |                          |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 07-Mar-2012                                                                                                                                                                                                                         | 8445413              | EXPEDITED (15-DAY) | Y                  | CA, HO, OT      | DE-FRI-1000028438        |                                          | < 1 DAY         | Male         | DEU            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation Neonatal; Atrial Septal Defect; Foetal Exposure During Pregnancy; Infantile Apnoea; Maternal Exposure During Breast Feeding; Neonatal Respiratory Distress Syndrome; Overdose; Patent Ductus Arteriosus; Pyelocaliectasis | Escitalopram Oxalate |                    |                    | S               | Transplacental           | 40 Mg                                    |                 | Forest       |                |
|                                                                                                                                                                                                                                     | Escitalopram Oxalate |                    |                    | S               | Transmammary             |                                          |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 08-Mar-2012                                                                                                                                                                                                                         | 8430530              | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2012049897 |                                          |                 | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Insomnia; Mania; Weight Increased                                                                                                                                                                                          | Zoloft               |                    |                    | S               |                          | Unk                                      |                 | Pfizer       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |                 |              |
|---------------------|---|-----------------|--------------|
| Celexa              | S | Unk             | Not Reported |
| Paxil               | S | 5 Mg, Unk       | Not Reported |
| Prozac              | S | Unk             | Not Reported |
| Ativan              | S | 0.5 Mg, 3x/Day  | Not Reported |
| Lexapro             | S | Unk             | Not Reported |
| Brovana             | C | 15 Ug, 2x/Day   | Not Reported |
| Budesonide          | C | 0.25 Mg, 2x/Day | Not Reported |
| Ipratropium Bromide | C | 0.2 %, 1x/Day   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-Mar-2012              | 8447002       | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16422461 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Thrombosis            | Abilify        |              |            | S           |              |                    |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2012              | 8447531       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000028893    |                      | 60 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Acute Respiratory Distress Syndrome; Overdose; Respiratory Failure; Somnolence | Escitalopram Oxalate |              |            | S           | Oral         | 1 Df               |                 | Forest       |
|                                                                                | Prazepam             |              |            | S           | Oral         | 2 Df               |                 | Not Reported |
|                                                                                | Levothyrox           |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Amisulpride          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Mirtazapine          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Pantoprazole         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                | Praxinor             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2012              | 8455645       | EXPEDITED (15-DAY) | Y                  | CA              | 2012020256           |                      |            | Female     | DEU            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                       |   |                |                |              |
|--------------------------|-----------------------|---|----------------|----------------|--------------|
| Maternal Drugs Affecting | Zolpidem              | S | Transplacental | Transplacental | Not Reported |
| Foetus; Oesophageal      | Mycophenolate Mofetil | S | Transplacental | Transplacental | Not Reported |
| Atresia; Premature Baby; | Escitalopram Oxalate  | S | Transplacental | Transplacental | Not Reported |
| Tracheal Atresia         | Lorazepam             | S | Transplacental | Transplacental | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-Mar-2012              | 8461083       | EXPEDITED (15-DAY) | N                  | OT              | DSA_55286_2012       |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Seizure               | Wellbutrin XI (Not Specified) |              |            | S           |              | (300 Mg, )         |                 | Not Reported |
|                       | Viibryd                       |              |            | S           |              | (Df)               |                 | Not Reported |
|                       | Lexapro                       |              |            | S           |              | (Df)               |                 | Not Reported |
|                       | Ambien                        |              |            | S           |              | (Df)               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Mar-2012              | 8450335       | EXPEDITED (15-DAY) | Y                  | LT, OT          | DE-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-00779RO |                      | 43 YR      | Male       | DEU            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Emotional Distress;    | Ropinirole           |              |            | S           |              | 0.75 Mg            |                 | Roxane       |
| Gambling Disorder;     | Ropinirole           |              |            | S           |              | 2 Mg               |                 | Roxane       |
| Nicotine Dependence;   | Escitalopram Oxalate |              |            | S           |              | 30 Mg              |                 | Not Reported |
| Suicide Attempt; Theft | Escitalopram Oxalate |              |            | S           |              | 20 Mg              |                 | Not Reported |
|                        | Quetiapine           |              |            | S           |              | 100 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 09-Mar-2012              | 8456200       | DIRECT           |                    |                 |                      |                      | 29 YR      | Female     | USA            |

| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Affect Lability; Agitation; | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
| Alanine Aminotransferase    | Actigall             |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |            |   |              |
|----------------------------|------------|---|--------------|
| Increased; Anxiety;        | Prednisone | C | Not Reported |
| Aspartate                  | Ativan     | C | Not Reported |
| Aminotransferase           | Imuran     | C | Not Reported |
| Increased; Autoimmune      | Phenergan  | C | Not Reported |
| Hepatitis; Blood Bilirubin | Zyprexa    | C | Not Reported |
| Increased; Chromaturia;    |            |   |              |
| Crying; Dyspnoea;          |            |   |              |
| Encephalopathy; Fatigue;   |            |   |              |
| Hallucination; Insomnia;   |            |   |              |
| International Normalised   |            |   |              |
| Ratio Increased; Jaundice; |            |   |              |
| Liver Disorder; Liver      |            |   |              |
| Injury; Nausea; Pruritus;  |            |   |              |
| Rash                       |            |   |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Mar-2012              | 8437815       | EXPEDITED (15-DAY) | Y                  | OT              | CY-FRI-1000028374    |                      | 26 YR      | Male       | CYP            |

| <u>Preferred Term</u>                                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Creatine<br>Phosphokinase Increased;<br>Overdose | Escitalopram Oxalate |              |            | S           | Oral         | 40 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Mar-2012              | 8453640       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012060644 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Anger; Anxiety; Apathy;<br>Blood Pressure   | Effexor Xr           |              |            | S           | Oral         | 150 Mg, 1x/Day (1 Cap Po<br>Nightly) |                 | Pfizer       |
| Decreased; Crying;<br>Depression; Feeling   | Effexor Xr           |              |            | S           | Oral         | 75 Mg, 1x/Day (1 Cap Po<br>Nightly)  |                 | Pfizer       |
| Abnormal; Hunger;<br>Nicotine Dependence;   | Lexapro              |              |            | S           |              | Unk                                  |                 | Not Reported |
| Obsessive Thoughts;<br>Onychophagia; Weight | Lexapro              |              |            | S           |              | 60 Mg, Daily                         |                 | Not Reported |
| Increased                                   | Metoprolol Succinate |              |            | S           |              | 50 Mg, Daily                         |                 | Not Reported |
|                                             | Elavil               |              |            | C           |              | Unk                                  |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |                  |              |
|-------------|---|------------------|--------------|
| Nicoderm Cq | C | Unk              | Not Reported |
| Dexidrine   | C | Unk              | Not Reported |
| Oxybutynin  | C | 5 Mg             | Not Reported |
| Ativan      | C | 0.5 Mg 1 1/2/Day | Not Reported |
| Micronor    | C | Unk              | Not Reported |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Mar-2012                       | 8454623                | EXPEDITED (15-DAY)        | N                           | CA                       | US-FRI-1000028952             |                               | < 1 DAY             | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Coarctation Of The Aorta       | Lexapro                 |                       |                     | S                    | Transplacental        |                             |                          | Forest              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 12-Mar-2012                       | 8454923                | EXPEDITED (15-DAY)        | Y                           | DE                       | NL-ASTRAZENECA-2012SE15410    |                               | 26 YR               | Female              | NLD                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Completed Suicide; Death       | Seroquel                |                       |                     | S                    | Oral                  |                             |                          | Zeneca              |
|                                | Lexapro                 |                       |                     | S                    | Oral                  |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Mar-2012                       | 8455615                | EXPEDITED (15-DAY)        | Y                           | HO, LT                   | FR-FRI-1000028997             |                               | 19 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Lung Disorder                  | Escitalopram Oxalate    |                       |                     | S                    | Oral                  | 20 Mg                       |                          | Forest              |
|                                | Prazepam                |                       |                     | C                    |                       |                             |                          | Not Reported        |
|                                | Varnoline               |                       |                     | C                    |                       |                             |                          | Not Reported        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Mar-2012                       | 8455647                | EXPEDITED (15-DAY)        | Y                           | OT                       | FR-FRI-1000029004             |                               | 77 YR               | Female              | FRA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |                        |   |      |         |              |
|---------|------------------------|---|------|---------|--------------|
| Purpura | Escitalopram Oxalate   | S | Oral | 10 Mg   | Forest       |
|         | Xanax                  | C | Oral | 0.25 Mg | Not Reported |
|         | Stilnox                | C | Oral |         | Not Reported |
|         | Isoptin                | C |      |         | Not Reported |
|         | Lescol                 | C |      |         | Not Reported |
|         | Orocal D3              | C |      |         | Not Reported |
|         | Tramadol Hydrochloride | C | Oral |         | Not Reported |

| <u>FDA Received Date</u>                                                        | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Mar-2012                                                                     | 8456001        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000028955    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Congenital Anomaly;<br>Craniosynostosis; Foetal<br>Exposure During<br>Pregnancy | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 13-Mar-2012                                    | 8456256        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000028957    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cleft Lip; Cleft Palate;<br>Congenital Anomaly | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                                                                                                            | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 13-Mar-2012                                                                                                                                                         | 8456664                      | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2012AU019801     |                      | 25 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                               | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Akathisia; Depression;<br>Drug Interaction;<br>Ejaculation Failure;<br>Feeling Of Despair;<br>Homicidal Ideation;<br>Impulsive Behaviour; | Sertraline Hydrochloride     |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Novartis     |                |
|                                                                                                                                                                     | Escitalopram Oxalate         |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |
|                                                                                                                                                                     | Hypericum Perforatum Extract |                    |                    | S               |                      | Unk Ukn, Unk         |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Mania; Paranoia;  
Personality Change;  
Serotonin Syndrome;  
Suicide Attempt

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2012              | 8456804       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000011010    |                      | 50 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                  | <u>Product</u>                             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------|--------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebral Vasoconstriction;<br>Cerebrovascular Accident | Escitalopram Oxalate                       |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                                                        | Derinox (Naphazoline Nitrate\Prednisolone) |              |            | S           | Nasal        | 3 Dosage Form      |                 | Not Reported |
|                                                        | Relpax                                     |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                        | Flurbiprofen                               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                        | Codeine                                    |              |            | C           | Oral         | 45 Ml              |                 | Not Reported |
|                                                        | Cefuroxime                                 |              |            | C           | Oral         | 500 Mg             |                 | Not Reported |
|                                                        | Paracetamol                                |              |            | C           | Oral         | 1500 Mg            |                 | Not Reported |
|                                                        | Paracetamol                                |              |            | C           | Oral         | 3 Gram             |                 | Not Reported |
|                                                        | Topalgic (France)                          |              |            | C           | Oral         | 300 Mg             |                 | Not Reported |
|                                                        | Oxazepam                                   |              |            | C           | Oral         | 25 Mg              |                 | Not Reported |
|                                                        | Loprazolam Mesilate                        |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                                        | Propranolol                                |              |            | C           | Oral         | 160 Mg             |                 | Not Reported |
|                                                        | Depakote                                   |              |            | C           | Oral         | 750 Mg             |                 | Not Reported |
|                                                        | Citalopram                                 |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2012              | 8456856       | EXPEDITED (15-DAY) | Y                  | HO              | SE-FRI-1000021521    |                      | 48 YR      | Female     | SWE            |

| <u>Preferred Term</u>         | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amyotrophic Lateral Sclerosis | Escitalopram Oxalate        |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                               | Influenza Virus Vaccine Nos |              |            | S           | Other        |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |   |      |              |
|---------------------------|---|------|--------------|
| Almogran                  | C | Oral | Not Reported |
| Levothyroxine Sodium      | C | Oral | Not Reported |
| Treo                      | C | Oral | Not Reported |
| Acetaminophen And Codeine | C | Oral | Not Reported |
| Zopiclone                 | C | Oral | Not Reported |
| Naprosyn                  | C | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Mar-2012              | 8456912       | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000019377    |                      | 30 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Gestational Diabetes;<br>Pregnancy; Premature<br>Delivery | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 2.5 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>              | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------|----------------------|------------|------------|----------------|
| 14-Mar-2012              | 8457792       | EXPEDITED (15-DAY) | N                  | HO, OT          | US-US-EMD SERONO,<br>INC.-7117365 |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Depression; Fatigue; Self-<br>Injurious Ideation | Rebif          |              |            | S           | Subcutaneous |                    |                 | Not Reported |
|                                                  | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
|                                                  | Marijuana      |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2012              | 8467440       | DIRECT           | Y                  | HO              |                      |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|------------------------------------------|----------------------|-----------------|--------------|
| Arrhythmia; Bundle<br>Branch Block Right;<br>Cardiomyopathy;<br>Electrocardiogram Qt<br>Prolonged;<br>Electrocardiogram T Wave | Ondansetron          |              |            | S           | Intravenous (not<br>otherwise specified) | 4 Mg/ Once Iv Recent |                 | Not Reported |
|                                                                                                                                | Droperidol           |              |            | S           | Intravenous (not<br>otherwise specified) | 0.625 Once Iv Recent |                 | Not Reported |
|                                                                                                                                | Escitalopram Oxalate |              |            | S           | Oral                                     | Po Chronic           |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                |                             |   |              |
|----------------------------------------------------------------|-----------------------------|---|--------------|
| Inversion; Electrolyte Imbalance; Post Procedural Complication | Alprazolam                  | C | Not Reported |
|                                                                | Lexapro                     | C | Not Reported |
|                                                                | M.V.I. Adult                | C | Not Reported |
|                                                                | Aprepitant                  | C | Not Reported |
|                                                                | Dexamethasone               | C | Not Reported |
|                                                                | Midazolam                   | C | Not Reported |
|                                                                | Ondansetron                 | C | Not Reported |
|                                                                | Scopolamine                 | C | Not Reported |
|                                                                | Clodomycin                  | C | Not Reported |
|                                                                | Magnesium Sulfate           | C | Not Reported |
|                                                                | Hydromorphone Hydrochloride | C | Not Reported |
|                                                                | Promethazine                | C | Not Reported |
|                                                                | Lr                          | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2012              | 8469179       | DIRECT           | Y                  | OT              |                      |                      | 22 YR      | Male       | USA            |

| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Depression; Product Substitution Issue | Escitalopram Oxalate |              |            | S           |              | 20mg 1 Wk With Generic |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2012              | 8469474       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2012-01364   |                      | 67 YR      | Male       |                |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Aggression; Decreased Interest; Depressed Mood; Drug Interaction; Fatigue; Hypomania; Insomnia | Mirtazapine (Mirtazapine)                   |              |            | S           |              | (7.5 Mg, 1 D), Unknown |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate (Escitalopram Oxalate) |              |            | S           |              | (10 Mg, 1 D), Unknown  |                 | Not Reported |
|                                                                                                | Amlodipine                                  |              |            | C           |              |                        |                 | Not Reported |
|                                                                                                | Losartan Potassium                          |              |            | C           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-Mar-2012              | 8487846       | NON-EXPEDITED    | N                  |                 | PHHY2011US62097      |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abnormal Behaviour;   | Fanapt         |              |            | S           |              | 8 Mg, Bid          |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                          |   |              |
|----------------------------|--------------------------|---|--------------|
| Insomnia; Weight Increased | Saphris                  | S | Not Reported |
|                            | Lexapro                  | S | Not Reported |
|                            | Seroquel                 | S | Not Reported |
|                            | Risperdal                | S | Not Reported |
|                            | Pristiq Extended Release | C | Not Reported |
|                            | Effexor Xr               | C | Not Reported |

| <u>FDA Received Date</u>                             | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------|--------------------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 15-Mar-2012                                          | 8221463                                    | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | FR-PFIZER INC-2011261856 |                      | 31 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ascites; Oedema<br>Peripheral; Pulmonary<br>Embolism | Stediril [Ethinyl<br>Estradiol/Norgestrel] |                    |                    | S               | Oral                     | 1 Df, Cyclic         |                 | Pfizer       |                |
|                                                      | Alprazolam                                 |                    |                    | S               | Oral                     | 0.25 Mg, 3x/Day      |                 | Pfizer       |                |
|                                                      | Zyprexa                                    |                    |                    | S               | Oral                     | 5 Mg, 1x/Day         | 28 DAY          | Not Reported |                |
|                                                      | Escitalopram Oxalate                       |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 15-Mar-2012              | 8461833        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000028973    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Craniosynostosis         | Lexapro        |                    |                    | S               | Transplacental       |                      |                 | Forest     |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2012                                        | 8438314                 | EXPEDITED (15-DAY) | Y                  |                 | JP-FRI-1000028736    |                      | 83 YR           | Female       | JPN            |
| <u>Preferred Term</u>                              | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Feeling Abnormal;<br>Headache; Nausea;<br>Vomiting | Lexapro                 |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                    | Eperisone Hydrochloride |                    |                    | C               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                    | Nexium                  |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                    | Teprenone               |                    |                    | C               | Oral                 | 180 Mg               |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|--------------|----------------|
| 16-Mar-2012                                                                                                                                                               | 8462981                  | EXPEDITED (15-DAY) | Y                  | OT              | AU-MYLANLABS-2012S1005008 |                      | 24 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Drug Interaction; Suicide Attempt                                                                                                                              | Sertraline Hydrochloride |                    |                    | S               | Unknown                   |                      |                 | Mylan        |                |
|                                                                                                                                                                           | Escitalopram Oxalate     |                    |                    | S               | Unknown                   | 10 Mg/Day            |                 | Not Reported |                |
|                                                                                                                                                                           | Hypericum Perforatum     |                    |                    | S               | Unknown                   | 900 Mg/Day           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2012                                                                                                                                                               | 8464189                  | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000029128         |                      | 46 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Epilepsy; Tetany                                                                                                                                                          | Escitalopram Oxalate     |                    |                    | S               |                           | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                           | Mirtazapine              |                    |                    | C               |                           | 15 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2012                                                                                                                                                               | 8464233                  | EXPEDITED (15-DAY) | Y                  | CA, HO          | ES-FRI-1000024659         |                      | 35 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                                                                                                                                     | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Hyperinsulinism; Hypoglycaemia Neonatal; Macrocephaly; Patent Ductus Arteriosus; Periventricular Leukomalacia | Escitalopram Oxalate     |                    |                    | S               | Transplacental            | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                           | Escitalopram Oxalate     |                    |                    | S               | Transplacental            | 10 Mg                |                 | Not Reported |                |
|                                                                                                                                                                           | Escitalopram Oxalate     |                    |                    | S               | Transplacental            | 5 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                           | Bromazepam               |                    |                    | S               | Transplacental            | 3 Mg                 |                 | Not Reported |                |
|                                                                                                                                                                           | Bromazepam               |                    |                    | S               | Transplacental            | 1.5 Mg               |                 | Not Reported |                |
|                                                                                                                                                                           | Lormetazepam             |                    |                    | S               | Transplacental            | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Mar-2012                                                                                                                                                               | 8464234                  | EXPEDITED (15-DAY) | Y                  | CA, HO          | ES-FRI-1000024660         |                      | 35 YR           | Male         | ESP            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|--------------|----------------|
| Anaemia Neonatal; Atrial Septal Defect; Foetal Exposure During Pregnancy; Hypocalcaemia; Hypoparathyroidism | Escitalopram Oxalate        |                    |                    | S               | Transplacental                           | 10 Mg                |                 | Forest       |                |
|                                                                                                             | Escitalopram Oxalate        |                    |                    | S               | Transplacental                           | 10 Mg                |                 | Not Reported |                |
|                                                                                                             | Escitalopram Oxalate        |                    |                    | S               | Transplacental                           | 5 Mg                 |                 | Not Reported |                |
|                                                                                                             | Bromazepam                  |                    |                    | S               | Transplacental                           | 3 Mg                 |                 | Not Reported |                |
|                                                                                                             | Bromazepam                  |                    |                    | S               | Transplacental                           | 1.5 Mg               |                 | Not Reported |                |
|                                                                                                             | Lormetazepam                |                    |                    | S               | Transplacental                           | 1 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2012                                                                                                 | 8430015                     | EXPEDITED (15-DAY) | N                  | OT              | US-BRISTOL-MYERS SQUIBB COMPANY-16409419 |                      | 65 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Deafness Unilateral                                                                                         | Abilify                     |                    |                    | S               | Oral                                     |                      |                 | Not Reported |                |
|                                                                                                             | Lipitor                     |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                             | Lexapro                     |                    |                    | S               |                                          |                      |                 | Not Reported |                |
|                                                                                                             | Xanax                       |                    |                    | S               |                                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                    | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 19-Mar-2012                                                                                                 | 8465217                     | EXPEDITED (15-DAY) | Y                  | HO              | BE-PFIZER INC-2012065935                 |                      | 88 YR           | Male         | BEL            |
| <u>Preferred Term</u>                                                                                       | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fall; Hypoglycaemia; Hypotonia; Muscular Weakness; Myoclonus; Paraesthesia                                  | Lyrica                      |                    |                    | S               | Oral                                     | 75 Mg, 1x/Day        | 9 DAY           | Pfizer       |                |
|                                                                                                             | Piperacillin And Tazobactam |                    |                    | S               | Intravenous (not otherwise specified)    | 4 G, 3x/Day          | 9 DAY           | Pfizer       |                |
|                                                                                                             | Cipralext                   |                    |                    | S               | Oral                                     | 10 Mg, 1x/Day        | 9 DAY           | Not Reported |                |
|                                                                                                             | Casodex                     |                    |                    | C               | Oral                                     | 50 Mg, 1x/Day        |                 | Not Reported |                |
|                                                                                                             | Leuprolide Acetate          |                    |                    | C               | Intramuscular                            | 1 Unk, Cyclic        |                 | Not Reported |                |
|                                                                                                             | Amlodipine Besylate         |                    |                    | C               | Oral                                     | 5 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                                             | Tamsulosin Hydrochloride    |                    |                    | C               | Oral                                     | 4 Mg, 1x/Day         |                 | Not Reported |                |
|                                                                                                             | Innohep                     |                    |                    | C               |                                          | 0.7 MI, 1x/Day       |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                 |   |      |                |              |
|--|-----------------|---|------|----------------|--------------|
|  | Ferrous Sulfate | C | Oral | 525 Mg, 1x/Day | Not Reported |
|  | Vitamin D2      | C | Oral | Unk            | Not Reported |
|  | Bumetanide      | C | Oral | 1 Mg, 1x/Day   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 19-Mar-2012              | 8466503       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000029154    |                      | 75 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                                    | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------------------|------------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Coagulopathy; Drug Interaction; International Normalised Ratio Increased | Escitalopram Oxalate   |              |            | S           | Oral         | 15 Mg                |                 | Forest       |
|                                                                          | Tavanic                |              |            | S           | Oral         | 250 Mg               |                 | Not Reported |
|                                                                          | Previscan (Fluindione) |              |            | S           | Oral         | 3 Or 4 Tablets Daily |                 | Not Reported |
|                                                                          | Rifadine               |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Tildiem                |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Plavix                 |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Xanax                  |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Levothyrox             |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Aprovel                |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Movicol                |              |            | C           |              |                      |                 | Not Reported |
|                                                                          | Acetaminophen          |              |            | C           |              |                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 20-Mar-2012              | 8468469       | EXPEDITED (15-DAY) | N                  | HO              | US-FRI-1000024018    |                      | 90 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Diverticulitis; Fatigue; Gastrointestinal Haemorrhage; Poor Quality Sleep | Lexapro         |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                                                                    | Lexapro         |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                    | Proscar         |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Ferrous Sulfate |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Nexium          |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Docusate Sodium |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Multi-Vitamin   |              |            | C           |              |                    |                 | Not Reported |
|                                                                                    | Lisinopril      |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                                                    | Simvastatin     |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                                                                                    | Norvasc         |              |            | C           | Oral         | 2.5 Mg             |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                                                                                                                                                                             | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|---------------------------|-----------------|--------------|----------------|
| 20-Mar-2012                                                                                                                                                                                                                                                          | 8478928                                        | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2012-01409           |                           | 25 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Akathisia; Depression;<br>Ejaculation Failure; Mania;<br>Overdose; Paranoia;<br>Personality Change;<br>Substance Use; Suicide<br>Attempt; Toxicity To<br>Various Agents                                                                    | Sertraline Hydrochloride                       |                    |                    | S               |                              | 300 Mg (300 Mg, 1 In 1 D) |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                      | Escitalopram Oxalate<br>(Escitalopram Oxalate) |                    |                    | S               |                              | 10 Mg (10 Mg, 1 In 1 D)   |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                      | Hypericum Perforatum Extract                   |                    |                    | S               |                              | 900 Mg (900 Mg, 1 In 1 D) |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                             | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-Mar-2012                                                                                                                                                                                                                                                          | 8481359                                        | EXPEDITED (15-DAY) | Y                  | OT              | 2012AP000685                 |                           | 25 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Agitation;<br>Akathisia; Depression;<br>Drug Interaction;<br>Ejaculation Failure;<br>Feeling Of Despair;<br>Imprisonment; Impulsive<br>Behaviour; Mania;<br>Paranoia; Personality<br>Change; Physical Assault;<br>Serotonin Syndrome;<br>Suicide Attempt | Sertraline Hydrochloride                       |                    |                    | S               |                              |                           |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                      | Escitalopram Oxalate                           |                    |                    | S               |                              | 10 Mg;Qd                  |                 | Not Reported |                |
|                                                                                                                                                                                                                                                                      | Hypericum                                      |                    |                    | S               |                              | 900 Mg; Qd                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                                                                                             | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-Mar-2012                                                                                                                                                                                                                                                          | 8471264                                        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2012069691 |                           | 82 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                                                                                                | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>   |                |
| Pruritus                                                                                                                                                                                                                                                             | Aldactone                                      |                    |                    | S               |                              | Unk                       |                 | Pfizer       |                |
|                                                                                                                                                                                                                                                                      | Furosemide                                     |                    |                    | S               |                              | Unk                       |                 | Not Reported |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |               |              |
|------------|---|---------------|--------------|
| Ativan     | S | Unk           | Not Reported |
| Vitamin C  | S | Unk           | Not Reported |
| Lexapro    | S | 10 Mg, 2x/Day | Not Reported |
| Lexapro    | S | 10 Mg, 1x/Day | Not Reported |
| Prilosec   | S | Unk           | Not Reported |
| Fish Oil   | S | Unk           | Not Reported |
| Toprol XL  | C | Unk           | Not Reported |
| Gabapentin | C | Unk           | Not Reported |
| Carafate   | C | Unk           | Not Reported |
| Atarax     | C | Unk           | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Mar-2012              | 8471772              | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2012CA023350     |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt     | Furosemide           |                    |                    | S               |                      |                      |                 | Novartis     |                |
| Prolonged; Hypokalaemia; | Escitalopram Oxalate |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Torsade De Pointes       | Quetiapine           |                    |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Mar-2012                  | 8473900        | DIRECT           | N                  | OT              |                      |                      | 42 YR           | Male         | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Physical Assault | Lexapro        |                  |                    | S               | Oral                 | 10mg                 |                 | Not Reported |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-Mar-2012                                | 8476432        | DIRECT           |                    |                 |                      |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                      | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Medication Error; Product Dispensing Error | Lexapro        |                  |                    | S               | Oral                 | Tablet By Mouth      |                 | Not Reported |                |
|                                            | Lipitor        |                  |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|--------------|----------------|
| 23-Mar-2012                                                                                                             | 8473129                  | EXPEDITED (15-DAY) | Y                  | OT              | CA-MYLANLABS-2012S1005654  |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Torsade De Pointes                                                                      | Furosemide               |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                         | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                         | Quetiapine               |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2012                                                                                                             | 8474018                  | EXPEDITED (15-DAY) | Y                  | OT              | CA-TEVA-329059USA          |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Torsade De Pointes                                               | Furosemide               |                    |                    | S               | Unknown                    |                      |                 | Ivax         |                |
|                                                                                                                         | Quetiapine               |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
|                                                                                                                         | Escitalopram Oxalate     |                    |                    | S               | Unknown                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2012                                                                                                             | 8474418                  | EXPEDITED (15-DAY) | Y                  | OT              | AU-WATSON-2012-05131       |                      | 25 YR           | Male         | AUS            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aggression; Akathisia; Depression; Drug Interaction; Ejaculation Failure; Paranoia; Physical Assault; Suicidal Ideation | Sertraline Hydrochloride |                    |                    | S               | Oral                       |                      |                 | Watson       |                |
|                                                                                                                         | Escitalopram Oxalate     |                    |                    | S               |                            |                      |                 | Not Reported |                |
|                                                                                                                         | Hypericum Perforatum     |                    |                    | S               |                            |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Mar-2012                                                                                                             | 8474655                  | EXPEDITED (15-DAY) | Y                  | HO              | HU-ASTRAZENECA-2012SE17625 |                      | 53 YR           | Female       | HUN            |
| <u>Preferred Term</u>                                                                                                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Sinus Arrhythmia                                                                                                        | Quetiapine               |                    |                    | S               | Oral                       |                      |                 | Zeneca       |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |              |              |
|----------------------|---|--------------|--------------|
| Lithium Carbonate    | S | Unknown      | Not Reported |
| Carbamazepine        | S | Unknown      | Not Reported |
| Escitalopram Oxalate | S | Unknown      | Not Reported |
| Acetylsalicylic Acid | C |              | Not Reported |
| Amiloride            | C |              | Not Reported |
| Hydrochlorothiazide  | C |              | Not Reported |
| Levothyroxine        | C |              | Not Reported |
| Clonazepam           | C | 0.5-0.5-3 Mg | Not Reported |
| Cinolazepam          | C |              | Not Reported |
| Ketoconazole         | C |              | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-Mar-2012              | 8475034       | EXPEDITED (15-DAY) | Y                  | HO              | NO-FRI-1000026208    |                      | 69 YR      | Male       | NOR            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------------------|--------------------------|-----------------|--------------|
| Leukopenia; Neutropenia | Escitalopram Oxalate |              |            | S           |                          | 10 Mg                    |                 | Forest       |
|                         | Penicillin           |              |            | S           | Intravenous bolus        | 12 G                     |                 | Not Reported |
|                         | Ventolin             |              |            | C           | Respiratory (inhalation) | 5 Mg/MI Four Times Daily |                 | Not Reported |
|                         | Aspirin\Dipyridamole |              |            | C           | Oral                     | 2 Df                     |                 | Not Reported |
|                         | Theophylline         |              |            | C           | Oral                     | 700 Mg                   |                 | Not Reported |
|                         | Atrovent             |              |            | C           | Respiratory (inhalation) |                          |                 | Not Reported |
|                         | Simvastatin          |              |            | C           | Oral                     | 20 Mg                    |                 | Not Reported |
|                         | Prednisolone         |              |            | C           | Oral                     | 40 Mg Daily Tapering     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2012              | 8463402       | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-FRI-1000029073    |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Maternal Exposure During Breast | Escitalopram Oxalate |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                   | Escitalopram Oxalate |              |            | S           | Transmammary   |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Feeding; Neonatal  
Disorder; Restlessness;  
Selective Eating Disorder

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2012              | 8476923       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000029336    |                      | 91 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Spinal Cord Haemorrhage | Escitalopram Oxalate   |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                         | Previscan (Fluindione) |              |            | S           | Oral         | 5 Mg               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 26-Mar-2012              | 8477002       | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | IT-FRI-1000014266    |                      | 26 YR      | Female     | ITA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Arthralgia; Drug Reaction With Eosinophilia And Systemic Symptoms; Myalgia; Nausea | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                                                    | Lamotrigine          |              |            | S           | Oral         | 50 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2012              | 8479010       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000011613    |                      | 41 YR      | Female     | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Transaminases Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                         | Xanax                |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 27-Mar-2012              | 8504152       | NON-EXPEDITED    | Y                  | OT              | PHEH2009US13124      |                      | 71 YR      | Female     | USA            |

| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Crying; Depression; Insomnia | Gleevec        |              |            | S           | Oral         | 400 Mg, Qd, Oral   |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                               |                                      |                    |                    |                 |                         |                      |                 |              |                |
|-----------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| Lexapro                                       |                                      | S                  |                    | Not Reported    |                         |                      |                 |              |                |
| Cymbalta                                      |                                      | S                  |                    | Not Reported    |                         |                      |                 |              |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2012                                   | 8487516                              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54276 |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                             | Metformin Hydrochloride              |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                                               | Escitalopram Oxalate                 |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                               | Esomeprazole                         |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                               | Metoprolol                           |                    |                    | S               | Oral                    | Unk, Unk             |                 | Ipca         |                |
|                                               | Acetaminophen\Unspecified Ingredient |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 28-Mar-2012                                   | 8560148                              | NON-EXPEDITED      | N                  | OT              | PHHY2010US23539         |                      | 85 YR           | Male         | USA            |
| <u>Preferred Term</u>                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Inadequately Controlled        | Valturna                             |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                               | Escitalopram Oxalate                 |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                               | Valsartan                            |                    |                    | C               |                         |                      |                 | Not Reported |                |
|                                               | Carvedilol                           |                    |                    | C               |                         |                      |                 | Not Reported |                |
|                                               | Temazepam                            |                    |                    | C               |                         |                      |                 | Not Reported |                |
| Aspirin                                       |                                      |                    | C                  |                 |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                      | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 29-Mar-2012                                   | 8454267                              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000028962       |                      | 83 YR           | Female       | FRA            |
| <u>Preferred Term</u>                         | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State; Drug Level Increased; Fall | Escitalopram Oxalate                 |                    |                    | S               | Oral                    | 10 Mg                |                 | Forest       |                |
|                                               | Acetaminophen                        |                    |                    | S               |                         |                      |                 | Not Reported |                |
|                                               | Bromazepam                           |                    |                    | S               |                         | 12 Mg                |                 | Not Reported |                |
|                                               | Donormyl (Doxylamine Succinate)      |                    |                    | S               |                         | 15 Mg                |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |        |              |
|------------|---|------|--------|--------------|
| Levothyrox | C | Oral | 75 Mcg | Not Reported |
| Tanakan    | C | Oral | 120 Mg | Not Reported |
| Ramipril   | C | Oral |        | Not Reported |
| Inexium    | C | Oral | 20 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 29-Mar-2012              | 8481532       | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-JNJFOC-20120313231 |                      | 58 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>                              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------|---------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Disorientation; Drug<br>Interaction; Serotonin<br>Syndrome; Tachyphrenia | Tramadol Hydrochloride And<br>Acetaminophen |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                | Baclofen                                    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Xanax                                       |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Arthrotec                                   |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Zolpidem                                    |              |            | C           | Unknown      |                    |                 | Not Reported |
|                                                                                                | Escitalopram Oxalate                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                |                                             |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2012              | 8454317       | EXPEDITED (15-DAY) | Y                  | OT              | HU-FRI-1000028967    |                      | 47 YR      | Female     | HUN            |

| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Ventricular Extrasystoles | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                           | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Xanax                |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                           | Xanax                |              |            | C           | Oral         | 0.5 Mg             |                 | Not Reported |
|                           | Concor               |              |            | C           | Oral         | 1.25 Mg            |                 | Not Reported |
|                           |                      |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Mar-2012              | 8485694       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000029298    |                      |            | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>                                             |                |
|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|--------------------|------------------|----------------------|-----------------------------------------------------------------------------------|-----------------|--------------------------------------------------------|----------------|
| Muscle Spasticity;<br>Musculoskeletal Stiffness;<br>Pain                                                         | Lexapro<br>Wellbutrin<br>Cymbalta<br>Tramadol Hydrochloride |                    |                    | S<br>S<br>S<br>S |                      |                                                                                   |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 30-Mar-2012                                                                                                      | 8496597                                                     | EXPEDITED (15-DAY) | Y                  | HO               | 2012SP016141         |                                                                                   | 38 YR           | Female                                                 | CHE            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Electrocardiogram Qt<br>Prolonged; Intentional<br>Overdose; Somnolence;<br>Suicide Attempt; Vomiting             | Remeron<br>Ciprallex<br>Alcohol (Ethanol)                   |                    |                    | S<br>S<br>S      | Oral<br>Oral         | 30 Mg;Once;Po<br>30 Mg;Once;Po                                                    |                 | Not Reported<br>Not Reported<br>Not Reported           |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 30-Mar-2012                                                                                                      | 8497597                                                     | DIRECT             |                    | DS, OT           |                      |                                                                                   |                 | Female                                                 | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Arthritis; Eye Disorder;<br>Glucose Tolerance<br>Impaired; Macular<br>Degeneration; Spinal<br>Stenosis; Tinnitus | Losartan Potassium<br>Lexapro                               |                    |                    | S<br>S           |                      | 100mg/ Cut To 50mg &<br>Also To 75mg 1 Per Day<br>5mg 1 X Per Nite                |                 | Not Reported<br>Not Reported                           |                |
| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>                                               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u> | <u>503B Facility</u>                                                              | <u>Age</u>      | <u>Sex</u>                                             | <u>Country</u> |
| 30-Mar-2012                                                                                                      | 8555336                                                     | NON-EXPEDITED      | Y                  | OT               | PHHY2011US55324      |                                                                                   |                 | Male                                                   | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>                                              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>         | <u>Dosage Text</u>                                                                | <u>Duration</u> | <u>Mfr</u>                                             |                |
| Hallucination, Visual                                                                                            | Exelon<br>Lexapro<br>Namenda                                |                    |                    | S<br>S<br>S      | Transdermal          | 1 Df, One Per Day (4.6<br>Mg), Transdermal<br>5 Mg, Per Day<br>2 Df, 5 Mg Per Day |                 | Not Reported<br>Not Reported<br>Not Reported           |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2012                                                                      | 8449558              | EXPEDITED (15-DAY) | Y                  | HO              | AU-FRI-1000028619    |                      | 44 YR           | Female       | AUS            |
| <u>Preferred Term</u>                                                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Circulatory Collapse;<br>Electrocardiogram Qt<br>Prolonged; Sinus<br>Bradycardia | Escitalopram Oxalate |                    |                    | S               |                      | 20 Mg                |                 | Forest       |                |
|                                                                                  | Seroquel             |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                  | Levothyroxine Sodium |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                  | Pariet               |                    |                    | C               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2012                                              | 8486830              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54470 |                      | 50 YR           | Female       | USA            |
| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed<br>Suicide; Respiratory Arrest | Lorazepam            |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                          | Escitalopram Oxalate |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                          | Oxcarbazepine        |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                          | Quetiapine           |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                          | Zolpidem Tartrate    |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                          | Bupropion            |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u>                                                    | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------|--------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2012                                                                 | 8487117            | DIRECT           | Y                  | HO              |                      |                      | 4 YR            | Female       | USA            |
| <u>Preferred Term</u>                                                       | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Restlessness;<br>Tachycardia; Therapy<br>Non-Responder; Vomiting | Vyvanse 30mg Shire |                  |                    | S               |                      |                      |                 | Shire        |                |
|                                                                             | Lexapro            |                  |                    | S               |                      |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 02-Apr-2012              | 8488078        | EXPEDITED (15-DAY) | Y                  | OT              | BR-FRI-1000029484    |                      | 34 YR           | Female     | BRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                        |            |   |      |       |              |
|----------------------------------------|------------|---|------|-------|--------------|
| Blood Pressure Increased;              | Lexapro    | S | Oral | 20 Mg | Forest       |
| Dyspepsia; Hyperhidrosis;              | Lexapro    | S | Oral | 10 Mg | Forest       |
| Pain In Extremity; Vaginal Haemorrhage | Alprazolam | C | Oral | 1 Mg  | Not Reported |
|                                        | Alprazolam | C |      |       | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2012              | 8488079       | EXPEDITED (15-DAY) | Y                  | CA              | DK-FRI-1000025965    |                      | 27 YR      | Male       | DNK            |

| <u>Preferred Term</u>                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>                        | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|-------------------------------------------|-----------------|------------|
| Foetal Exposure During Pregnancy; Motor Developmental Delay; Speech Disorder | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg Daily In First And Second Trimester |                 | Forest     |
| Developmental                                                                | Escitalopram Oxalate |              |            | S           | Transplacental | 30 Mg Daily In 3rd Trimester              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2012              | 8488237       | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000029463    |                      | 16 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------------------------|-----------------|------------|
| Intentional Overdose; Intentional Self-Injury; Off Label Use; Seizure | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg                                  |                 | Forest     |
|                                                                       | Escitalopram Oxalate |              |            | S           | Oral         | Overdose: Escitalopram (50 Mg At Once) |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 02-Apr-2012              | 8499850       | EXPEDITED (15-DAY) | Y                  | HO              | 2012SP016422         |                      | 23 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt Prolonged; Overdose; Restlessness;                      | Remeron        |              |            | S           | Oral         | Po                 |                 | Not Reported |
| Somnolence; Suicide Attempt; Tachycardia; Toxicity To Various Agents; Tremor | Lorazepam      |              |            | S           | Oral         | 10 Mg;Once;Po      |                 | Not Reported |
|                                                                              | Cipralext      |              |            | S           | Oral         | Po                 |                 | Not Reported |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-Apr-2012                                                                                                                                                                                  | 8500786                                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | 2012SP016446         |                      | 15 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agitation; Epilepsy;<br>Intentional Overdose;<br>Poisoning; Somnolence;<br>Suicide Attempt                                                                                                   | Remeron                                        |                    |                    | S               | Oral                 | 10 Df, Once, Po      |                 | Not Reported |                |
|                                                                                                                                                                                              | Ciprallex                                      |                    |                    | S               | Oral                 | 11 Df, Once, Po      |                 | Not Reported |                |
|                                                                                                                                                                                              | Cocaine (Cocaine)                              |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |
|                                                                                                                                                                                              | Cannabis Sativa Subsp. Sativa<br>Flowering Top |                    |                    | S               |                      | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-Apr-2012                                                                                                                                                                                  | 8660606                                        | NON-EXPEDITED      | N                  | OT              | PHHY2010US18795      |                      | 73 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Asthenia; Burning<br>Sensation; Chest Pain;<br>Depression; Dizziness;<br>Dyspnoea; Fatigue;<br>Hyperhidrosis; Myocardial<br>Depression; Pain In<br>Extremity; Palpitations;<br>Rash | Exforge                                        |                    |                    | S               |                      | 5/120 Mg             |                 | Not Reported |                |
|                                                                                                                                                                                              | Penicillin (Benzylpenicillin<br>Sodium)        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Sulfamethoxazole                               |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Prozac                                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Escitalopram Oxalate                           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Zoloft                                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Atenolol (Atenolol)                            |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Premarin                                       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Aspirin                                        |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                     | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2012                                                                                                                                                                                  | 8490835                                        | EXPEDITED (15-DAY) | Y                  | OT              | 2012SP000518         |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                        | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous                                                                                                                                                                         | Latuda                                         |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Metformin Hydrochloride                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Lexapro                                        |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Unspecified Ingredient                         |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                              | Aspirin                                        |                    |                    | S               |                      |                      |                 | Not Reported |                |

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|                                                       |                               |                    |                    |                 |                         |                      |                 |              |                |
|-------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| Lovenox                                               |                               | S                  |                    | Not Reported    |                         |                      |                 |              |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2012                                           | 8491296                       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54535 |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Lorazepam                     |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                       | Escitalopram Oxalate          |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                       | Alcohol                       |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2012                                           | 8491304                       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54541 |                      | 24 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Lorazepam                     |                    |                    | S               | Oral                    |                      |                 | Ranbaxy      |                |
|                                                       | Clonazepam                    |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate          |                    |                    | S               | Oral                    | Unk, Unk             |                 | Not Reported |                |
|                                                       | Bupropion Hydrochloride       |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                       | Trazodone Hydrochloride       |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2012                                           | 8491380                       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54598 |                      | 49 YR           | Female       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                     | Cyclobenzaprine Hydrochloride |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                       | Amitriptyline                 |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                       | Escitalopram Oxalate          |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-Apr-2012                                           | 8491766                       | EXPEDITED (15-DAY) | Y                  | LT              | AU-FRI-1000029495       |                      | 23 YR           | Male         | AUS            |

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| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
|----------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Erectile Dysfunction; Loss Of Libido; Memory Impairment; Suicidal Ideation | Lexapro                  |                    |                    | S               | Oral                         |                      |                 | Forest          |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Apr-2012                                                                | 8492086                  | EXPEDITED (15-DAY) | N                  | OT              | US-JNJFOC-20120400391        |                      |                 | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Muscle Spasticity; Musculoskeletal Stiffness; Pain       | Tramadol Hydrochloride   |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                            | Unspecified Ingredient   |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                            | Cymbalta                 |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                            | Lexapro                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                            | Wellbutrin               |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Apr-2012                                                                | 8492306                  | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0972041A |                      | 48 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective; Insomnia; Mood Swings; Paranoia; Suicidal Ideation       | Wellbutrin               |                    |                    | S               | Oral                         |                      |                 | Glaxosmithkline |                |
|                                                                            | Seroquel                 |                    |                    | S               | Unknown                      | 300mgd Per Day       | 3 YR            | Glaxosmithkline |                |
|                                                                            | Lexapro                  |                    |                    | S               | Unknown                      |                      |                 | Not Reported    |                |
|                                                                            | Pristiq Extended Release |                    |                    | S               | Unknown                      | 50mgd Per Day        |                 | Not Reported    |                |
| <u>FDA Received Date</u>                                                   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 03-Apr-2012                                                                | 8501420                  | EXPEDITED (15-DAY) | Y                  | HO, OT          | AUR-APL-2012-01601           |                      | 81 YR           | Female          | ITA            |
| <u>Preferred Term</u>                                                      | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Atrial Fibrillation; Bradyarrhythmia; Syncope                              | Atenolol (Atenolol)      |                    |                    | S               | Oral                         | (100 Mg, 1 D), Oral  |                 | Not Reported    |                |

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|                       |   |             |                                       |              |
|-----------------------|---|-------------|---------------------------------------|--------------|
| Rivastigmine Tartrate | S | Oral        | (1 Dosage Forms, 1 D),<br>Oral        | Not Reported |
| Minitran              | S | Transdermal | (1 Dosage Forms, 1 D0,<br>Transdermal | Not Reported |
| Amlodipine Besylate   | S | Oral        | (1 Dosage Forms), Oral                | Not Reported |
| Ramipril              | S | Oral        | (1 Dosage Forms), Oral                | Not Reported |
| Escitalopram Oxalate  | S | Oral        | (1 Dosage Forms), Oral                | Not Reported |
| Aspirin               | S | Oral        | 91 Dosage Forms), Oral                | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|-----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 03-Apr-2012               | 8502568         | EXPEDITED (15-DAY) | Y                  | HO              | 2012SP016684         |                      | 33 YR           | Female       | CHE            |
| <u>Preferred Term</u>     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Coma; Electrocardiogram   | Remeron         |                    |                    | S               | Oral                 | 30 Mg;Po             |                 | Not Reported |                |
| Qt Prolonged;             | Chlorprothixene |                    |                    | S               | Oral                 | 15 Mg;Po             |                 | Not Reported |                |
| Hypokalaemia; Intentional | Lorazepam       |                    |                    | S               | Oral                 | 1 Mg;Po              |                 | Not Reported |                |
| Overdose; Pneumonia       | Cipralelex      |                    |                    | S               | Oral                 | 10 Mg;Po             |                 | Not Reported |                |
| Aspiration; Poisoning;    |                 |                    |                    |                 |                      |                      |                 |              |                |
| Respiratory Failure;      |                 |                    |                    |                 |                      |                      |                 |              |                |
| Suicide Attempt;          |                 |                    |                    |                 |                      |                      |                 |              |                |
| Tachycardia               |                 |                    |                    |                 |                      |                      |                 |              |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| 04-Apr-2012              | 8354887        | EXPEDITED (15-DAY) | Y                  | HO              | CH-ASTRAZENECA-<br>2012SE04203 |                      | 17 YR           | Male         | CHE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Nausea                   | Seroquel Xr    |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Seroquel Xr    |                    |                    | S               | Oral                           |                      | 61 DAY          | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Oral                           |                      | 10 DAY          | Not Reported |                |
|                          | Cipralelex     |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Amisulpride    |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                          | Amisulpride    |                    |                    | S               | Oral                           |                      | 7 DAY           | Not Reported |                |
|                          | Amisulpride    |                    |                    | S               | Oral                           |                      | 4 DAY           | Not Reported |                |

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| <u>FDA Received Date</u>                                  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------|-----------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 04-Apr-2012                                               | 8411275         | EXPEDITED (15-DAY) | Y                  | HO              | JP-JNJFOC-20120205844   |                      | 59 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hepatic Function Abnormal                                 | Risperdal       |                    |                    | S               | Oral                    | 0.5-2 Mg/Day         |                 | Not Reported |                |
|                                                           | Risperdal       |                    |                    | S               | Oral                    | 0.5-2 Mg/Day         |                 | Not Reported |                |
|                                                           | Zoloft          |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                           | Zoloft          |                    |                    | S               | Oral                    | 25-100/Day           |                 | Not Reported |                |
|                                                           | Zoloft          |                    |                    | S               | Oral                    | 25-100/Day           |                 | Not Reported |                |
|                                                           | Zoloft          |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                           | Lexapro         |                    |                    | S               | Oral                    |                      |                 | Not Reported |                |
|                                                           | Lexapro         |                    |                    | S               | Oral                    | 10-20/Day            |                 | Not Reported |                |
|                                                           | Magnesium Oxide |                    |                    | C               | Oral                    | 100-600/Day          |                 | Not Reported |                |
|                                                           | Sennoside       |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                           | Sulpiride       |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
|                                                           | Brotizolam      |                    |                    | C               | Oral                    |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2012                                               | 8484636         | EXPEDITED (15-DAY) | Y                  | HO              | US-FRI-1000028430       |                      | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Bacteraemia; Disorientation; Overdose; Serotonin Syndrome | Lexapro         |                    |                    | S               |                         | 40 Mg                |                 | Forest       |                |
|                                                           | Zyvox           |                    |                    | S               |                         |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2012                                               | 8493334         | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54660 |                      | 62 YR           | Male         | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                         | Carvedilol      |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |

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|                         |   |      |              |
|-------------------------|---|------|--------------|
| Diazepam                | S | Oral | Not Reported |
| Diltiazem Hydrochloride | S | Oral | Not Reported |
| Escitalopram Oxalate    | S | Oral | Not Reported |
| Lisinopril              | S | Oral | Ranbaxy      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493349       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54673 |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Completed Suicide; Respiratory Arrest | Acetaminophen              |              | Y          | S           | Oral         | Unk                |                 | Ranbaxy      |
|                                                       | Escitalopram Oxalate       |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                       | Propoxyphene Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493355       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54682 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>                                                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------|----------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cardiac Arrest; Death; Respiratory Arrest | Simvastatin                                                                      |              |            | S           | Oral         |                    |                 | Ranbaxy      |
|                                           | Escitalopram Oxalate                                                             |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Memantine                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Metoprolol                                                                       |              |            | S           | Oral         | Unk                |                 | Ipca         |
|                                           | Solifenacin Succinate                                                            |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Dextroamphet Saccharat, Amphet Aspartate, Dextroamphet Sulfate And Amphet Sulfat |              |            | S           | Oral         |                    |                 | Not Reported |
|                                           | Clozapine                                                                        |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493386       | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-54736 |                      | 35 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |                      |   |      |     |              |
|---------------------|----------------------|---|------|-----|--------------|
| Accidental Overdose | Gabapentin           | S | Oral | Unk | Ranbaxy      |
|                     | Escitalopram Oxalate | S | Oral | Unk | Not Reported |
|                     | Quetiapine           | S | Oral | Unk | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493534       | EXPEDITED (15-DAY) | Y                  | HO              | ES-FRI-1000029528    |                      | 74 YR      | Female     | ESP            |

| <u>Preferred Term</u>              | <u>Product</u>                          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|-----------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia | Escitalopram Oxalate                    |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                    | Amiloride Hcl W/<br>Hydrochlorothiazide |              |            | S           |              | 5 Mg/50 Mg         |                 | Not Reported |
|                                    | Ferrous Sulfate                         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                    | Calcifediol                             |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493709       | EXPEDITED (15-DAY) | Y                  | OT              | SE-FRI-1000029532    |                      | 39 YR      | Female     | SWE            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Electric Shock        | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493713       | EXPEDITED (15-DAY) | Y                  |                 | DE-FRI-1000027466    |                      | 36 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                             | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Agitation; Drug Interaction;<br>Feeling Abnormal;<br>Restlessness | Escitalopram Oxalate |              |            | S           |              | Changing Dosages       |                 | Forest       |
|                                                                   | Escitalopram Oxalate |              |            | S           |              | 20 Mg                  |                 | Forest       |
|                                                                   | Escitalopram Oxalate |              |            | S           |              | Decreased Dosage (Nos) |                 | Forest       |
|                                                                   | Nystatin             |              |            | S           |              |                        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-Apr-2012              | 8493745       | EXPEDITED (15-DAY) | Y                  | OT              | IE-FRI-1000029534    |                      |            | Female     | IRL            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|----------------------------------------------------------------------------------------------------|----------------------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|-----------------|--------------|----------------|
| Contusion; Vaginal<br>Haemorrhage                                                                  | Lexapro                    |                    |                    | S               | Oral                                                |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2012                                                                                        | 8494069                    | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000029479                                   |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Congenital Anomaly;<br>Respiratory Distress;<br>Ventricular Septal Defect | Lexapro                    |                    |                    | S               | Transplacental                                      |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2012                                                                                        | 8494434                    | EXPEDITED (15-DAY) | Y                  | DE              | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-00949RO |                      |                 | Unknown      | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Toxicity To Various Agents                                                                         | Methadone Hydrochloride    |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                                                    | Alprazolam                 |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                                                    | Citalopram                 |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                                                    | Amlodipine                 |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                                                    | Naproxen                   |                    |                    | S               |                                                     |                      |                 | Roxane       |                |
|                                                                                                    | Promethazine               |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                    | Marijuana                  |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                    | Pioglitazone Hydrochloride |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                    | Trazodone Hydrochloride    |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
|                                                                                                    | Escitalopram Oxalate       |                    |                    | S               |                                                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                           | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-Apr-2012                                                                                        | 8510434                    | DIRECT             | Y                  |                 |                                                     |                      | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                              | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Depression;<br>Disease Recurrence; Drug<br>Ineffective; Product                           | Escitalopram Oxalate       |                    |                    | S               | Oral                                                | 20mg One Qd Oral     |                 | Mylan        |                |
|                                                                                                    | Lexapro                    |                    |                    | S               |                                                     |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Substitution Issue

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2012              | 8432307       | EXPEDITED (15-DAY) | N                  | CA, HO, OT      | US-FRI-1000028126    |                      | < 1 DAY    | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Atrial Septal Defect;<br>Cardiomegaly;<br>Hydronephrosis;<br>Hypertension; Jaundice<br>Neonatal; Nodal Rhythm;<br>Urinary Tract Infection<br>Neonatal; Ventricular<br>Septal Defect | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2012              | 8432837       | EXPEDITED (15-DAY) | N                  | CA, HO          | US-FRI-1000028145    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                                                                                                                              | <u>Product</u>                                      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------|------------|-----------------------|----------------|--------------------|-----------------|------------------------------------------------------------------------|
| Congenital Tricuspid Valve<br>Atresia; Pleural Effusion;<br>Pneumothorax; Pulmonary<br>Valve Stenosis; Subdural<br>Haemorrhage;<br>Transposition Of The<br>Great Vessels; Urinary<br>Tract Infection; Ventricular<br>Septal Defect | Lexapro<br>Prenatabs Fa<br>Iron<br>Pepcid<br>Colace |              |            | S<br>C<br>C<br>C<br>C | Transplacental |                    |                 | Forest<br>Not Reported<br>Not Reported<br>Not Reported<br>Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Apr-2012              | 8483734       | EXPEDITED (15-DAY) | Y                  | LT, OT          | DE-FRI-1000029424    |                      | 23 YR      | Female     | DEU            |

| <u>Preferred Term</u>                                                 | <u>Product</u>                               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                     | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>             |
|-----------------------------------------------------------------------|----------------------------------------------|--------------|------------|-------------|----------------------------------|--------------------|-----------------|------------------------|
| Cerebral Haemorrhage<br>Neonatal; Foetal Exposure<br>During Pregnancy | Escitalopram Oxalate<br>Escitalopram Oxalate |              |            | S<br>S      | Transplacental<br>Transplacental | 10 Mg<br>5 Mg      |                 | Forest<br>Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------------|-----------------|-------------------------|----------------------|-----------------|--------------|----------------|
| 05-Apr-2012                                                                                                                                          | 8495385                              | DIRECT             | N                  | OT              |                         |                      | 46 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Crying;<br>Depression; Drug<br>Withdrawal Syndrome;<br>Product Substitution Issue;<br>Tremor                                                | Escitalopram Oxalate                 |                    |                    | S               | Oral                    | 20.0 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2012                                                                                                                                          | 8495886                              | EXPEDITED (15-DAY) | Y                  | DE              | US-RANBAXY-2012US-55008 |                      | 48 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Death                                                                                                                                                | Acetaminophen\Hydrocodone Bitartrate |                    |                    | S               | Oral                    | Unk                  |                 | Ranbaxy      |                |
|                                                                                                                                                      | Escitalopram Oxalate                 |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
|                                                                                                                                                      | Buprenorphine\Naloxone               |                    |                    | S               | Oral                    | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2012                                                                                                                                          | 8496058                              | EXPEDITED (15-DAY) | N                  | HO, OT          | PHHY2010IN37440         |                      | 46 YR           | Female       | IND            |
| <u>Preferred Term</u>                                                                                                                                | <u>Product</u>                       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>            | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anhedonia; Anxiety; Blood Follicle Stimulating Hormone Increased; Depressed Mood; Drug Interaction; Galactorrhoea; Intracranial Mass; Sleep Disorder | Glyburide                            |                    |                    | S               |                         | 5 Mg Per Day         |                 | Novartis     |                |
|                                                                                                                                                      | Imipramine                           |                    |                    | S               |                         | 75 Mg Per Day        |                 | Not Reported |                |
|                                                                                                                                                      | Escitalopram Oxalate                 |                    |                    | S               |                         | 20 Mg Per Day        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                             | <u>Case #</u>                        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 05-Apr-2012                                                                                                                                          | 8496656                              | EXPEDITED (15-DAY) | Y                  | DE              | GB-FRI-1000029577       |                      |                 | Male         | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Overdose; Respiratory Failure                                                                                                                                         | Escitalopram Oxalate |                    |                    | S               | Oral                 | 50 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2012                                                                                                                                                           | 8433984              | EXPEDITED (15-DAY) | N                  | CA, HO, OT      | US-FRI-1000028153    |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arnold-Chiari Malformation; Dehydration; Dilatation Ventricular; Epilepsy; Hydrocele; Hydrocephalus; Hypoglycaemia; Hypotension; Microcephaly; Phimosis; Spina Bifida | Lexapro              |                    |                    | S               | Transplacental       |                      |                 | Forest       |                |
|                                                                                                                                                                       | Prenate Elite        |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Pepcid               |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Prevacid             |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Tums                 |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Roloids              |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Prilosec             |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Tylenol              |                    |                    | C               | Transplacental       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2012                                                                                                                                                           | 8497994              | EXPEDITED (15-DAY) | Y                  | HO              | ES-FRI-1000026524    |                      | 67 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscular Weakness; Myopathy                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                                                                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2012                                                                                                                                                           | 8498321              | EXPEDITED (15-DAY) | Y                  | HO              | JP-FRI-1000028442    |                      | 65 YR           | Male         | JPN            |
| <u>Preferred Term</u>                                                                                                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Loss Of Consciousness                                                                                                                                                 | Lexapro              |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                                                                                                                       | Sulpiride            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |
|                                                                                                                                                                       | Anafranil            |                    |                    | C               | Oral                 |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                 |                              |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Cymbalta                                                                                                                                                                                        |                              |                    | C                  |                 | Oral                 |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 06-Apr-2012                                                                                                                                                                                     | 8498407                      | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029453    |                      | 18 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Fatigue; Feeling Abnormal; Homicidal Ideation; Nausea                                                                                                                                           | Lexapro                      |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                                                                                                                                 | Lexapro                      |                    |                    | S               |                      |                      | 14 DAY          | Forest       |                |
|                                                                                                                                                                                                 | Klonopin                     |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2012                                                                                                                                                                                     | 8339845                      | EXPEDITED (15-DAY) | Y                  | OT              | 2011SP060107         |                      | 29 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Agranulocytosis; Asthenia; Infection; Viral Upper Respiratory Tract Infection                                                                                                                   | Celestamine                  |                    |                    | S               | Oral                 | 1 Df;Qd;Po           |                 | Not Reported |                |
|                                                                                                                                                                                                 | Disulfiram                   |                    |                    | S               | Oral                 | 500 Mg;Po            |                 | Not Reported |                |
|                                                                                                                                                                                                 | Escitalopram Oxalate         |                    |                    | S               | Oral                 | Po                   |                 | Not Reported |                |
|                                                                                                                                                                                                 | Dienogest\Estradiol Valerate |                    |                    | S               | Oral                 | 1 Df;Qd;Po           |                 | Not Reported |                |
|                                                                                                                                                                                                 | Aerius (Desloratadine)       |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                                                                                                                                 | Augmentin                    |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                        | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 09-Apr-2012                                                                                                                                                                                     | 8485767                      | EXPEDITED (15-DAY) |                    | HO              | IE-FRI-1000029419    |                      | 80 YR           | Female       | IRL            |
| <u>Preferred Term</u>                                                                                                                                                                           | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Sodium Decreased; Cardiac Failure; Condition Aggravated; Dysphagia; Fall; Fluid Intake Reduced; General Physical Health Deterioration; Pleural Effusion; Psychotic Disorder; Therapy Non- | Lexapro                      |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                                                                                                                                 | Unspecified Ingredient       |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Responder; Urinary Tract  
Infection

| <u>FDA Received Date</u>                              | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>             | <u>Country</u> |
|-------------------------------------------------------|-------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------------------|----------------|
| 09-Apr-2012                                           | 8491424                             | EXPEDITED (15-DAY) |                    | OT              | IE-FRI-1000029458    |                      | 28 YR           | Male                   | IRL            |
| <u>Preferred Term</u>                                 | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>             |                |
| Blood Prolactin Increased;<br>Galactorrhoea; Headache | Escitalopram Oxalate<br>Risperidone |                    |                    | S<br>S          |                      |                      |                 | Forest<br>Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>                                                                                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                                                                 | <u>Country</u> |
|----------------------------|----------------------------------------------------------------------------------------------------------------|--------------------|--------------------|----------------------------|-----------------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------------|----------------|
| 09-Apr-2012                | 8499746                                                                                                        | EXPEDITED (15-DAY) | Y                  | DE                         | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-00964RO |                      |                 | Unknown                                                                    | USA            |
| <u>Preferred Term</u>      | <u>Product</u>                                                                                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                                        | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                                                                 |                |
| Toxicity To Various Agents | Methadone Hydrochloride<br>Diazepam<br>Quetiapine Fumarate<br>Topiramate<br>Escitalopram Oxalate<br>Clonazepam |                    |                    | S<br>S<br>S<br>S<br>S<br>S |                                                     |                      |                 | Roxane<br>Roxane<br>Roxane<br>Not Reported<br>Not Reported<br>Not Reported |                |

| <u>FDA Received Date</u>                                                                                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------------------------------------------------------------------------------------|--------------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Apr-2012                                                                                                      | 8500148                  | DIRECT           | N                  | DE              |                      |                      | 23 YR           | Male       | USA            |
| <u>Preferred Term</u>                                                                                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abnormal Behaviour; Gun<br>Shot Wound; Intentional<br>Self-Injury; Partner Stress;<br>Product Substitution Issue | Escitalopram 20 Mg Mylan |                  |                    | S               |                      |                      |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-------------------------------|----------------------|----------------------|-----------------|------------|----------------|
| 09-Apr-2012              | 8500184        | DIRECT           | N                  | CA, DE, DS, HO,<br>LT, RI, OT |                      |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                              |                          |   |      |           |       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---|------|-----------|-------|
| Anger; Anxiety; Crying;<br>Disturbance In Attention;<br>Drug Ineffective;<br>Emotional Disorder;<br>Irritability; Mood Swings;<br>Product Substitution Issue | Escitalopram 20 Mg Mylan | S | Oral | 2 Tablets | Mylan |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---|------|-----------|-------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 09-Apr-2012              | 8500430       | EXPEDITED (15-DAY) | Y                  | DE              | US-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-00972RO |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Toxicity To Various Agents | Methadone Hydrochloride |              |            | S           |              |                    |                 | Roxane       |
|                            | Citalopram              |              |            | S           |              |                    |                 | Roxane       |
|                            | Alprazolam              |              |            | S           |              |                    |                 | Roxane       |
|                            | Promethazine            |              |            | S           |              |                    |                 | Not Reported |
|                            | Quinine Sulfate         |              |            | S           |              |                    |                 | Not Reported |
|                            | Trazodone Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                            | Escitalopram Oxalate    |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2012              | 8291269       | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2011US108287     |                      | 56 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Metoprolol           |              |            | S           |              |                    |                 | Novartis     |
|                       | Clonazepam           |              |            | S           |              |                    |                 | Not Reported |
|                       | Quetiapine           |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |
|                       | Metoclopramide       |              |            | S           |              |                    |                 | Not Reported |
|                       | Duloxetine           |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2012              | 8478941       | EXPEDITED (15-DAY) | Y                  | HO              | NL-FRI-1000029362    |                      | 81 YR      | Female     | NLD            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Condition     | Citalopram     |              |            | S           | Oral         | 20 Mg              |                 | Forest     |
| Aggravated; Feeling Of | Citalopram     |              |            | S           |              |                    |                 | Forest     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |            |   |      |       |              |
|---------------------------------------------------|------------|---|------|-------|--------------|
| Despair; Malaise; Nausea;<br>Nervousness; Tension | Citalopram | S | Oral | 20 Mg | Forest       |
|                                                   | Citalopram | S | Oral | 10 Mg | Forest       |
|                                                   | Citalopram | S | Oral | 20 Mg | Forest       |
|                                                   | Lexapro    | S | Oral | 10 Mg | Forest       |
|                                                   | Lexapro    | S |      |       | Forest       |
|                                                   | Alprazolam | C | Oral |       | Not Reported |
|                                                   | Oxazepam   | C |      |       | Not Reported |

| <u>FDA Received Date</u>                                                                                                    | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|-----------------|-----------------|----------------|
| 10-Apr-2012                                                                                                                 | 8498096                | EXPEDITED (15-DAY) | Y                  | OT              | US-<br>GLAXOSMITHKLINE-<br>A0972437A |                      | 42 YR           | Male            | USA            |
| <u>Preferred Term</u>                                                                                                       | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Cerebrovascular Accident;<br>Drug Ineffective;<br>Hypertension; Muscle<br>Spasticity;<br>Musculoskeletal Stiffness;<br>Pain | Wellbutrin             |                    |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                                                                             | Lexapro                |                    |                    | S               | Unknown                              |                      |                 | Not Reported    |                |
|                                                                                                                             | Cymbalta               |                    |                    | S               | Oral                                 |                      |                 | Glaxosmithkline |                |
|                                                                                                                             | Tramadol Hydrochloride |                    |                    | S               | Unknown                              |                      |                 | Glaxosmithkline |                |
|                                                                                                                             | Unspecified Ingredient |                    |                    | S               | Unknown                              |                      | 4 YR            | Glaxosmithkline |                |

| <u>FDA Received Date</u>                                                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------------|----------------------|-----------------|--------------|----------------|
| 10-Apr-2012                                                                                                          | 8501324              | EXPEDITED (15-DAY) | Y                  | OT              | CA-SANOFI-AVENTIS-<br>2012SA023308 |                      | 67 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Electrocardiogram Qt<br>Prolonged; Electrolyte<br>Imbalance; Hypokalaemia;<br>Hypomagnesaemia;<br>Torsade De Pointes | Furosemide           |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                      | Quetiapine Fumarate  |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |
|                                                                                                                      | Escitalopram Oxalate |                    |                    | S               | Unknown                            |                      |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2012              | 8501352        | EXPEDITED (15-DAY) | N                  | HO              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16490807 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                   |          |   |                                               |              |
|---------------------------------------------------|----------|---|-----------------------------------------------|--------------|
| Loss Of Consciousness;<br>Orthostatic Hypotension | Abilify  | S | Initially Given 5 Mg Then<br>Reduced To 2.5mg | Not Reported |
|                                                   | Lexapro  | S | Dose:5mg                                      | Not Reported |
|                                                   | Vitamins | C |                                               | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2012              | 8502037       | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029593    |                      |            | Female     | USA            |

| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Heart Rate Increased;<br>Nephrolithiasis; Suicidal<br>Ideation | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|------------|------------|----------------|
| 10-Apr-2012              | 8502603       | EXPEDITED (15-DAY) | Y                  | OT              | CA-ARROW GEN-2012-<br>05912 |                      | 67 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Electrocardiogram Qt<br>Prolonged; Torsade De<br>Pointes | Furosemide           |              |            | S           | Unknown      | Unk                |                 | Watson       |
|                                                          | Quetiapine           |              |            | S           | Unknown      | Unk                |                 | Not Reported |
|                                                          | Escitalopram Oxalate |              |            | S           | Unknown      | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 10-Apr-2012              | 8693880       | NON-EXPEDITED    | Y                  | OT              | AUR-APL-2011-05649   |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                 | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Angioedema; Drug<br>Hypersensitivity; Lip<br>Swelling; Swollen Tongue | Lisinopril (Lisinopril) |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                       | Penicillin              |              |            | S           |              | Unknown            |                 | Not Reported |
|                                                                       | Benadryl                |              |            | S           |              |                    |                 | Not Reported |
|                                                                       | Lexapro                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                       | Mobic                   |              |            | S           | Oral         | 1 D, Oral          |                 | Not Reported |
|                                                                       | Prinzide                |              |            | S           | Oral         | 1 D, Oral          |                 | Not Reported |
|                                                                       | Celebrex                |              |            | C           |              |                    |                 | Not Reported |
|                                                                       | Allegra-D (Allegra-D)   |              |            | C           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                        |                                                                     |                    |                    |                 |                              |                      |                 |                 |                |
|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|-----------------|----------------|
| Amoxicillin                                                                                                                            |                                                                     | C                  |                    | Not Reported    |                              |                      |                 |                 |                |
| Nasonex                                                                                                                                |                                                                     | C                  |                    | Not Reported    |                              |                      |                 |                 |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Apr-2012                                                                                                                            | 8140357                                                             | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-GLAXOSMITHKLINE-B0746122A |                      | 48 YR           | Female          | FRA            |
| <u>Preferred Term</u>                                                                                                                  | <u>Product</u>                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Agranulocytosis;<br>Bacteraemia; Bone<br>Marrow Failure; Cellulitis;<br>Hyperthermia; Respiratory<br>Disorder; Sepsis; Septic<br>Shock | Betamethasone                                                       |                    |                    | S               | Topical                      |                      | 49 DAY          | Glaxosmithkline |                |
|                                                                                                                                        | Escitalopram Oxalate                                                |                    |                    | S               | Oral                         | 15mg Per Day         | 49 DAY          | Unknown         |                |
|                                                                                                                                        | Cyamemazine                                                         |                    |                    | S               | Oral                         | 112.5mg Per Day      | 49 DAY          | Unknown         |                |
|                                                                                                                                        | Tropatepine                                                         |                    |                    | S               | Oral                         | 10mg Per Day         | 28 DAY          | Unknown         |                |
|                                                                                                                                        | Chlormadinone Acetate                                               |                    |                    | S               | Oral                         | 10mg Per Day         | 42 DAY          | Unknown         |                |
|                                                                                                                                        | Estradiol                                                           |                    |                    | S               | Oral                         | 2mg Per Day          | 42 DAY          | Unknown         |                |
|                                                                                                                                        | Milnacipran Hydrochloride                                           |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Xanax                                                               |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Lyrica                                                              |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Paracetamol                                                         |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Tegretol                                                            |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Mineral Oil                                                         |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Magnesium Lactate\Magnesium<br>Pidolate\Pyridoxine<br>Hydrochloride |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Lormetazepam                                                        |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Amorolfine Hydrochloride                                            |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Aerius (Desloratadine)                                              |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Crataegus                                                           |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
|                                                                                                                                        | Heptaminol Hydrochloride                                            |                    |                    | C               | Unknown                      |                      |                 | Unknown         |                |
| <u>FDA Received Date</u>                                                                                                               | <u>Case #</u>                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Apr-2012                                                                                                                            | 8476993                                                             | EXPEDITED (15-DAY) | Y                  | OT              | BE-FRI-1000029299            |                      | 44 YR           | Female          | BEL            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|-----------------------|-----------------|--------------|----------------|
| Eye Haemorrhage                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 10 Mg                 |                 | Forest       |                |
|                                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 15 Mg                 |                 | Forest       |                |
|                                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 20 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2012                                                                                                                                               | 8503639              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000029687    |                       |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Affect Lability; Agitation;<br>Flat Affect; Irritability;<br>Overdose                                                                                     | Escitalopram Oxalate |                    |                    | S               | Oral                 | Overdose: 40 Mg Daily |                 | Forest       |                |
|                                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | Overdose: 25 Mg Daily |                 | Forest       |                |
|                                                                                                                                                           | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-Apr-2012                                                                                                                                               | 8525074              | DIRECT             | Y                  | OT              |                      |                       | 21 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Akathisia; Amnesia;<br>Anxiety; Disturbance In<br>Attention; Dyskinesia;<br>Memory Impairment;<br>Mental Status Changes;<br>Panic Attack;<br>Restlessness | Abilify              |                    |                    | S               | Oral                 | 5mg Daily Oral        |                 | Not Reported |                |
|                                                                                                                                                           | Lexapro              |                    |                    | S               | Oral                 | 10mg Daily Oral       |                 | Forest       |                |
|                                                                                                                                                           | Citalopram           |                    |                    | S               |                      |                       |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 12-Apr-2012                                                                                                                                               | 8468680              | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000029135    |                       | 38 YR           | Female       | JPN            |
| <u>Preferred Term</u>                                                                                                                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Loss Of<br>Consciousness; Nausea;<br>Photopsia                                                                                                  | Lexapro              |                    |                    | S               | Oral                 | 10 Mg                 |                 | Forest       |                |
|                                                                                                                                                           | Lithium Carbonate    |                    |                    | C               | Oral                 | 400 Mg                |                 | Not Reported |                |
|                                                                                                                                                           | Ludiomil             |                    |                    | C               | Oral                 | 20 Mg                 |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |         |              |
|------------|---|------|---------|--------------|
| Myslee     | C | Oral | 10 Mg   | Not Reported |
| Brotizolam | C | Oral | 0.25 Mg | Not Reported |
| Nizatidine | C | Oral | 150 Mg  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2012              | 8483743       | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000029398    |                      | 78 YR      | Female     | ITA            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Bradykinesia;                             | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Forest     |
| Bradyphrenia; Intentional Overdose; Sopor | Escitalopram Oxalate |              |            | S           | Oral         | Overdose: 300 Mg   |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-Apr-2012              | 8505816       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2012090048 |                      | 66 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Urine Odour Abnormal  | Lipitor        |              |            | S           | Oral         | 40 Mg, Daily       |                 | Pfizer       |
|                       | Lipitor        |              |            | S           | Oral         | 40 Mg, Daily       |                 | Pfizer       |
|                       | Lexapro        |              |            | S           |              | 10 Mg, Daily       |                 | Not Reported |
|                       | Lexapro        |              |            | S           |              | 10 Mg, Daily       |                 | Not Reported |
|                       | Glucophage     |              |            | C           |              | 1000 Mg, 2x/Day    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2012              | 8507862       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000029638    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Anal Atresia          | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 12-Apr-2012              | 8520425       | EXPEDITED (15-DAY) | Y                  | RI, OT          | FK201200929          |                      | 67 YR      | Female     | CAN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Potassium<br>Decreased; Torsade De<br>Pointes | Furosemide           |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Quetiapine Fumarate  |              |            | S           |              |                    |                 | Not Reported |
|                                                     | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2012              | 8445161       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000024586    |                      |            | Male       | USA            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|----------------|---------------------------------|-----------------|--------------|
| Supraventricular<br>Extrasystoles | Lexapro        |              |            | S           | Transplacental | 20 Mg                           | 8 MTH           | Forest       |
|                                   | Lexapro        |              |            | S           |                |                                 |                 | Forest       |
|                                   | Valtrex        |              |            | C           | Transplacental | 500 Mg                          |                 | Not Reported |
|                                   | Zofran         |              |            | C           | Transplacental | 4 Mg Every 8 Hours As<br>Needed |                 | Not Reported |
|                                   | Prenatabs Fa   |              |            | C           | Transplacental |                                 |                 | Not Reported |
|                                   | Zinc Sulfate   |              |            | C           | Transplacental |                                 |                 | Not Reported |
|                                   | Fish Oil       |              |            | C           | Transplacental |                                 |                 | Not Reported |
|                                   | Vitamin B12    |              |            | C           | Transplacental |                                 |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2012              | 8455927       | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-FRI-1000028966    |                      | 66 YR      | Male       | ESP            |

| <u>Preferred Term</u>              | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hyponatraemia | Escitalopram Oxalate      |              |            | S           | Oral         | 15 Mg              |                 | Forest       |
|                                    | Furosemide                |              |            | S           | Oral         | 80 Mg              |                 | Not Reported |
|                                    | Omeprazole                |              |            | C           | Oral         | 20 Mg              |                 | Not Reported |
|                                    | Manidipine Hydrochloride  |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |
|                                    | Cardura                   |              |            | C           | Oral         | 8 Mg               |                 | Not Reported |
|                                    | Venlafaxine Hydrochloride |              |            | C           | Oral         | 75 Mg              |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 13-Apr-2012                                         | 8509553           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012088013 |                      | 55 YR           | Unknown      | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity                               | Morphine Sulfate  |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                     | Lexapro           |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                     | Sulfur            |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                     | Oxycodone         |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2012                                         | 8510731           | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029674        |                      | 20 YR           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Off Label Use; Stress Fracture                      | Lexapro           |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                     | Multivitamins     |                    |                    | C               |                          |                      |                 | Not Reported |                |
|                                                     | Calcium Carbonate |                    |                    | C               |                          |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2012                                         | 8511027           | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012089981 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Muscular Weakness; Renal Pain; Urine Odour Abnormal | Lipitor           |                    |                    | S               | Oral                     | 40 Mg, Daily         |                 | Pfizer       |                |
|                                                     | Lipitor           |                    |                    | S               |                          |                      |                 | Pfizer       |                |
|                                                     | Lexapro           |                    |                    | S               |                          | 10 Mg, Daily         |                 | Not Reported |                |
|                                                     | Glucophage        |                    |                    | C               |                          | 1000 Mg, 2x/Day      |                 | Not Reported |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 13-Apr-2012                                         | 8522811           | DIRECT             | Y                  |                 |                          |                      | 3 DAY           | Female       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Substitution Issue; Escitalopram Oxalate S Oral 10 Mg Daily Po Not Reported  
Urticaria

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2012              | 8523360       | EXPEDITED (15-DAY) | N                  | OT              | DSA_56063_2012       |                      |            | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cerebrovascular Accident;  | Wellbutrin             |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
| Drug Ineffective; Muscle   | Tramadol Hydrochloride |              |            | S           |              | (Df)               |                 | Not Reported |
| Spasticity;                | Lexapro                |              |            | S           |              | (Df)               |                 | Not Reported |
| Musculoskeletal Stiffness; | Cymbalta               |              |            | S           | Oral         | (Df Oral)          |                 | Not Reported |
| Pain                       | Unspecified Ingredient |              |            | S           |              | (Df)               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 13-Apr-2012              | 8530320       | DIRECT           | Y                  | HO              |                      |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Dizziness; Fall; Insomnia; | Lexapro        |              |            | S           |              |                    |                 | Not Reported |
| Nausea;                    | Premarin       |              |            | C           |              |                    |                 | Not Reported |
| Pneumocephalus; Skull      |                |              |            |             |              |                    |                 |              |
| Fracture; Syncope          |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8362554       | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012022337 |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia; Cerebrovascular  | Geodon         |              |            | S           |              | 40 Mg, Daily       |                 | Pfizer       |
| Accident; Insomnia;       | Geodon         |              |            | S           |              | 80 Mg, Daily       |                 | Pfizer       |
| Malaise; Mental Disorder; | Risperdal      |              |            | S           |              | 4 Mg, Daily        |                 | Not Reported |
| Nervous System Disorder;  | Risperdal      |              |            | S           |              | 3 Mg, Daily        |                 | Not Reported |
| Stress                    | Risperdal      |              |            | S           |              | 2 Mg, Daily        |                 | Not Reported |
|                           | Risperdal      |              |            | S           |              | Unk                |                 | Not Reported |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |                |              |
|------------|---|----------------|--------------|
| Lexapro    | S | 20 Mg, Daily   | Not Reported |
| Klonopin   | C | 1 Mg, 3x/Day   | Not Reported |
| Klonopin   | C |                | Not Reported |
| Wellbutrin | C | 75 Mg, 2x/Day  | Not Reported |
| Zocor      | C | 40 Mg, Daily   | Not Reported |
| Coreg      | C | 6.25 Mg, Daily | Not Reported |
| Altace     | C | 5 Mg, Daily    | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8494000       | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000028669    |                      | 80 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                      | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|---------------------|-----------------|--------------|
| Agitation; Anxiety;<br>Disorientation;<br>Hallucination; Impaired<br>Driving Ability; Suicidal<br>Ideation | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg                |                 | Forest       |
|                                                                                                            | Celiprolol           |              |            | C           | Oral         |                     |                 | Not Reported |
|                                                                                                            | Prazepam             |              |            | C           | Oral         | 5 Mg If Necessary   |                 | Not Reported |
|                                                                                                            | Zolpidem             |              |            | C           | Oral         | 0.5 Df If Necessary |                 | Not Reported |
|                                                                                                            | Avodart              |              |            | C           | Oral         | 1 Df If Necessary   |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8514036       | DIRECT           | N                  | OT              |                      |                      | 52 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anxiety; Depression; Drug<br>Ineffective; Emotional<br>Disorder; Feeling<br>Abnormal; Product<br>Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         |                    | 2.5 WEEK        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8514353       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000029668    |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                         |                                |                    |                    |                 |                      |                      |                 |              |                |
|-------------------------------------------------------------------------|--------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Blood Glucose Fluctuation                                               | Escitalopram Oxalate           | S                  | 10 Mg              | Forest          |                      |                      |                 |              |                |
|                                                                         | Oral Hypoglycemic Agents (Nos) | C                  |                    | Not Reported    |                      |                      |                 |              |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2012                                                             | 8514354                        | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000029669    |                      |                 | Female       | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Glucose Fluctuation                                               | Escitalopram Oxalate           |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                         | Oral Hypoglycemic Agents Nos   |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2012                                                             | 8514676                        | EXPEDITED (15-DAY) | Y                  | HO, OT          | DE-FRI-1000029755    |                      | 28 YR           | Female       | DEU            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Pregnancy; Pyelonephritis                                               | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                                         | Femibion                       |                    |                    | C               | Oral                 | 0.4 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2012                                                             | 8514694                        | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000029759    |                      | 93 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cognitive Disorder; Drug Dependence; Renal Failure; Withdrawal Syndrome | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                                         | Escitalopram Oxalate           |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-Apr-2012                                                             | 8514763                        | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000029769    |                      |                 | Female       | CAN            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                          |                             |   |                |         |  |              |
|----------------------------------------------------------|-----------------------------|---|----------------|---------|--|--------------|
| Diarrhoea; Hypertonia;<br>Poor Quality Sleep;<br>Trismus | Escitalopram Oxalate        | S | Transplacental |         |  | Forest       |
|                                                          | Benzotropine Mesylate       | S |                |         |  | Not Reported |
|                                                          | Gabapentin                  | S |                | 600 Mg  |  | Not Reported |
|                                                          | Gabapentin                  | S |                | 1200 Mg |  | Not Reported |
|                                                          | Methadone Hydrochloride     | S |                |         |  | Not Reported |
|                                                          | Nortriptyline Hydrochloride | S |                |         |  | Not Reported |
|                                                          | Rabeprazole                 | S |                |         |  | Not Reported |
|                                                          | Seroquel                    | S | Transplacental | 300 Mg  |  | Not Reported |
|                                                          | Zopiclone                   | S |                |         |  | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8514782       | EXPEDITED (15-DAY) | Y                  | OT              | FR-PFIZER INC-2012092328 |                      | 60 YR      | Male       | FRA            |

| <u>Preferred Term</u>                       | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Intentional Overdose;<br>Status Epilepticus | Xanax                           |              |            | S           |              | Unk                |                 | Pfizer       |
|                                             | Escitalopram Oxalate            |              |            | S           |              | Unk                |                 | Not Reported |
|                                             | Prozac                          |              |            | S           |              | Unk                |                 | Not Reported |
|                                             | Acetaminophen\Codeine Phosphate |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8514822       | EXPEDITED (15-DAY) | Y                  | CA              | DE-FRI-1000029756    |                      | < 1 DAY    | Male       | DEU            |

| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Foetal Exposure During<br>Pregnancy; Naevus<br>Flammeus | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                                         | Escitalopram Oxalate |              |            | S           | Transplacental | 20 Mg              |                 | Not Reported |
|                                                         | Femibion             |              |            | C           | Transplacental | 0.4 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Apr-2012              | 8523961       | DIRECT           | Y                  | OT              |                      |                      | 62 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                            |                      |   |      |                     |       |
|------------------------------------------------------------|----------------------|---|------|---------------------|-------|
| Abnormal Dreams;<br>Insomnia; Psychomotor<br>Hyperactivity | Escitalopram Oxalate | S | Oral | 10mg By Mouth Daily | Mylan |
|                                                            | Synthroid            | C |      |                     |       |
|                                                            | Prograf              | C |      |                     |       |
|                                                            | Lovaza               | C |      |                     |       |
|                                                            | Metoprolol Tartrate  | C |      |                     |       |
|                                                            | Ramipril             | C |      |                     |       |
|                                                            | Alprazolam           | C |      |                     |       |
|                                                            | Vivelle Dot          | C |      |                     |       |
|                                                            | Actos                | C |      |                     |       |
|                                                            | Crestor              | C |      |                     |       |
|                                                            | Furosemide           | C |      |                     |       |
|                                                            | Alendronate          | C |      |                     |       |
|                                                            | Prednisone           | C |      |                     |       |
|                                                            | Smz/Tmp Ds           | C |      |                     |       |
|                                                            | Azithromycin         | C |      |                     |       |
|                                                            | Acyclovir            | C |      |                     |       |
|                                                            | Allopurinol          | C |      |                     |       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8494557       | EXPEDITED (15-DAY) | Y                  | OT              | IE-FRI-1000029585    |                      |            | Male       | IRL            |

| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Liver Function Test<br>Abnormal | Lexapro        |              |            | S           | Oral         | 5 Mg               |                 | Forest       |
|                                 | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                 | Nexium         |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8515903       | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000029790    |                      | 50 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Seizure               | Lexapro        |              |            | S           | Oral         |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8516762       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000029699    |                      | 17 YR      | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>                                          | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy | Lexapro                 |              |            | S           | Oral         |                    |                 | Forest       |
|                                                                | Latuda                  |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                | Metformin Hydrochloride |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Aspirin                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Lovenox                 |              |            | S           |              |                    |                 | Not Reported |
|                                                                | Folic Acid              |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                 | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8516913       | EXPEDITED (15-DAY) | Y                  | OT              | JP-<br>GLAXOSMITHKLINE-<br>B0783764A |                      | 37 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                                                                                                                                                  | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u>      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|------------|-------------|--------------|---------------------|-----------------|-----------------|
| Chills; Drug Eruption;<br>Erythema; Erythema<br>Multiforme; Generalised<br>Erythema; Malaise;<br>Myalgia; Pyrexia; Rash;<br>Rash Generalised;<br>Swelling Face; Toxic Skin<br>Eruption | Lamictal          |              |            | S           | Oral         | 25mg Alternate Days | 2 WEEK          | Glaxosmithkline |
|                                                                                                                                                                                        | Paxil             |              |            | S           | Oral         | 20mg Per Day        |                 | Glaxosmithkline |
|                                                                                                                                                                                        | Depakene          |              |            | S           | Oral         | 600mg Per Day       | 15 DAY          | Not Reported    |
|                                                                                                                                                                                        | Lexapro           |              |            | S           | Oral         | 10mg Per Day        | 8 WEEK          | Not Reported    |
|                                                                                                                                                                                        | Clotiazepam       |              |            | S           | Oral         | 15mg Per Day        |                 | Not Reported    |
|                                                                                                                                                                                        | Mosapride Citrate |              |            | S           | Oral         | 10mg Per Day        |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8517651       | EXPEDITED (15-DAY) | Y                  | OT              | TR-FRI-1000016976    |                      | 45 YR      | Male       | TUR            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Cataract Subcapsular  | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Ferrous Carbonate    |              |            | C           | Oral         |                    |                 | Not Reported |
|                       | Lansoprazole         |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8517653       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-FRI-1000029792    |                      |            | Male       | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                                                                                                                                   |                      |   |      |         |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---|------|---------|--------------|
| Agitation; Anxiety;                                                                                                                               | Escitalopram Oxalate | S | Oral | 10 Mg   | Forest       |
| Electrocardiogram Qt                                                                                                                              | Paroxetine           | S | Oral | 80 Tabs | Not Reported |
| Prolonged; Hallucination,                                                                                                                         | Zolpidem             | S | Oral | 17 Tabs | Not Reported |
| Auditory; Hyperhidrosis;                                                                                                                          | Lorazepam            | S | Oral | 5 Tabs  | Not Reported |
| Intentional Overdose; Loss Of Consciousness; Muscle Rigidity; Myoclonus; Serotonin Syndrome; Sinus Tachycardia; Suicide Attempt; Tremor; Vomiting |                      |   |      |         |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8517664       | EXPEDITED (15-DAY) | Y                  | DS, HO          | CA-FRI-1000029794    |                      | 45 YR      | Male       | CAN            |

| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Withdrawal Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 17-Apr-2012              | 8517689       | EXPEDITED (15-DAY) | Y                  | LT              | JP-FRI-1000029813    |                      |            | Female     | JPN            |

| <u>Preferred Term</u> | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Constipation; Sepsis  | Lexapro                     |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                       | Lexapro                     |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
|                       | Cymbalta                    |              |            | C           | Oral         | 50 Mg              |                 | Not Reported |
|                       | Amitriptyline Hydrochloride |              |            | C           | Oral         | 40 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-Apr-2012              | 8503671       | EXPEDITED (15-DAY) | Y                  | OT              | AU-FRI-1000029684    |                      | 72 YR      | Male       | AUS            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Erectile Dysfunction;   | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg              |                 | Forest       |
| Fatigue; Hyperhidrosis; | Felodipine           |              |            | C           |              | 5 Mg               |                 | Not Reported |
| Transient Ischaemic     |                      |              |            |             |              |                    |                 |              |

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|                             |                               |                    |                    |                 |                      |                      |                 |              |                |
|-----------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| Attack; Tremor              | Olmotec                       |                    | C                  |                 |                      | 40/12.5              |                 | Not Reported |                |
|                             | Clopidogrel                   |                    | C                  |                 |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2012                 | 8505670                       | EXPEDITED (15-DAY) | N                  | HO              | PHHY2012FR030122     |                      | 52 YR           | Male         | FRA            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Alcoholic Liver Disease;    | Alprazolam                    |                    |                    | S               | Oral                 | 0.25 Mg, Tid         |                 | Novartis     |                |
| Ascites; Blood Albumin      | Anafranil                     |                    |                    | S               | Oral                 | 0.25 Mg, Tid         |                 | Not Reported |                |
| Decreased; Condition        | Aliskiren\Hydrochlorothiazide |                    |                    | S               | Oral                 | 1 Df, Daily          |                 | Not Reported |                |
| Aggravated; Hepatic         | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 20 Mg, Daily         |                 | Not Reported |                |
| Cirrhosis; Hepatic Failure; | Zyprexa                       |                    |                    | S               | Oral                 | 5 Mg, Daily          | 44 DAY          | Not Reported |                |
| Hepatitis;                  | Prazepam                      |                    |                    | C               |                      |                      |                 | Not Reported |                |
| Hepatosplenomegaly;         |                               |                    |                    |                 |                      |                      |                 |              |                |
| Jaundice; Liver Injury;     |                               |                    |                    |                 |                      |                      |                 |              |                |
| Prothrombin Level           |                               |                    |                    |                 |                      |                      |                 |              |                |
| Decreased                   |                               |                    |                    |                 |                      |                      |                 |              |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2012                 | 8520518                       | EXPEDITED (15-DAY) | Y                  | OT              | DE-FRI-1000029886    |                      |                 | Male         | DEU            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myasthenia Gravis           | Escitalopram Oxalate          |                    |                    | S               |                      |                      |                 | Forest       |                |
|                             | Mirtazapine                   |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                             | Venlafaxine Hydrochloride     |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                             | Opipramol Hydrochloride       |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 18-Apr-2012                 | 8520670                       | DIRECT             | Y                  | OT              |                      |                      | 67 YR           | Female       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Disturbance In Attention;   | Lexapro                       |                    |                    | S               | Oral                 | 20.0 Mg              |                 | Forest       |                |
| Memory Impairment           |                               |                    |                    |                 |                      |                      |                 |              |                |

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| <u>FDA Received Date</u>                                               | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|------------------------------------------------------------------------|---------------------------------------|--------------------|--------------------|-----------------|------------------------------------------|----------------------|-----------------|----------------------|----------------|
| 19-Apr-2012                                                            | 8521189                               | EXPEDITED (15-DAY) | Y                  | OT              | US-MYLANLABS-2012S1007501                |                      | 29 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy         | Metformin Hydrochloride               |                    |                    | S               | Oral                                     |                      |                 | Mylan                |                |
|                                                                        | Latuda                                |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Lexapro                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Aspirin                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Lovenox                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Pyridoxine Hydrochloride              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Apr-2012                                                            | 8524101                               | EXPEDITED (15-DAY) | N                  | HO              | FR-BRISTOL-MYERS SQUIBB COMPANY-16519340 |                      | 81 YR           | Female               | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Interaction;<br>Hyponatraemia;<br>Hyponatraemic<br>Encephalopathy | Inexium                               |                    |                    | S               | Oral                                     | Tab                  |                 | Not Reported         |                |
|                                                                        | Irbesartan And<br>Hydrochlorothiazide |                    |                    | S               |                                          | 1df=1 Tab            |                 | Bristol Myers Squibb |                |
|                                                                        | Escitalopram Oxalate                  |                    |                    | S               |                                          | Tab                  |                 | Not Reported         |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 20-Apr-2012                                                            | 8524354                               | EXPEDITED (15-DAY) | N                  | HO              | US-PURDUE-USA-2012-0085521               |                      | 92 YR           | Female               | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Asthenia; Blood Sodium<br>Decreased; Confusional<br>State; Somnolence  | Colace                                |                    | Y                  | S               |                                          |                      |                 | Purdue Pharma        |                |
|                                                                        | Tenormin                              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Benicar                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Lexapro                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Namenda                               |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Xanax                                 |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Travatan                              |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Synthroid                             |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Ascorbic Acid\Calcium                 |                    |                    | S               |                                          |                      |                 | Not Reported         |                |
|                                                                        | Pantothenate\Ergocalciferol\Pyri      |                    |                    |                 |                                          |                      |                 | Not Reported         |                |

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doxine  
Hydrochloride\Retinol\Riboflavin\  
Thiamine Hydrochloride  
Ascorbic Acid  
Calcium Carbonate  
Aspirin  
Lutein

S  
S  
S  
S

Not Reported  
Not Reported  
Not Reported  
Not Reported

| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
|-------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|----------------------------------------|----------------|
| 20-Apr-2012                                                             | 8524404                       | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029729              |                      | 36 YR           | Female                                 | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Maternal Exposure During Pregnancy;<br>Oligohydramnios; Seizure         | Lexapro<br>Lasix<br>Potassium |                    |                    | S<br>C<br>C     | Oral                           | 40 Mg                |                 | Forest<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 20-Apr-2012                                                             | 8524507                       | EXPEDITED (15-DAY) | N                  | CA, OT          | US-FRI-1000029730              |                      | < 1 DAY         | Male                                   | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Cardiac Murmur;<br>Congenital Cardiovascular Anomaly; Unevaluable Event | Lexapro<br>Lasix<br>Potassium |                    |                    | S<br>C<br>C     | Transplacental                 | 40 Mg                |                 | Forest<br>Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 21-Apr-2012                                                             | 8534240                       | DIRECT             | Y                  |                 |                                |                      |                 | Female                                 | USA            |
| <u>Preferred Term</u>                                                   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                             |                |
| Dizziness; Fear; Muscle Spasms; Tremor                                  | Escitalopram Oxalate          |                    |                    | S               |                                |                      |                 | Not Reported                           |                |
| <u>FDA Received Date</u>                                                | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                             | <u>Country</u> |
| 23-Apr-2012                                                             | 8525561                       | EXPEDITED (15-DAY) | Y                  | OT              | US-SANOFI-AVENTIS-2012SA024842 |                      | 28 YR           | Female                                 | USA            |



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| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|-----------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|--------------|----------------|
| Abortion Spontaneous;<br>Maternal Exposure During<br>Pregnancy                                | Lovenox                 |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Unspecified Ingredient  |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                               | Metformin Hydrochloride |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                               | Aspirin                 |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                               | Unspecified Ingredient  |                    |                    | S               |                                |                      |                 | Not Reported |                |
|                                                                                               | Lexapro                 |                    |                    | S               |                                |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2012                                                                                   | 8525933                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-ASTRAZENECA-<br>2012SE25563 |                      | 27 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Depressed<br>Level Of Consciousness;<br>Drug Interaction;<br>Intentional Overdose | Seroquel                |                    |                    | S               | Oral                           | 6 Tablets            | 1 DAY           | Zeneca       |                |
|                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                           |                      | 1 DAY           | Not Reported |                |
|                                                                                               | Akineton                |                    |                    | S               | Oral                           | 20 Tablets           | 1 DAY           | Not Reported |                |
|                                                                                               | Invega                  |                    |                    | S               | Oral                           | 281                  | 1 DAY           | Not Reported |                |
|                                                                                               | Rivotril                |                    |                    | S               | Oral                           | 60 Tablets           | 1 DAY           | Not Reported |                |
|                                                                                               | Zyprexa                 |                    |                    | S               | Oral                           | 28 Tablets           | 1 DAY           | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-Apr-2012                                                                                   | 8526207                 | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-JNJFOC-<br>20120408242      |                      | 27 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Aspiration; Depressed<br>Level Of Consciousness;<br>Drug Interaction;<br>Intentional Overdose | Invega                  |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Akineton                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Escitalopram Oxalate    |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Rivotril                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Seroquel                |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |
|                                                                                               | Zyprexa                 |                    |                    | S               | Oral                           |                      |                 | Not Reported |                |

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| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-------------------------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 24-Apr-2012                                                                                                       | 8527601              | DIRECT           | Y                  | OT              |                      |                      | 43 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Diarrhoea;<br>Product Substitution Issue;<br>Tinnitus                                                    | Escitalopram Oxalate |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2012                                                                                                       | 8527641              | DIRECT           | Y                  | HO              |                      |                      | 87 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Confusional State;<br>Disorientation; Fall; Mental<br>Status Changes;<br>Unresponsive To Stimuli                  | Lexapro              |                  |                    | S               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-Apr-2012                                                                                                       | 8532815              | DIRECT           | Y                  |                 |                      |                      | 28 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety                                                                                                           | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20 Mg Daily Oral     |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-Apr-2012                                                                                                       | 8529509              | DIRECT           | N                  |                 |                      |                      | 64 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Anger; Muscle Spasms;<br>Musculoskeletal Pain;<br>Neck Pain; Product<br>Substitution Issue | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10mg                 |                 | Teva         |                |

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| <u>FDA Received Date</u>                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
|------------------------------------------------|---------------------------------------|--------------------|--------------------|-------------------------------|----------------------|----------------------------------------|-----------------|------------------------------|----------------|
| 25-Apr-2012                                    | 8529552                               | DIRECT             | N                  | CA, DE, DS, HO,<br>LT, RI, OT |                      |                                        | 21 YR           | Male                         | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Completed Suicide; Gun<br>Shot Wound; Paranoia | Lexapro                               |                    |                    | S                             | Oral                 | Daily                                  |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>                         | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>               | <u>Mfr Control #</u> | <u>503B Facility</u>                   | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 25-Apr-2012                                    | 8529556                               | EXPEDITED (15-DAY) | Y                  | HO                            | IT-ROCHE-1062041     |                                        | 44 YR           | Female                       | ITA            |
| <u>Preferred Term</u>                          | <u>Product</u>                        | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                   | <u>Route</u>         | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u>                   |                |
| Bradypnoea; Sopor                              | Rivotril                              |                    |                    | S                             |                      | Started More Or Less Two<br>Months Ago |                 | Not Reported                 |                |
|                                                | Rivotril                              |                    |                    | S                             | Oral                 |                                        |                 | Not Reported                 |                |
|                                                | Acetaminophen\Codeine<br>Phosphate    |                    |                    | S                             |                      | As Required                            |                 | Not Reported                 |                |
|                                                | Acetaminophen\Codeine<br>Phosphate    |                    |                    | S                             | Oral                 | Form Strength 500 Mg +<br>30 Mg        |                 | Not Reported                 |                |
|                                                | Cipralelex                            |                    |                    | S                             |                      | Started More Or Less Two<br>Months Ago |                 | Not Reported                 |                |
|                                                | Cipralelex                            |                    |                    | S                             | Oral                 |                                        |                 | Not Reported                 |                |
|                                                | Xanax                                 |                    |                    | S                             |                      | Started More Or Less Two<br>Months Ago |                 | Not Reported                 |                |
|                                                | Xanax                                 |                    |                    | S                             | Oral                 |                                        |                 | Not Reported                 |                |
|                                                | Lormetazepam                          |                    |                    | S                             |                      | Started More Or Less Two<br>Months Ago |                 | Not Reported                 |                |
|                                                | Lormetazepam                          |                    |                    | S                             | Oral                 |                                        |                 | Not Reported                 |                |
|                                                | Lyrica                                |                    |                    | C                             | Oral                 |                                        |                 | Not Reported                 |                |
|                                                | Duloxetine Hydrochloride              |                    |                    | C                             |                      | Started More Or Less Two<br>Months Ago |                 | Not Reported                 |                |
|                                                | Duloxetine Hydrochloride<br>Cardirene |                    |                    | C                             |                      |                                        |                 | Not Reported<br>Not Reported |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2012              | 8530524       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000026942    |                      | 49 YR      | Male       | FRA            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Arthralgia; Joint Destruction; Tendonitis | Escitalopram Oxalate |              |            | S           | Oral         | 15 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2012              | 8530626       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030047    |                      | 79 YR      | Female     | FRA            |

| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion | Citalopram           |              |            | S           |              | 20 Mg              |                 | Forest       |
|                                                             | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                                             | Myambutol            |              |            | C           | Oral         | 800 Mg             |                 | Not Reported |
|                                                             | Rimifon              |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                                                             | Rifadine             |              |            | C           | Oral         | 300 Mg             |                 | Not Reported |
|                                                             | Rifadine             |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |
|                                                             | Pyrazinamide         |              |            | C           | Oral         | 1000 Mg            |                 | Not Reported |
|                                                             | Vitamin B1 B6        |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                                             | Ramipril             |              |            | C           | Oral         | 1.25 Mg            |                 | Not Reported |
|                                                             | Atarax               |              |            | C           | Oral         | 3 Df               |                 | Not Reported |
|                                                             | Foradil              |              |            | C           | Oral         | 2 Df               |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Apr-2012              | 8538061       | DIRECT           | N                  | OT              |                      |                      | 37 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anxiety; Blood Pressure Increased; Chest Discomfort; Influenza Like Illness; Insomnia; Product | Escitalopram Oxalate |              |            | S           | Oral         | 10mg 1 Day Oral    |                 | Mylan      |

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Substitution Issue;  
Restlessness; Skin Warm

| <u>FDA Received Date</u>             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 25-Apr-2012                          | 8538082        | DIRECT           | N                  | OT              |                      |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Oedema Peripheral; Pain In Extremity | Lexapro        |                  |                    | S               | Oral                 | 5 Mg 1 X Day Oral    |                 | Mylan      |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                  | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------------|---------------------------------------|-----------------|--------------|----------------|
| 25-Apr-2012                                       | 8588665              | EXPEDITED (15-DAY) | Y                  | HO              | FR-ASTRAZENECA-2012SE24175 |                                       | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                             | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                    | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia;<br>Hyponatraemic<br>Encephalopathy | Inexium              |                    |                    | S               | Oral                       |                                       | 4 DAY           | Astrazeneca  |                |
|                                                   | Inexium              |                    |                    | S               | Oral                       |                                       |                 | Astrazeneca  |                |
|                                                   | Escitalopram Oxalate |                    |                    | S               | Oral                       |                                       | 8 DAY           | Not Reported |                |
|                                                   | Coaprovel            |                    |                    | S               | Oral                       | 150 Mg / 12.5 Mg, 1 Dosage Form Daily | 5 MTH           | Not Reported |                |

| <u>FDA Received Date</u>                                                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|------------------------------------------------------------------------------------|----------------|--------------------|--------------------|-----------------|------------------------------|--------------------------|-----------------|-----------------|----------------|
| 26-Apr-2012                                                                        | 8422872        | EXPEDITED (15-DAY) | N                  | OT              | US-GLAXOSMITHKLINE-A0967017A |                          | 60 YR           | Female          | USA            |
| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>      |                |
| Balance Disorder; Drug Ineffective; Drug Interaction; Epilepsy; Somnolence; Tremor | Lamictal       |                    |                    | S               | Oral                         | 150mg Twice Per Day      |                 | Glaxosmithkline |                |
|                                                                                    | Provera        |                    |                    | S               | Oral                         | 10mg Per Day             | 20 YR           | Not Reported    |                |
|                                                                                    | Premarin       |                    |                    | S               | Oral                         | .625mg Per Day           |                 | Not Reported    |                |
|                                                                                    | Topamax        |                    |                    | S               | Oral                         | 300mg Per Day            |                 | Glaxosmithkline |                |
|                                                                                    | Vimpat         |                    |                    | S               | Unknown                      | 100mg Four Times Per Day |                 | Glaxosmithkline |                |
|                                                                                    | Lexapro        |                    |                    | S               | Unknown                      | 20mg Per Day             |                 | Not Reported    |                |

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| <u>FDA Received Date</u>                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------|--------------------------|------------------|--------------------|-----------------|------------------------------|-----------------------------------|-----------------|--------------|----------------|
| 26-Apr-2012                                 | 8531661                  | NON-EXPEDITED    | N                  | OT              | US-TEVA-US022005             |                                   | 88 YR           | Female       | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Hallucination;<br>Oral Candidiasis | Provigil                 |                  |                    | S               | Oral                         | 100 Milligram;                    |                 | Not Reported |                |
|                                             | Risperdal                |                  |                    | S               | Oral                         | 1.25 Milligram;                   |                 | Not Reported |                |
|                                             | Risperdal                |                  |                    | S               | Oral                         | .25 Milligram;                    |                 | Not Reported |                |
|                                             | Lexapro                  |                  |                    | S               | Oral                         | 20 Milligram;                     |                 | Not Reported |                |
|                                             | Namenda                  |                  |                    | C               | Oral                         | 20 Milligram;                     |                 | Not Reported |                |
|                                             | Protonix                 |                  |                    | C               | Oral                         | 20 Milligram;                     |                 | Not Reported |                |
|                                             | Potassium                |                  |                    | C               | Oral                         |                                   |                 | Not Reported |                |
|                                             | Lasix                    |                  |                    | C               | Oral                         |                                   |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2012                                 | 8531851                  | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012101146 |                                   | 60 YR           | Male         | USA            |
| <u>Preferred Term</u>                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>   |                |
| Libido Decreased                            | Cardura                  |                  |                    | S               |                              | Unk                               |                 | Pfizer       |                |
|                                             | Lexapro                  |                  |                    | S               | Oral                         | 10 Mg, 1x/Day (10mg, 1 In<br>1 D) |                 | Not Reported |                |
|                                             | Lexapro                  |                  |                    | S               |                              | 10 Mg, Daily                      |                 | Not Reported |                |
|                                             | Tamsulosin Hydrochloride |                  |                    | S               |                              | Unk                               |                 | Not Reported |                |
|                                             | Wellbutrin               |                  |                    | C               |                              | Unk                               |                 | Not Reported |                |
|                                             | Tricor                   |                  |                    | C               |                              | Unk                               |                 | Not Reported |                |
|                                             | Lipitor                  |                  |                    | C               |                              | Unk                               |                 | Not Reported |                |
|                                             | Alphagan P               |                  |                    | C               |                              | Unk                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2012                                 | 8532232                  | NON-EXPEDITED    | Y                  | HO              | US-TEVA-US025061             |                                   | 14 YR           | Female       | USA            |

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| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|------------------------------|-----------------|--------------|----------------|
| Anxiety; Clonus; Delirium;<br>Diarrhoea; Dry Mouth;<br>Hyperhidrosis;<br>Hypervigilance; Intentional<br>Overdose; Suicide<br>Attempt; Tachycardia | Provigil                                 |                    |                    | S               | Oral                 |                              |                 | Not Reported |                |
|                                                                                                                                                   | Lexapro                                  |                    |                    | S               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                   | Depakote                                 |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                   | Amitriptyline                            |                    |                    | C               |                      |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 26-Apr-2012                                                                                                                                       | 8540760                                  | DIRECT             | Y                  | OT              |                      |                              | 41 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Headache; Nausea;<br>Urticaria                                                                                                                    | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | Es-Citalopram One Qday<br>Po |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                          | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2012                                                                                                                                       | 8444013                                  | EXPEDITED (15-DAY) | Y                  | OT              | SE-FRI-1000026059    |                              | 15 YR           | Female       | SWE            |
| <u>Preferred Term</u>                                                                                                                             | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anal Haemorrhage;<br>Epistaxis; Nasal<br>Congestion; Off Label<br>Use; Pruritus; Rash; Scab;<br>Weight Increased                                  | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 5 Mg                         |                 | Forest       |                |
|                                                                                                                                                   | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg                        |                 | Forest       |                |
|                                                                                                                                                   | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 15 Mg                        |                 | Forest       |                |
|                                                                                                                                                   | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 20 Mg                        |                 | Forest       |                |
|                                                                                                                                                   | Nexium                                   |                    |                    | C               | Oral                 | 40 Mg                        |                 | Not Reported |                |
|                                                                                                                                                   | Calcium Carbonate                        |                    |                    | C               |                      |                              |                 | Not Reported |                |
|                                                                                                                                                   | Niferex (Polysaccharide-Iron<br>Complex) |                    |                    | C               | Oral                 | 100 Mg                       |                 | Not Reported |                |
|                                                                                                                                                   | Folic Acid                               |                    |                    | C               | Oral                 |                              |                 | Not Reported |                |
|                                                                                                                                                   | Methotrexate                             |                    |                    | C               | Oral                 | 1.4286 Mg                    |                 | Not Reported |                |
|                                                                                                                                                   | Prednisolone                             |                    |                    | C               | Oral                 | 15 Mg                        |                 | Not Reported |                |
|                                                                                                                                                   | Melatonin                                |                    |                    | C               | Oral                 | 6 Mg                         |                 | Not Reported |                |
|                                                                                                                                                   | Theralen                                 |                    |                    | C               | Oral                 | 35 Mg                        |                 | Not Reported |                |
|                                                                                                                                                   | Symbicort                                |                    |                    | C               |                      |                              |                 | Not Reported |                |

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|                        |   |             |              |
|------------------------|---|-------------|--------------|
| Pulmicort Flexhaler    | C |             | Not Reported |
| Singulair              | C | 5 Mg        | Not Reported |
| Aerius (Desloratadine) | C | 10 Mg       | Not Reported |
| Tramadol Hydrochloride | C |             | Not Reported |
| Diazepam               | C |             | Not Reported |
| Propavan               | C | 1-2 Tablets | Not Reported |
| Lactitol               | C |             | Not Reported |
| Clemastine Fumarate    | C |             | Not Reported |
| Pulmozyme              | C | 5 MI        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2012              | 8533158       | EXPEDITED (15-DAY) | Y                  | OT              | ES-PFIZER INC-2012100960 |                      | 44 YR      | Female     | ESP            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction; Vaginal Haemorrhage | Celebrex             |              |            | S           | Oral         | 200 Mg, 1x/Day     | 28 DAY          | Pfizer       |
|                                       | Lorazepam            |              |            | C           | Oral         | 1 Mg, Unk          |                 | Not Reported |
|                                       | Zonegran             |              |            | C           | Oral         | 25 Mg, Unk         |                 | Not Reported |
|                                       | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg, 1x/Day      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 27-Apr-2012              | 8533800       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2012SA027941 |                      | 78 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Duodenitis; Oesophageal Stenosis | Stilnox              |              |            | S           | Oral         | Long-Term Therapy. |                 | Not Reported |
|                                  | Atarax               |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Galantamine          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                  | Haldol               |              |            | S           | Oral         | 2 Mg/MI.           |                 | Not Reported |
|                                  | Alprazolam           |              |            | S           | Oral         | Long-Term Therapy. |                 | Not Reported |
|                                  | Escitalopram Oxalate |              |            | S           | Oral         | Long-Term Therapy. |                 | Not Reported |



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|---------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 27-Apr-2012                                                                     | 8534008              | EXPEDITED (15-DAY) | Y                  | HO              | FR-JNJFOC-20120411208 |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenitis; Gastritis;<br>Oesophageal Stenosis                                  | Reminyl              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                 | Haldol               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                 | Atarax               |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                 | Stilnox              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                 | Alprazolam           |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2012                                                                     | 8534313              | EXPEDITED (15-DAY) | Y                  | LT              | CA-FRI-1000030087     |                      | 54 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abnormal Behaviour;<br>Somnambulism;<br>Therapeutic Product Effect<br>Decreased | Escitalopram Oxalate |                    |                    | S               | Oral                  | 20 Mg                |                 | Forest       |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                  | 15 Mg                |                 | Forest       |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                  | 5 Mg                 |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                  | 10 Mg                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2012                                                                     | 8534784              | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2012US035679      |                      | 25 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Completed Suicide                                                               | Carbamazepine        |                    |                    | S               |                       |                      |                 | Novartis     |                |
|                                                                                 | Alprazolam           |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                 | Escitalopram Oxalate |                    |                    | S               |                       |                      |                 | Not Reported |                |
|                                                                                 | Lamotrigine          |                    |                    | S               |                       |                      |                 | Not Reported |                |

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|---------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|-------------------------|-----------------|--------------|----------------|
| 27-Apr-2012                                 | 8535091              | EXPEDITED (15-DAY) | Y                  | HO              | CA-FRI-1000030099        |                         |                 | Female       | CAN            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Heart Rate Irregular            | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg                   |                 | Forest       |                |
|                                             | Escitalopram Oxalate |                    |                    | S               | Oral                     | 20 Mg                   |                 | Not Reported |                |
|                                             | Naproxen             |                    |                    | C               |                          | Daily Dose Not Reported |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2012                                 | 8535104              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030073        |                         | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Interstitial Lung Disease                   | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg                   |                 | Forest       |                |
|                                             | Lyrica               |                    |                    | S               | Oral                     |                         |                 | Not Reported |                |
|                                             | Bromazepam           |                    |                    | S               | Oral                     |                         |                 | Not Reported |                |
|                                             | Klipal               |                    |                    | S               | Oral                     | 2 Df                    |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 27-Apr-2012                                 | 8588666              | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030051        |                         | 81 YR           | Female       | FRA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Hyponatraemia; Hyponatraemic Encephalopathy | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg                   |                 | Forest       |                |
|                                             | Inexium              |                    |                    | S               | Oral                     | 20 Mg                   |                 | Not Reported |                |
|                                             | Coaprovel            |                    |                    | S               | Oral                     | 150 Mg/12.5 Mg Daily    |                 | Not Reported |                |
| <u>FDA Received Date</u>                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2012                                 | 8532522              | EXPEDITED (15-DAY) | Y                  | HO              | IT-PFIZER INC-2012099309 |                         | 44 YR           | Female       | ITA            |
| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                            |                                 |   |      |                    |        |              |
|--------------------------------------------|---------------------------------|---|------|--------------------|--------|--------------|
| Bradypnoea; Intentional Self-Injury; Sopor | Xanax                           | S | Oral | 20 Tablets         | 1 DAY  | Pfizer       |
|                                            | Acetaminophen\Codeine Phosphate | S | Oral | 16 Tablets         | 1 DAY  | Not Reported |
|                                            | Rivotril                        | S | Oral | 10 Tablets (2 Mg)  | 1 DAY  | Not Reported |
|                                            | Cipralext                       | S | Oral | 28 Tablets (20 Mg) | 1 DAY  | Not Reported |
|                                            | Lormetazepam                    | S | Oral | 30 Tablets (1 Mg)  | 1 DAY  | Not Reported |
|                                            | Lyrica                          | C | Oral | 150 Mg, 1x/Day     |        | Not Reported |
|                                            | Duloxetine Hydrochloride        | C |      | 60 Mg, Unk         | 61 DAY | Not Reported |
|                                            | Cardirene                       | C |      | Unk                |        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2012              | 8534858       | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2012US035391     |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide     | Metoprolol                      |              |            | S           |              |                    |                 | Novartis     |
|                       | Metformin Hydrochloride         |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate            |              |            | S           |              |                    |                 | Not Reported |
|                       | Esomeprazole                    |              |            | S           |              |                    |                 | Not Reported |
|                       | Acetaminophen\Codeine Phosphate |              |            | S           |              |                    |                 | Not Reported |
|                       | Unspecified Ingredient          |              |            | S           |              | Unk                |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 30-Apr-2012              | 8534890       | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2012US035360     |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>                                                                                       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|------------------------------------------------------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Death                 | Metoprolol                                                                                           |              |            | S           |              |                    |                 | Novartis     |
|                       | Clozapine                                                                                            |              |            | S           |              |                    |                 | Not Reported |
|                       | Escitalopram Oxalate                                                                                 |              |            | S           |              |                    |                 | Not Reported |
|                       | Amphetamine Aspartate And Amphetamine Sulfate And Dextroamphetamine Saccharate And Dextroamphetamine |              |            | S           |              |                    |                 | Not Reported |
|                       | Memantine Hydrochloride                                                                              |              |            | S           |              |                    |                 | Not Reported |
|                       | Simvastatin                                                                                          |              |            | S           |              |                    |                 | Not Reported |
|                       |                                                                                                      |              |            |             |              |                    |                 |              |
|                       |                                                                                                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                                   |                    |                    |                 |                       |                      |                 |              |                |
|---------------------------------------|-----------------------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| Solifenacin Succinate                 |                                   |                    |                    | S               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2012                           | 8536244                           | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030083     |                      | 39 YR           | Female       | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Speech Disorder                       | Escitalopram Oxalate              |                    |                    | S               | Oral                  | 1 Df                 |                 | Forest       |                |
|                                       | Topiramate                        |                    |                    | S               | Oral                  | 50 Mg                |                 | Not Reported |                |
|                                       | Stilnox                           |                    |                    | C               |                       |                      |                 | Not Reported |                |
|                                       | Atarax                            |                    |                    | C               |                       |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2012                           | 8536276                           | EXPEDITED (15-DAY) | Y                  | DE, HO          | FR-FRI-1000030089     |                      | 88 YR           | Female       | FRA            |
| <u>Preferred Term</u>                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Haemorrhage Intracranial; Overdose    | Escitalopram Oxalate              |                    |                    | S               | Oral                  | 25 Mg                |                 | Forest       |                |
|                                       | Plavix                            |                    |                    | S               | Oral                  | 75 Mg                |                 | Not Reported |                |
|                                       | Tareg                             |                    |                    | C               | Oral                  | 40 Mg                |                 | Not Reported |                |
|                                       | Digoxine                          |                    |                    | C               | Oral                  | 0.7143 Df            |                 | Not Reported |                |
|                                       | Omeprazole                        |                    |                    | C               | Oral                  | 20 Mg                |                 | Not Reported |                |
|                                       | Sinemet                           |                    |                    | C               | Oral                  | 250 Mg/25 Mg Daily   |                 | Not Reported |                |
| <u>FDA Received Date</u>              | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 30-Apr-2012                           | 8536982                           | EXPEDITED (15-DAY) | Y                  | HO              | ES-MERCK-1204ESP00036 |                      | 87 YR           | Male         | ESP            |
| <u>Preferred Term</u>                 | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Gastric Haemorrhage | Zocor                             |                    |                    | S               | Oral                  |                      |                 | Merck        |                |
|                                       | Escitalopram Oxalate              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                       | Acenocoumarol                     |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                       | Calcium Carbonate\Cholecalciferol |                    |                    | C               | Oral                  |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |                          |              |
|---------------------|---|--------------------------|--------------|
| Enalapril Maleate   | C | Oral                     | Not Reported |
| Formoterol Fumarate | C | Respiratory (inhalation) | Not Reported |
| Budesonide          | C | Unknown                  | Not Reported |

| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 30-Apr-2012               | 8537384                | EXPEDITED (15-DAY) | Y                  | OT              | CH-FRI-1000030137    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>     | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anaemia; Colitis; Melaena | Escitalopram Oxalate   |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                           | Acemetacin             |                    |                    | S               | Oral                 | 180 Mg               |                 | Not Reported |                |
|                           | Trimethoprim           |                    |                    | S               |                      |                      |                 | Not Reported |                |
|                           | Pantozol (Switzerland) |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |

| <u>FDA Received Date</u>     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|------------|----------------|
| 01-May-2012                  | 8283678        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2011292301 |                            | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Affective Disorder;          | Zoloft         |                    |                    | S               |                          | 25mg, A Day For Seven Days | 7 DAY           | Pfizer     |                |
| Agitation; Anxiety;          | Zoloft         |                    |                    | S               |                          | 50mg, For Four Weeks       |                 | Pfizer     |                |
| Arteriosclerosis; Bipolar li | Zoloft         |                    |                    | S               |                          | 75 Mg, 1x/Day              |                 | Pfizer     |                |
| Disorder; Cholelithiasis;    | Zoloft         |                    |                    | S               |                          | 20 Mg, 1x/Day For 4 Weeks  |                 | Pfizer     |                |
| Depression; Drug             | Zoloft         |                    |                    | S               |                          | 50 Mg, 1x/Day              |                 | Pfizer     |                |
| Ineffective; Feeling         | Zoloft         |                    |                    | S               |                          | 100 Mg, 1x/Day             |                 | Pfizer     |                |
| Abnormal; Folliculitis;      | Zoloft         |                    |                    | S               |                          | 50 Mg, 2x/Day              |                 | Pfizer     |                |
| Hysterectomy; Insomnia;      | Zoloft         |                    |                    | S               |                          | 75 Mg, Unk                 |                 | Pfizer     |                |
| Libido Decreased;            | Zoloft         |                    |                    | S               |                          | 50 Mg, Unk                 |                 | Pfizer     |                |
| Memory Impairment;           | Zoloft         |                    |                    | S               |                          | 100 Mg, For 6 Months       |                 | Pfizer     |                |
| Migraine; Obesity;           | Zoloft         |                    |                    | S               | Oral                     | 0.25 Mg, 2x/Day            |                 | Pfizer     |                |
| Respiratory Tract            | Zoloft         |                    |                    | S               |                          |                            |                 | Pfizer     |                |
| Infection; Salpingo-         | Zoloft         |                    |                    | S               |                          |                            |                 | Pfizer     |                |
| Oophorectomy Bilateral;      | Zoloft         |                    |                    | S               |                          |                            |                 | Pfizer     |                |
| Seborrhoea; Sinusitis;       | Zoloft         |                    |                    | S               |                          |                            |                 | Pfizer     |                |
| Stress; Withdrawal           | Zoloft         |                    |                    | S               |                          |                            |                 | Pfizer     |                |
| Syndrome                     | Xanax          |                    |                    | S               |                          |                            |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |                                           |              |
|------------|---|------|-------------------------------------------|--------------|
| Xanax      | S |      | 0.5 Mg, Every 8 Hours                     | Pfizer       |
| Effexor    | S |      | 37.5 Mg, 1x/Day 7 DAY                     | Pfizer       |
| Effexor    | S |      | 75 Mg, 1x/Day                             | Pfizer       |
| Calan      | S |      | Unk                                       | Pfizer       |
| Inderal La | S |      | 60mg 1 At Night                           | Pfizer       |
| Ultram     | S |      | 50 Mg, As Needed, Every 8 Hours           | Not Reported |
| Elavil     | S |      | Unk                                       | Not Reported |
| Lexapro    | S |      | 10 Mg, Unk                                | Not Reported |
| Wellbutrin | S |      | 200mg, One Daily 3 DAY                    | Not Reported |
| Wellbutrin | S |      | 150 Mg, 1x/Day                            | Not Reported |
| Wellbutrin | S |      | 300 Mg, Unk                               | Not Reported |
| Topamax    | S |      | 25, Twice A Day For Seven Days            | Not Reported |
| Topamax    | S |      | 50 Mg And 25 Mg In The Morning For 7 Days | Not Reported |
| Topamax    | S |      | 25 Mg, X7days In The Morning              | Not Reported |
| Topamax    | S |      | 25 Mg, At Night For 17 Days               | Not Reported |
| Lortab     | S |      | 7.5/500 One Every 6-8 Hours As Needed     | Not Reported |
| Lortab     | S |      | 5/500 One Every 8 Hours 16 DAY As Needed  | Not Reported |
| Lunesta    | S |      | Unk                                       | Not Reported |
| Mirapex    | S |      |                                           | Not Reported |
| Cymbalta   | S |      | 30 Mg, 1x/Day                             | Not Reported |
| Paxil      | S | Oral | 10 Mg, 1x/Day                             | Not Reported |
| Paxil      | S |      | 20 Mg, 1x/Day                             | Not Reported |
| Midrin     | S |      | Two Capsules At Start Of Migraine         | Not Reported |
| Motrin     | S |      |                                           | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                   |                          |                    |                    |                 |                                                 |                      |                 |                              |                |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|-----------------|------------------------------|----------------|
| Excedrin Migraine<br>Ortho-Novum                                                                                  |                          |                    | S<br>C             |                 | Unk                                             |                      |                 | Not Reported<br>Not Reported |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 01-May-2012                                                                                                       | 8538348                  | EXPEDITED (15-DAY) |                    | HO              | ES-FRI-1000030121                               |                      | 27 YR           | Female                       | ESP            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Depressed Level Of<br>Consciousness;<br>Intentional Overdose                                                      | Escitalopram Oxalate     |                    |                    | S               | Oral                                            | None Reported        |                 | Forest                       |                |
|                                                                                                                   | Akineton                 |                    |                    | S               | Oral                                            | 2 Mg In Total        |                 | Not Reported                 |                |
|                                                                                                                   | Paliperidone             |                    |                    | S               | Oral                                            | 3 Mg In Total        |                 | Not Reported                 |                |
|                                                                                                                   | Clonazepam               |                    |                    | S               | Oral                                            | 3 Mg In Total        |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-May-2012                                                                                                       | 8474807                  | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-<br>2012072681                    |                      | 29 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Dizziness; Feeling<br>Abnormal; Headache;<br>Nausea; Withdrawal<br>Syndrome                                       | Pristiq Extended Release |                    |                    | S               | Oral                                            | 15 Mg, Daily         |                 | Pfizer                       |                |
|                                                                                                                   | Pristiq Extended Release |                    |                    | S               |                                                 |                      |                 | Pfizer                       |                |
|                                                                                                                   | Lexapro                  |                    |                    | S               |                                                 | 10 Mg, Daily         |                 | Not Reported                 |                |
|                                                                                                                   | Lexapro                  |                    |                    | S               |                                                 |                      |                 | Not Reported                 |                |
|                                                                                                                   | Zyrtec                   |                    |                    | C               |                                                 | 10 Mg, Daily         |                 | Not Reported                 |                |
| <u>FDA Received Date</u>                                                                                          | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                   | <u>Country</u> |
| 02-May-2012                                                                                                       | 8506346                  | EXPEDITED (15-DAY) | Y                  | OT              | US-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16504102 |                      | 56 YR           | Female                       | USA            |
| <u>Preferred Term</u>                                                                                             | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                   |                |
| Electrocardiogram Qt<br>Prolonged; Oedema Due<br>To Cardiac Disease;<br>Pericardial Effusion;<br>Weight Increased | Abilify                  |                    |                    | S               | Oral                                            | Qam                  | 3 MTH           | Not Reported                 |                |
|                                                                                                                   | Celexa                   |                    |                    | S               | Oral                                            | Qam                  |                 | Not Reported                 |                |
|                                                                                                                   | Lexapro                  |                    |                    | S               |                                                 |                      |                 | Not Reported                 |                |
|                                                                                                                   | Effexor                  |                    |                    | S               |                                                 |                      |                 | Not Reported                 |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-May-2012                                                                                   | 8510315                 | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029664    |                      | 46 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Blood Pressure Decreased; Heart Rate Decreased; Legal Problem; Malaise; Myocardial Infarction | Lexapro                 |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                                               | Trazodone Hydrochloride |                    |                    | S               |                      | 200 Mg Qhs           |                 | Not Reported |                |
|                                                                                               | Klonopin                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Neurontin               |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                                   | 8520162                 | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000024535    |                      | 22 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Oesophageal Achalasia                                                                         | Lexapro                 |                    |                    | S               |                      | 10 Mg                |                 | Forest       |                |
|                                                                                               | Lexapro                 |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                               | Lexapro                 |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                                                               | Alprazolam              |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                      | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                                   | 8541628                 | EXPEDITED (15-DAY) | Y                  | DE, HO          | CH-FRI-1000030205    |                      |                 | Female       | CHE            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Cerebral Haemorrhage                                                                          | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                                                               | Marcumar                |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                                                               | Aricept                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Adalat                  |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Beloc-Zok               |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Digoxin                 |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Seroquel                |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                                                                               | Torsemide               |                    |                    | C               |                      |                      |                 | Not Reported |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------|-------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 02-May-2012                                    | 8541629                 | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030174    |                      | 36 YR           | Male         | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Homicidal Ideation; Suicidal Ideation | Escitalopram Oxalate    |                    |                    | S               | Oral                 |                      |                 | Forest       |                |
|                                                | Escitalopram Oxalate    |                    |                    | S               |                      |                      |                 | Forest       |                |
|                                                | Citalopram Hydrobromide |                    |                    | S               |                      | 1/2 Drop Daily       |                 | Forest       |                |
|                                                | Citalopram Hydrobromide |                    |                    | S               |                      | 2 Drops Daily        |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                    | 8541726                 | EXPEDITED (15-DAY) | Y                  | HO              | ES-FRI-1000030208    |                      | 65 YR           | Male         | ESP            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Hyponatraemia                | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest       |                |
|                                                | Trileptal               |                    |                    | S               | Oral                 | 1200 Mg              |                 | Not Reported |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                    | 8541806                 | EXPEDITED (15-DAY) | Y                  | OT              | DE-FRI-1000022480    |                      | 40 YR           | Female       | DEU            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Caesarean Section; Pregnancy                   | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                    | 8541817                 | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030183    |                      | 78 YR           | Male         | FRA            |
| <u>Preferred Term</u>                          | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Duodenitis; Oesophageal Stenosis               | Escitalopram Oxalate    |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                | Atarax                  |                    |                    | S               | Oral                 | 100 Mg               |                 | Not Reported |                |
|                                                | Reminyl                 |                    |                    | S               | Oral                 | 8 Mg                 |                 | Not Reported |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                | Haldol               | S                | Oral               | 24 Df           |                      | Not Reported                  |                 |              |                |
|--------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|-------------------------------|-----------------|--------------|----------------|
|                                                                                | Stilnox              | S                | Oral               | 10 Mg           |                      | Not Reported                  |                 |              |                |
|                                                                                | Alprazolam           | S                | Oral               | 1.5 Mg          |                      | Not Reported                  |                 |              |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                    | 8549461              | DIRECT           | Y                  | OT              |                      |                               | 39 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Product Substitution Issue;<br>Rash                                            | Escitalopram Oxalate |                  |                    | S               | Oral                 | Once Tab Po Qd                |                 | Not Reported |                |
|                                                                                | Seroquel             |                  |                    | C               |                      |                               |                 | Not Reported |                |
|                                                                                | Depakote             |                  |                    | C               |                      |                               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                    | 8553588              | DIRECT           | Y                  |                 |                      |                               | 45 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Therapy Non-Responder                                                          | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20 Mg Qd Po @3/15/12 X<br>4/7 |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                    | 8553782              | DIRECT           | Y                  | OT              |                      |                               | 8 YR            | Male         | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Crying; Drug Ineffective;<br>Emotional Disorder;<br>Product Substitution Issue | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10mg One Qd Oral              |                 | Mylan        |                |
| <u>FDA Received Date</u>                                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>          | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 02-May-2012                                                                    | 8554654              | DIRECT           | Y                  | OT              |                      |                               | 60 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>            | <u>Duration</u> | <u>Mfr</u>   |                |
| Depression; Product                                                            | Lexapro              |                  |                    | S               | Oral                 | 20mg One Qhs P.O.             |                 | Teva         |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |                 |   |              |
|---------------------|-----------------|---|--------------|
| Substitution Issue; | Synthroid       | C | Not Reported |
| Suicidal Ideation   | Wellbutrin XL   | C | Not Reported |
|                     | Zyprexa         | C | Not Reported |
|                     | Glucophage      | C | Not Reported |
|                     | Vesicare        | C | Not Reported |
|                     | Lithobid 450 Mg | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2012              | 8544591       | EXPEDITED (15-DAY) | Y                  | OT              | US-FRI-1000030091    |                      | 99 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Alcohol Increased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2012              | 8544841       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030084    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Talipes               | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2012              | 8545520       | EXPEDITED (15-DAY) | N                  | OT              | US-WATSON-2012-06804 |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                              | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Blood Pressure Decreased; Heart Rate Decreased; Leg Problem; Myocardial Infarction | Trazodone Hydrochloride |              |            | S           | Oral         | 200 Mg Qhs         |                 | Watson       |
|                                                                                    | Lexapro                 |              |            | S           | Oral         | 1 Tab Daily        |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 03-May-2012              | 8545662       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030101    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                        |                      |                    |                    |                 |                              |                              |                 |              |                |
|------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|------------------------------|-----------------|--------------|----------------|
| Congenital Anomaly;<br>Congenital Spinal Cord<br>Anomaly; Microcephaly |                      | Lexapro            |                    | S               | Transplacental               |                              |                 | Forest       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 03-May-2012                                                            | 8545680              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030171            |                              | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Septal Defect;<br>Ventricular Septal Defect                     | Lexapro              |                    |                    | S               | Transplacental               |                              |                 | Forest       |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2012                                                            | 8535138              | EXPEDITED (15-DAY) | Y                  | HO              | CN-FRI-1000030072            |                              | 38 YR           | Male         | CHN            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Gastric Ulcer                                                          | Lexapro              |                    |                    | S               | Oral                         | 10 Mg                        |                 | Forest       |                |
|                                                                        | Mirtazapine          |                    |                    | C               | Oral                         |                              |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2012                                                            | 8535547              | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-<br>2012100726 |                              | 51 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Interstitial Lung<br>Disease; Raynaud'S<br>Phenomenon      | Lyrica               |                    |                    | S               | Oral                         | Unk                          |                 | Pfizer       |                |
|                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                         | Unk                          | 218 DAY         | Not Reported |                |
|                                                                        | Bromazepam           |                    |                    | S               | Oral                         | Unk                          |                 | Not Reported |                |
|                                                                        | Klinal               |                    |                    | S               | Oral                         | Two Dosages Forms Per<br>Day |                 | Not Reported |                |
| <u>FDA Received Date</u>                                               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 04-May-2012                                                            | 8545996              | EXPEDITED (15-DAY) | N                  | OT              | US-SHIRE-ALL1-2012-<br>02058 |                              | 61 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u>   |                |

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                            |            |   |      |                                       |              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---|------|---------------------------------------|--------------|
| Chills; Depression;<br>Disturbance In Attention;<br>Drug Ineffective; Product<br>Prescribing Error; Product<br>Quality Issue; Pyrexia;<br>Sluggishness; Tremor;<br>Yawning | Vyvanse    | S | Oral | 50 Mg, 3-4 Times Per<br>Week As Req'D | Shire        |
|                                                                                                                                                                            | Vyvanse    | S | Oral | 30 Mg, 1x/Day:Qd                      | Shire        |
|                                                                                                                                                                            | Amoxapine  | S | Oral | Unk, 1x/Day:Qd                        | Not Reported |
|                                                                                                                                                                            | Wellbutrin | S | Oral | Unk, 1x/Day:Qd                        | Not Reported |
|                                                                                                                                                                            | Lexapro    | S |      | Unk, 1x/Day:Qd                        | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u>          | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------|------------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 04-May-2012              | 8546029                | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-<br>2012107268 |                      |                 | Female       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>         | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Hypersensitivity    | Zoloft                 |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Doxycycline Hyclate    |                  |                    | S               |                              | Unk                  |                 | Pfizer       |                |
|                          | Tramadol Hydrochloride |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Lexapro                |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Duragesic              |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Paxil                  |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Compazine              |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Droperidol             |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |
|                          | Codeine                |                  |                    | S               |                              | Unk                  |                 | Not Reported |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-May-2012              | 8547293              | EXPEDITED (15-DAY) | Y                  | LT              | MY-FRI-1000030253    |                      | 56 YR           | Male       | MYS            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Seizure                  | Escitalopram Oxalate |                    |                    | S               | Oral                 | 15 Mg                |                 | Forest     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 04-May-2012              | 8547451        | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030194    |                      | < 1 DAY         | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                         |         |   |                |        |
|-----------------------------------------|---------|---|----------------|--------|
| Congenital Anomaly;<br>Craniosynostosis | Lexapro | S | Transplacental | Forest |
|-----------------------------------------|---------|---|----------------|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 04-May-2012              | 8547487       | EXPEDITED (15-DAY) | N                  | OT              | US-ABBOTT-12P-163-0929570-00 |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Pain Upper;      | Humira         |              |            | S           |              |                    |                 | Not Reported |
| Anxiety; Arthralgia;       | Lexapro        |              |            | S           |              | Daily Dose: 5mg    |                 | Not Reported |
| Burning Sensation;         | Xanax          |              |            | S           |              |                    |                 | Not Reported |
| Choking Sensation;         |                |              |            |             |              |                    |                 |              |
| Dizziness; Drug            |                |              |            |             |              |                    |                 |              |
| Ineffective; Dyspnoea; Eye |                |              |            |             |              |                    |                 |              |
| Swelling; Headache;        |                |              |            |             |              |                    |                 |              |
| Nausea; Neck Pain; Panic   |                |              |            |             |              |                    |                 |              |
| Attack; Pharyngeal         |                |              |            |             |              |                    |                 |              |
| Oedema; Pruritus;          |                |              |            |             |              |                    |                 |              |
| Psoriasis; Swelling Face;  |                |              |            |             |              |                    |                 |              |
| Swollen Tongue             |                |              |            |             |              |                    |                 |              |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2012              | 8547757       | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030207    |                      | < 1 DAY    | Male       | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|------------|
| Congenital                | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest     |
| Hydrocephalus; Multiple   |                |              |            |             |                |                    |                 |            |
| Congenital Abnormalities; |                |              |            |             |                |                    |                 |            |
| Spina Bifida              |                |              |            |             |                |                    |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 04-May-2012              | 8547966       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030256    |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;    | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Forest       |
| Disorientation;       | Coumadin             |              |            | S           | Oral         | 2 Mg               |                 | Not Reported |
| Encephalopathy        |                      |              |            |             |              |                    |                 |              |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |         |              |
|------------|---|------|---------|--------------|
| Alprazolam | S | Oral |         | Not Reported |
| Ramipril   | C | Oral | 5 Mg    | Not Reported |
| Aldactone  | C | Oral | 25 Mg   | Not Reported |
| Tahor      | C | Oral |         | Not Reported |
| Carvedilol | C | Oral | 12.5 Mg | Not Reported |
| Furosemide | C | Oral | 20 Mg   | Not Reported |
| Omeprazole | C | Oral |         | Not Reported |

| <u>FDA Received Date</u>                                                                       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                         | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|------------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------------------------------|-----------------|--------------|----------------|
| 04-May-2012                                                                                    | 8555533              | DIRECT           | Y                  | RI              |                      |                                              | 51 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                           | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Drug Intolerance;<br>Feeling Abnormal;<br>Insomnia; Mood Altered;<br>Weight Increased | Escitalopram Oxalate |                  |                    | S               | Oral                 | 10mg Once Daily Oral<br>Early 2012 X 1 Month |                 | Not Reported |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 07-May-2012                | 8541718        | EXPEDITED (15-DAY) | N                  | OT              | PHHY2012US034939     |                      |                 | Female       | USA            |
| <u>Preferred Term</u>      | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abortion Spontaneous;      | Bufferin       |                    | Y                  | S               |                      |                      |                 | Novartis     |                |
| Blood Cholesterol          | Morphine       |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Blood Glucose   | Codeine        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Blood Pressure  | Maxalt         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Increased; Crying; Drug    | Topamax        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Ineffective; Gastric       | Effexor        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Disorder; Incorrect Dose   | Inderal        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Administered; Incorrect    | Prozac         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Product Administration     | Paxil          |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Duration; Maternal         | Serzone        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Exposure During            | Lexapro        |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Pregnancy; Micturition     | Zantac         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Urgency; Migraine; Panic   | Lortab         |                    |                    | S               |                      |                      |                 | Not Reported |                |
| Attack; Suicidal Ideation; | Tylenol        |                    |                    | S               |                      |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                            |               |   |              |
|----------------------------|---------------|---|--------------|
| Vomiting; Weight Increased | Advil         | S | Not Reported |
|                            | Aleve         | S | Not Reported |
|                            | Bayer Aspirin | S | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8548503       | EXPEDITED (15-DAY) | Y                  | DE              | PHHY2012CH037631     |                      |            | Unknown    | CHE            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------------------------|-----------------|--------------|
| Completed Suicide     | Ritalin        |              |            | S           |              |                                      |                 | Novartis     |
|                       | Chantix        |              |            | S           | Oral         |                                      |                 | Not Reported |
|                       | Cipralex       |              |            | S           | Oral         | 10 Mg, Daily                         |                 | Not Reported |
|                       | Remeron        |              |            | S           | Oral         | 15 Mg Oral Dose ¼ - ½ Tablet Per Day |                 | Not Reported |
|                       | Lorazepam      |              |            | C           |              |                                      |                 | Not Reported |
|                       | Zopiclone      |              |            | C           |              |                                      |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------------------------------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8548627       | NON-EXPEDITED    | N                  |                 | US-B.I.<br>PHARMACEUTICALS,I<br>NC./RIDGEFIELD-2012-<br>BP-09 |                      | 60 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Sexual Dysfunction    | Flomax         |              |            | S           | Oral         |                    |                 | Boehringer Ingelheim |
|                       | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Not Reported         |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported         |
|                       | Cardura        |              |            | S           |              |                    |                 | Not Reported         |
|                       | Wellbutrin     |              |            | C           |              |                    |                 | Not Reported         |
|                       | Tricor         |              |            | C           |              |                    |                 | Not Reported         |
|                       | Lipitor        |              |            | C           |              |                    |                 | Not Reported         |
|                       | Alphagan P     |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8549690       | EXPEDITED (15-DAY) | Y                  | OT              | IT-JNJFOC-<br>20120412742 |                      | 31 YR      | Female     | ITA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |                      |   |      |              |
|--------------------------|----------------------|---|------|--------------|
| Intentional Overdose;    | Haldol               | S | Oral | Not Reported |
| Intentional Self-Injury; | Delorazepam          | S | Oral | Not Reported |
| Sopor                    | Escitalopram Oxalate | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8550211       | EXPEDITED (15-DAY) | Y                  | CA              | TR-FRI-1000030270    |                      |            | Unknown    | TUR            |

| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------|----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Congenital<br>Musculoskeletal Anomaly | Escitalopram Oxalate |              |            | S           | Transplacental | 10 Mg              |                 | Forest       |
|                                       | Remeron              |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                       | Medazepam            |              |            | S           | Transplacental |                    |                 | Not Reported |
|                                       | Xanax                |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8559915       | EXPEDITED (15-DAY) | Y                  | DE              | 2012SP023212         |                      | 30 YR      | Female     | CHE            |

| <u>Preferred Term</u>            | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Completed Suicide;<br>Depression | Remeron             |              |            | S           | Oral         | 15 Mg;Qd;Po        |                 | Not Reported |
|                                  | Chantix             |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                  | Cipralext           |              |            | S           | Oral         | 10 Mg;Qid;Po       |                 | Not Reported |
|                                  | Ritalin             |              |            | S           | Oral         | Po                 |                 | Not Reported |
|                                  | Temesta (Lorazepam) |              |            | C           |              |                    |                 | Not Reported |
|                                  | Imovane             |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 08-May-2012              | 8531100       | EXPEDITED (15-DAY) | Y                  | HO, OT          | MX-RANBAXY-2012RR-55804 |                      | 76 YR      | Female     | MEX            |

| <u>Preferred Term</u>                | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------------|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Interaction; Lactic<br>Acidosis | Metformin Hydrochloride |              |            | S           | Unknown      | 850 Mg/ 8h         |                 | Ranbaxy    |
|                                      | Ibuprofen               |              |            | S           | Unknown      | 600 Mg, Tid        |                 | Ranbaxy    |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |         |           |              |
|--|----------------------|---|---------|-----------|--------------|
|  | Escitalopram Oxalate | S | Unknown | 20 Mg/Day | Not Reported |
|  | Mirtazapine          | S | Unknown | 30 Mg/Day | Not Reported |
|  | Simvastatin          | S | Unknown | 40 Mg/Day | Ranbaxy      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2012              | 8544862       | EXPEDITED (15-DAY) | Y                  | OT              | PHHY2012IN037006     |                      | 67 YR      | Male       | IND            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Drug Interaction;<br>Hypomania | Clonazepam           |              |            | S           |              | 0.5 Mg/ Day        |                 | Novartis     |
|                                | Amlodipine           |              |            | C           |              | 2.5 Mg/ Day        |                 | Not Reported |
|                                | Losartan Potassium   |              |            | C           |              | 25 Mg/ Day         |                 | Not Reported |
|                                | Escitalopram Oxalate |              |            | S           |              | 10 Mg/Day          |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------------------|----------------------|------------|------------|----------------|
| 08-May-2012              | 8551122       | EXPEDITED (15-DAY) | N                  | DE, HO          | FR-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16558868 |                      | 79 YR      | Male       | FRA            |

| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>           |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|----------------------|
| Cardiac Failure;<br>Confusional State; Death;<br>Disorientation;<br>Encephalopathy; Urinary<br>Retention | Coumadin             |              |            | S           | Oral         |                    |                 | Bristol Myers Squibb |
|                                                                                                          | Escitalopram Oxalate |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                                                                          | Alprazolam           |              |            | S           | Oral         |                    |                 | Not Reported         |
|                                                                                                          | Ramipril             |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                          | Aldactone            |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                          | Tahor                |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                          | Carvedilol           |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                          | Furosemide           |              |            | C           |              |                    |                 | Not Reported         |
|                                                                                                          | Omeprazole           |              |            | C           |              |                    |                 | Not Reported         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2012              | 8552683       | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030169    |                      | 44 YR      | Male       | FRA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                           |                      |   |      |       |              |
|-------------------------------------------|----------------------|---|------|-------|--------------|
| Deep Vein Thrombosis;<br>Drug Intolerance | Escitalopram Oxalate | S | Oral | 5 Mg  | Forest       |
|                                           | Escitalopram Oxalate | S | Oral | 20 Mg | Forest       |
|                                           | Escitalopram Oxalate | S | Oral | 10 Mg | Forest       |
|                                           | Escitalopram Oxalate | S | Oral | 5 Mg  | Not Reported |
|                                           | Agomelatine          | S | Oral | 25 Mg | Not Reported |

| <u>FDA Received Date</u>                                                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------------------------------------------------------------------|----------------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 08-May-2012                                                                                   | 8557493              | DIRECT           | Y                  | OT              |                      |                      | 50 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                         | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Withdrawal Syndrome; Feeling Abnormal; Product Dose Omission; Product Substitution Issue | Escitalopram Oxalate |                  |                    | S               | Oral                 | 20mg Daily Po        |                 | Not Reported |                |

| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------------------------------------------|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 08-May-2012                                                    | 8558857        | DIRECT           | N                  | OT              |                      |                      | 53 YR           | Male       | USA            |
| <u>Preferred Term</u>                                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Withdrawal Syndrome; Influenza Like Illness; Paraesthesia | Lexapro        |                  |                    | S               | Oral                 | 20mg 1/Day Oral      |                 | Forest     |                |

| <u>FDA Received Date</u>                                                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
| 09-May-2012                                                                           | 8537016              | EXPEDITED (15-DAY) | Y                  | HO, LT          | FR-ABBOTT-12P-056-0928789-00 |                      | 52 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Asterixis; Encephalopathy; Hepatic Failure; Hepatitis Toxic; Jaundice; Liver Disorder | Progesterone         |                    |                    | S               | Oral                         |                      |                 | Not Reported |                |
|                                                                                       | Escitalopram Oxalate |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                                       | Disulfiram           |                    |                    | S               | Unknown                      |                      |                 | Not Reported |                |
|                                                                                       | Oxazepam             |                    |                    | C               | Oral                         |                      |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                                                                                                | Levothyroxine        | C                  | Unknown            |                 |                              |                      |                 | Not Reported |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|--------------|----------------|
|                                                                                                                                                                                                | Estradiol            | C                  | Oral               |                 |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Milnacipran          | C                  | Unknown            |                 |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-May-2012                                                                                                                                                                                    | 8532701              | EXPEDITED (15-DAY) | Y                  | HO              | ES-ABBOTT-12P-144-0928203-00 |                      | 27 YR           | Female       | ESP            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Depressed Level Of Consciousness; Intentional Overdose                                                                                                                                         | Akineton             |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |
|                                                                                                                                                                                                | Escitalopram Oxalate |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |
|                                                                                                                                                                                                | Invega               |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |
|                                                                                                                                                                                                | Rivotril             |                    |                    | S               | Oral                         | Total                |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 10-May-2012                                                                                                                                                                                    | 8556549              | EXPEDITED (15-DAY) | Y                  | DE, HO          | TR-FRI-1000030396            |                      | 44 YR           | Male         | TUR            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Syncope                                                                                                                                                                                        | Escitalopram Oxalate |                    |                    | S               | Oral                         |                      |                 | Forest       |                |
|                                                                                                                                                                                                | Moclobemide          |                    |                    | S               |                              |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                                                                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2012                                                                                                                                                                                    | 8192244              | EXPEDITED (15-DAY) | Y                  | DS, HO, OT      | 2010SP063654                 |                      | 36 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                                                                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Abdominal Distension; Accident At Work; Acute Sinusitis; Adnexa Uteri Mass; Anger; Apathy; Arthralgia; Arthritis; Asthenia; Back Pain; Bacterial Vulvovaginitis; Bipolar Disorder; Blood 1,25- | Nuvaring             |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Lexapro              |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Reglan               |                    |                    | S               |                              |                      |                 | Not Reported |                |
|                                                                                                                                                                                                | Coumadin             |                    |                    | S               |                              |                      |                 | Not Reported |                |

Dihydroxycholecalciferol  
Decreased; Blood  
Homocysteine Increased;  
Bradykinesia; Bruxism;  
Central Nervous System  
Lesion; Cerebellar  
Haemorrhage; Chest  
Discomfort; Constipation;  
Diplopia; Dizziness; Drug  
Ineffective; Drug  
Intolerance; Dry Eye;  
Dysgeusia;  
Dysmenorrhoea;  
Dyspnoea; Dysuria;  
Epstein-Barr Virus  
Infection; Eye Injury; Eye  
Pain; Fatigue; Feeling  
Jittery; Fibromyalgia;  
Flatulence; Folate  
Deficiency; Gastritis;  
Genital Discharge;  
Headache; Herpes  
Dermatitis; Hot Flush;  
Hypercoagulation;  
Hyperhidrosis;  
Hypersensitivity;  
Hypotension; Impaired  
Work Ability; Infectious  
Mononucleosis; Influenza  
Like Illness; Insomnia;  
International Normalised  
Ratio Decreased;  
International Normalised  
Ratio Increased; Iritis; Iron  
Deficiency Anaemia;  
Irritable Bowel Syndrome;  
Joint Swelling;  
Labyrinthitis; Listless; Loss  
Of Libido; Lower  
Respiratory Tract Infection  
Viral; Lymphadenopathy;  
Lymphoedema; Major

Depression; Malaise;  
Mastoptosis; Memory  
Impairment; Meniere'S  
Disease; Menorrhagia;  
Metrorrhagia; Micturition  
Urgency; Migraine;  
Migraine With Aura; Mood  
Swings; Multiple Injuries;  
Muscle Spasms; Muscle  
Strain; Musculoskeletal  
Chest Pain; Myositis;  
Nausea; Neck Pain;  
Nightmare; Oedema  
Peripheral; Onychoclasia;  
Osteoarthritis; Ovarian  
Cyst; Pain; Pain In  
Extremity; Paraesthesia;  
Pelvic Pain; Pharyngitis;  
Pollakiuria; Premenstrual  
Syndrome; Proctalgia;  
Protein C Decreased;  
Pulmonary Embolism;  
Rash; Sedation; Sleep  
Apnoea Syndrome; Sleep  
Disorder; Snoring;  
Somnolence; Suicidal  
Ideation; Systemic Lupus  
Erythematosus; Tension  
Headache; Thrombosis;  
Tinnitus; Treatment  
Noncompliance; Tricuspid  
Valve Incompetence;  
Urinary Tract Infection;  
Uterine Leiomyoma;  
Vertigo Positional; Viral  
Infection; Vitamin B12  
Deficiency; Vitamin D  
Deficiency; Vomiting;  
Vulvovaginal Mycotic  
Infection; Weight  
Decreased; Weight  
Increased

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# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| 11-May-2012                                             | 8558990              | EXPEDITED (15-DAY) | Y                  | HO              | CA-ROCHE-1064985         |                      | 27 YR           | Female       | CAN            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Autonomic Nervous System Imbalance;                     | Tamiflu              |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| Clonus; Dizziness; Drug Interaction; Hyperreflexia;     | Clonazepam           |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
| Mydriasis; Restlessness; Serotonin Syndrome; Tremor     | Ciprallex            |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 11-May-2012                                             | 8559282              | EXPEDITED (15-DAY) | N                  | CA              | US-FRI-1000030352        |                      | < 1 DAY         | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Spina Bifida                                            | Lexapro              |                    |                    | S               | Transplacental           |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 14-May-2012                                             | 8441533              | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012054125 |                      |                 | Male         | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Arthralgia; Back Pain;                                  | Lipitor              |                    |                    | S               |                          | 80 Mg, Daily         |                 | Pfizer       |                |
| Bipolar Disorder;                                       | Lipitor              |                    |                    | S               |                          |                      |                 | Pfizer       |                |
| Diarrhoea; Drug Intolerance; Eating Disorder; Headache; | Nitrostat            |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Hypersensitivity; Influenza Like Illness; Neck Pain;    | Xanax                |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
| Pain In Extremity; Pyrexia; Weight Decreased            | Alprazolam           |                    |                    | S               |                          | Unk                  |                 | Pfizer       |                |
|                                                         | Carvedilol           |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                         | Escitalopram Oxalate |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                         | Lexapro              |                    |                    | S               |                          | Unk                  |                 | Not Reported |                |
|                                                         | Nitrostat            |                    |                    | C               |                          | Unk                  |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |              |              |
|-----------|---|--------------|--------------|
| Aspirin   | C | 81 Mg, Unk   | Not Reported |
| Quinapril | C | Unk, Daily   | Not Reported |
| Xanax     | C | 2 Mg, 3x/Day | Not Reported |
| Coreg     | C | 25 Mg, Unk   | Not Reported |
| Plavix    | C | 75 Mg, Unk   | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2012              | 8475062       | EXPEDITED (15-DAY) | N                  | CA, HO, OT      | US-FRI-1000029169    |                      |            | Male       | USA            |

| <u>Preferred Term</u>                                                                                                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Cerebral Haemorrhage Neonatal; Foetal Exposure During Pregnancy; Pyloric Stenosis; Transposition Of The Great Vessels | Lexapro        |              |            | S           | Transplacental |                    |                 | Forest       |
|                                                                                                                       | Prozac         |              |            | C           |                |                    |                 | Not Reported |
|                                                                                                                       | Natachew       |              |            | C           |                |                    |                 | Not Reported |
|                                                                                                                       | Esgic-Plus     |              |            | C           |                |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2012              | 8498399       | EXPEDITED (15-DAY) | N                  | OT              | US-FRI-1000029168    |                      | 27 YR      | Female     | USA            |

| <u>Preferred Term</u>                                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|--------------|
| Gestational Hypertension; Maternal Exposure During Pregnancy | Lexapro        |              |            | S           | Oral         |                        |                 | Forest       |
|                                                              | Prozac         |              |            | C           | Oral         | 10 Mg                  |                 | Not Reported |
|                                                              | Natachew       |              |            | C           | Oral         | 1 Mg                   |                 | Not Reported |
|                                                              | Esgic-Plus     |              |            | C           | Oral         | 500 Mg/50 Mg/40 Mg Q6h |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 14-May-2012              | 8560609       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-ABBOTT-12P-151-0934037-00 |                      | 46 YR      | Female     | CHE            |

| <u>Preferred Term</u>                                                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Asterixis; Chills; Confusional State; Decreased Appetite; Drug Interaction; Drug Level | Norvir         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                        | Truvada        |              |            | C           | Oral         |                    |                 | Not Reported |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                            |                  |   |                          |                 |              |
|----------------------------|------------------|---|--------------------------|-----------------|--------------|
| Increased; Fatigue;        | Morphine Sulfate | C | Oral                     | 340 Am + 320 Pm | Not Reported |
| Hepatic Pain;              | Wellvone         | C | Oral                     |                 | Not Reported |
| Hyperhidrosis; Hypertonia; | Noroxin          | C | Oral                     |                 | Not Reported |
| Jaundice; Muscle Rigidity; | Oxazepam         | C | Oral                     |                 | Not Reported |
| Mydriasis; Myoclonus;      | Torseamide       | C | Oral                     |                 | Not Reported |
| Nausea; Psychomotor        | Lactitol         | C | Oral                     |                 | Not Reported |
| Skills Impaired; Serotonin | Seretide         | C | Respiratory (inhalation) |                 | Not Reported |
| Syndrome; Tremor;          | Nasonex          | C | Nasal                    |                 | Not Reported |
| Vertigo; Vomiting          | Flunitrazepam    | C | Oral                     |                 | Not Reported |
|                            | Aldactone        | C |                          | Daily           | Not Reported |
|                            | Lansoprazole     | C |                          | Daily           | Not Reported |
|                            | Cipralex         | S | Oral                     |                 | Not Reported |
|                            | Prezista         | S | Oral                     |                 | Not Reported |
|                            | Nexium           | S | Oral                     |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 14-May-2012              | 8571405       | DIRECT           | Y                  |                 |                      |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Nausea; Product Quality Issue; Product Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 1 Daily Po         |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2012              | 8541753       | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000030215    |                      | 44 YR      | Female     | ITA            |

| <u>Preferred Term</u>                         | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------------------------------|-----------------|--------------|
| Bradypnoea; Medication Error; Overdose; Sopor | Escitalopram Oxalate            |              |            | S           | Oral         | Overdose: 28 Unit Dose (Frequency - Total) |                 | Forest       |
|                                               | Acetaminophen\Codeine Phosphate |              |            | S           | Oral         | Overdose: 16 Unit Dose                     |                 | Not Reported |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |   |      |                                                                      |              |
|--------------------------|---|------|----------------------------------------------------------------------|--------------|
| Rivotril                 | S | Oral | (Frequency - Total)<br>Overdose: 10 Unit Dose<br>(Frequency - Total) | Not Reported |
| Xanax                    | S | Oral | Overdose: 20 Unit Dose<br>(Frequency - Total)                        | Not Reported |
| Lormetazepam             | S | Oral | Overdose: 30 Unit Dose<br>(Frequency - Total)                        | Not Reported |
| Lyrica                   | C | Oral | 150 Mg                                                               | Not Reported |
| Duloxetine Hydrochloride | C | Oral | 60 Mg                                                                | Not Reported |
| Cardirene                | C |      |                                                                      | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 15-May-2012              | 8561453       | EXPEDITED (15-DAY) | CA, OT             |                 | PHHY2012DE039585     |                      |            | Unknown    | DEU            |

| <u>Preferred Term</u>                                                                   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|----------------------------|-----------------|--------------|
| Foetal Exposure During Pregnancy; Oesophageal Atresia; Premature Baby; Tracheal Atresia | Escitalopram          |              |            | S           | Transplacental |                            |                 | Not Reported |
|                                                                                         | Lorazepam             |              |            | S           | Transplacental |                            |                 | Novartis     |
|                                                                                         | Zolpidem              |              |            | S           | Transplacental |                            |                 | Not Reported |
|                                                                                         | Mycophenolate Mofetil |              |            | S           | Transplacental | (Maternal Dose: 0.5 G/Day) |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 15-May-2012              | 8562106       | EXPEDITED (15-DAY) | Y                  | HO              | FR-SANOFI-AVENTIS-2012SA033040 |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u>         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder; Fall | Stilnox              |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Amisulpride          |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Rivotril             |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Theralene            |              |            | S           | Oral         |                    |                 | Not Reported |
|                               | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|---------------------------|------------------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------|-----------------|--------------|----------------|
| 15-May-2012               | 8562190                                  | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000024137    |                         | 25 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| No Adverse Event          | Escitalopram Oxalate                     |                    |                    | S               | Oral                 |                         |                 | Forest       |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2012               | 8562746                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030478    |                         | 33 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Neutropenia; Overdose     | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | Overdose Of 30 Mg Daily |                 | Forest       |                |
|                           | Mirtazapine                              |                    |                    | S               | Oral                 | 15 Mg                   |                 | Not Reported |                |
|                           | Risperdal                                |                    |                    | S               | Oral                 | 2 Mg                    |                 | Not Reported |                |
|                           | Lovenox                                  |                    |                    | C               | Subcutaneous         | 120 Mg/1.26 MI Daily    |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 15-May-2012               | 8562748                                  | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030479    |                         | 84 YR           | Female       | FRA            |
| <u>Preferred Term</u>     | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Seizure | Escitalopram Oxalate                     |                    |                    | S               | Oral                 | 10 Mg                   |                 | Forest       |                |
|                           | Tramadol Hydrochloride And Acetaminophen |                    |                    | S               | Oral                 |                         |                 | Not Reported |                |
|                           | Tenormin                                 |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Hydrochlorothiazide\Valsartan            |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Aspirin                                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Crestor                                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Cytomel                                  |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Alendronate Sodium                       |                    |                    | C               |                      |                         |                 | Not Reported |                |
|                           | Lorazepam                                |                    |                    | C               |                      |                         |                 | Not Reported |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 16-May-2012               | 8491744                                  | EXPEDITED (15-DAY) | Y                  | OT              | JP-FRI-1000029494    |                         |                 | Female       | JPN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>     | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------|--------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hepatic Function Abnormal | Lexapro            |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                           | Pravastatin Sodium |              |            | S           |              | 1 Df               |                 | Not Reported |
|                           | Lansoprazole       |              |            | C           | Oral         | 30 Mg              |                 | Not Reported |
|                           | Brotizolam         |              |            | C           | Oral         | 0.25 Mg            |                 | Not Reported |
|                           | Flunitrazepam      |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                           | Nitrazepam         |              |            | C           | Oral         | 10 Mg              |                 | Not Reported |
|                           | Seroquel           |              |            | C           | Oral         | 700 Mg             |                 | Not Reported |
|                           | Lithium Carbonate  |              |            | C           | Oral         | 600 Mg             |                 | Not Reported |
|                           | Magtect            |              |            | C           | Oral         | 35 MI              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2012              | 8530636       | EXPEDITED (15-DAY) | Y                  | HO              | JP-FRI-1000030013    |                      | 74 YR      | Female     | JPN            |

| <u>Preferred Term</u>                                    | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Abdominal Distension; Enterocolitis; Nausea; Pollakiuria | Lexapro               |              |            | S           |              | 10 Mg              |                 | Forest       |
|                                                          | Amlodipine            |              |            | C           | Oral         | 5 Mg               |                 | Not Reported |
|                                                          | Candesartan Cilexetil |              |            | C           | Oral         | 4 Mg               |                 | Not Reported |
|                                                          | Amaryl                |              |            | C           | Oral         | 1 Mg               |                 | Not Reported |
|                                                          | Actos                 |              |            | C           | Oral         | 15 Mg              |                 | Not Reported |
|                                                          | Biofermin             |              |            | C           | Oral         | 3 G                |                 | Not Reported |
|                                                          | Lac-B                 |              |            | C           | Oral         | 3 G                |                 | Not Reported |
|                                                          | Rhubarb               |              |            | C           | Oral         | 0.5 G              |                 | Not Reported |
|                                                          | Seibule               |              |            | C           | Oral         | 150 Mg             |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2012              | 8565762       | EXPEDITED (15-DAY) |                    | HO, LT          | ES-ROCHE-1065964     |                      | 27 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                           |                      |   |      |              |
|-----------------------------------------------------------|----------------------|---|------|--------------|
| Depressed Level Of Consciousness;<br>Intentional Overdose | Clonazepam           | S | Oral | Not Reported |
|                                                           | Escitalopram Oxalate | S | Oral | Not Reported |
|                                                           | Biperiden            | S | Oral | Not Reported |
|                                                           | Paliperidone         | S | Oral | Not Reported |
|                                                           | Quetiapine Fumarate  | S | Oral | Not Reported |
|                                                           | Olanzapine           | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2012              | 8565831       | EXPEDITED (15-DAY) | N                  | HO              | US-FRI-1000030389    |                      | 15 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Aggression; Intentional Self-Injury | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg              |                 | Forest     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2012              | 8573891       | DIRECT           | Y                  | OT              |                      |                      | 54 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Akathisia; Dizziness; Nausea; Product Substitution Issue; Withdrawal Syndrome | Escitalopram Oxalate |              |            | S           | Oral         | 20 Mg Daily 047 (Oral) |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-May-2012              | 8574275       | DIRECT           | N                  | LT, OT          |                      |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>                                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Malaise; Product Dispensing Error; Wrong Product Administered | Escitalopram Oxalate |              |            | S           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-May-2012              | 8566665       | EXPEDITED (15-DAY) | Y                  | DS, OT          | AT-PFIZER INC-2012116612 |                      | 22 YR      | Female     | AUT            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                       | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------------------------------------------------------|---------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| C-Reactive Protein Increased; Depression; Psychotic Disorder; Spinal Pain; Weight Increased | Ziprasidone Hydrochloride |              |            | S           |              | 60 Mg Daily        |                 | Pfizer       |
|                                                                                             | Ciprallex                 |              |            | S           |              | 20 Mg Daily        |                 | Not Reported |
|                                                                                             | Lithium Carbonate         |              |            | S           |              | 950 Mg Daily       |                 | Not Reported |
|                                                                                             | Seroquel                  |              |            | S           |              | 35 Mg Daily        |                 | Not Reported |
|                                                                                             | Abilify                   |              |            | S           |              | 15 Mg Daily        |                 | Not Reported |
|                                                                                             | Edronax                   |              |            | C           |              | 6 Mg, Unk          |                 | Not Reported |
|                                                                                             | Inderal                   |              |            | C           |              | 10 Mg Daily        |                 | Not Reported |
|                                                                                             | Euthyrox                  |              |            | C           |              | 50 Mg, Unk         |                 | Not Reported |
|                                                                                             | Euthyrox                  |              |            | C           |              | 75 Mg, Unk         |                 | Not Reported |
|                                                                                             | Euthyrox                  |              |            | C           |              | 100 Mg, Unk        |                 | Not Reported |
|                                                                                             | Trazodone Hydrochloride   |              |            | C           |              | 200 Mg, Unk        |                 | Not Reported |
|                                                                                             | Trazodone Hydrochloride   |              |            | C           |              | 150 Mg, Unk        |                 | Not Reported |
|                                                                                             | Sucalfate                 |              |            | C           |              | 3 G, Unk           |                 | Not Reported |
|                                                                                             | Pantoprazole Sodium       |              |            | C           |              | 20 Mg, Unk         |                 | Not Reported |
|                                                                                             | Bisoprolol Fumarate       |              |            | C           |              | 2.5 Mg, Unk        |                 | Not Reported |
|                                                                                             | Seloken                   |              |            | C           |              | 95 Mg, Unk         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 17-May-2012              | 8567205       | NON-EXPEDITED    | N                  |                 | US-GLAXOSMITHKLINE-A0973648A |                      | 75 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>      |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|-----------------|
| Malaise; Vomiting     | Votrient       |              |            | S           | Oral         | 800mgd Per Day     |                 | Glaxosmithkline |
|                       | Lexapro        |              |            | S           |              |                    |                 | Not Reported    |
|                       | Tums           |              |            | C           |              |                    |                 | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 7775716       | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-US-WYE-H11674109 |                      | 74 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



## Detailed Report

| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 18-May-2012                    | 8483744              | EXPEDITED (15-DAY) | Y                  |                 | IT-FRI-1000029399        |                      |                 | Male       | ITA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Ocular Procedural Complication | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg                |                 |            | Forest         |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2012                    | 8528501              | EXPEDITED (15-DAY) | Y                  | HO, OT          | FR-PFIZER INC-2012094513 |                      | 65 YR           | Female     | FRA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise; Meningitis            | Sulfasalazine        |                    |                    | S               | Oral                     | Unk                  | 4380 DAY        |            | Pfizer         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                      |                                          |   |      |     |              |
|--------------------------------------|------------------------------------------|---|------|-----|--------------|
| Aseptic; Paraesthesia;<br>Vasculitis | Lansoprazole                             | S | Oral | Unk | Unknown      |
|                                      | Pravastatin Sodium                       | S | Oral | Unk | Not Reported |
|                                      | Escitalopram Oxalate                     | S | Oral | Unk | Not Reported |
|                                      | Mesalazine                               | C |      |     | Not Reported |
|                                      | Azathioprine                             | C |      |     | Not Reported |
|                                      | Solupred (Prednisolone Sodium Metazoate) | C |      |     | Not Reported |
|                                      | Cirkan                                   | C |      |     | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8547195       | EXPEDITED (15-DAY) | Y                  | OT              | CA-FRI-1000028475    |                      | 16 YR      | Female     | CAN            |

| <u>Preferred Term</u>                                                                                                                        | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                             | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|------------------------------------------------|-----------------|--------------|
| Decreased Appetite; Drug Withdrawal Syndrome; Dyskinesia; Muscle Twitching; Off Label Use; Seizure; Tongue Paralysis; Urine Output Decreased | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg                                          |                 | Forest       |
|                                                                                                                                              | Escitalopram Oxalate |              |            | S           | Oral         | May Give 15 Mg Instead Of 10 Mg When Necessary |                 | Forest       |
|                                                                                                                                              | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg                                          |                 | Not Reported |
|                                                                                                                                              | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg                                          |                 | Not Reported |
|                                                                                                                                              | Escitalopram Oxalate |              |            | S           | Oral         | 5 Mg                                           |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8562785       | EXPEDITED (15-DAY) | Y                  | HO              | IT-FRI-1000030453    |                      | 65 YR      | Female     | ITA            |

| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Hallucination, Visual; Psychomotor Hyperactivity | Escitalopram Oxalate |              |            | S           | Oral         | 4 Df               |                 | Forest       |
|                                                  | Ranitidine           |              |            | C           |              | 150 Mg             |                 | Not Reported |
|                                                  | Ramipril             |              |            | C           |              | 1 Df               |                 | Not Reported |
|                                                  | Plavix               |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8568713       | EXPEDITED (15-DAY) | Y                  | HO, LT          | CH-JNJFOC-20120510996 |                      | 46 YR      | Female     | CHE            |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                                                                                                                           | <u>Product</u>   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Confusional State;<br>Decreased Appetite;<br>Dizziness; Fatigue;<br>Hepatic Cirrhosis;<br>Hyperhidrosis; Mydriasis;<br>Myoclonus; Serotonin<br>Syndrome; Tremor | Prezista         |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Cipralext        |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Norvir           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Nexium           |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Truvada          |              |            | S           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Morphine Sulfate |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Wellvone         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Noroxin          |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Oxazepam         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Torse mide       |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Lactitol         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Seretide         |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Nasonex          |              |            | C           | Nasal        |                    |                 | Not Reported |
|                                                                                                                                                                 | Flunitrazepam    |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Lansoprazole     |              |            | C           | Oral         |                    |                 | Not Reported |
|                                                                                                                                                                 | Spironolactone   |              |            | C           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------------------------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8568986       | EXPEDITED (15-DAY) | Y                  | CA, OT          | DE-ROXANE<br>LABORATORIES, INC.-<br>2012-RO-01257RO |                      |            | Female     | DEU            |

| <u>Preferred Term</u>                                       | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>   | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-------------------------------------------------------------|-----------------------|--------------|------------|-------------|----------------|--------------------|-----------------|--------------|
| Oesophageal Atresia;<br>Premature Baby; Tracheal<br>Atresia | Mycophenolate Mofetil |              |            | S           | Transplacental |                    | 10 WEEK         | Roxane       |
|                                                             | Lorazepam             |              |            | S           | Transplacental |                    |                 | Roxane       |
|                                                             | Zolpidem              |              |            | S           | Transplacental |                    |                 | Roxane       |
|                                                             | Escitalopram Oxalate  |              |            | S           | Transplacental |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8569444       | EXPEDITED (15-DAY) | N                  | HO              | CH-BRISTOL-MYERS<br>SQUIBB COMPANY- |                      | 28 YR      | Male       | CHE            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

16582520

| <u>Preferred Term</u> | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Serotonin Syndrome    | Abilify           |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Seroquel          |              |            | S           |              |                    |                 | Not Reported |
|                       | Ciprallex         |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Lithium Carbonate |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8569700       | EXPEDITED (15-DAY) | Y                  | HO              | US-FRI-1000030433    |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Malaise; Mental Disorder | Lexapro        |              |            | S           |              | 10 Mg              |                 | Forest       |
|                          | Xanax Xr       |              |            | S           | Oral         | 3 Mg               |                 | Not Reported |
|                          | Xanax Xr       |              |            | S           |              |                    |                 | Not Reported |
|                          | Xanax Xr       |              |            | S           |              |                    |                 | Not Reported |
|                          | Lipitor        |              |            | C           |              | 10 Mg              |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8578090       | DIRECT           | N                  | LT, OT          |                      |                      | 58 YR      | Male       | USA            |

| <u>Preferred Term</u>                                                                                                | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|----------------------|-----------------|--------------|
| Abnormal Dreams;<br>Agitation; Anxiety; Drug<br>Interaction; Insomnia;<br>Nervousness; Product<br>Substitution Issue | Escitalopram Oxalate |              |            | S           | Oral         | 10 Mg 1 Per Night Po |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 18-May-2012              | 8578105       | DIRECT           | N                  | OT              |                      |                      | 52 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
|------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|--------------|----------------|
| Anxiety; Product Substitution Issue                  | Escitalopram Oxalate |                    |                    | S               |                          | 10 Mg Daily          |                 | Teva         |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2012                                          | 8445218              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000028862        |                      | 52 YR           | Female       | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Ventricular Extrasystoles                            | Escitalopram Oxalate |                    |                    | S               |                          | 10 Mg                |                 | Forest       |                |
|                                                      | Escitalopram Oxalate |                    |                    | S               |                          |                      |                 | Forest       |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2012                                          | 8560792              | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-FRI-1000030452        |                      | 75 YR           | Male         | ESP            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Upper Gastrointestinal Haemorrhage | Escitalopram Oxalate |                    |                    | S               | Oral                     | 10 Mg                |                 | Forest       |                |
|                                                      | Gabapentin           |                    |                    | C               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Atorvastatin Calcium |                    |                    | C               | Oral                     | 80 Mg                |                 | Not Reported |                |
|                                                      | Seroquel             |                    |                    | C               | Oral                     | 25 Mg                |                 | Not Reported |                |
|                                                      | Acetylsalicylic Acid |                    |                    | S               | Oral                     |                      |                 | Not Reported |                |
|                                                      | Warfarin Sodium      |                    |                    | S               | Oral                     | 5 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 21-May-2012                                          | 8572243              | EXPEDITED (15-DAY) | Y                  | OT              | AT-PFIZER INC-2012116700 |                      | 41 YR           | Male         | AUT            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                                            | Lyrica               |                    |                    | S               | Oral                     | 150 Mg, 1x/Day       | 7 DAY           | Pfizer       |                |
|                                                      | Cipralext            |                    |                    | S               | Oral                     | 10 Mg, 1x/Day        |                 | Not Reported |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>          | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>                                                            | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|-----------------------------------|---------------------------|--------------------|--------------------|-----------------|-------------------------------------------------|---------------------------------------------------------------------------------|-----------------|--------------|----------------|
| 22-May-2012                       | 8572851                   | EXPEDITED (15-DAY) | N                  | DS              | AT-BRISTOL-MYERS<br>SQUIBB COMPANY-<br>16590309 |                                                                                 | 20 YR           | Female       | AUT            |
| <u>Preferred Term</u>             | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>                                                              | <u>Duration</u> | <u>Mfr</u>   |                |
| Spinal Disorder; Weight Increased | Abilify                   |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Abilify                   |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Ciprallex                 |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Ciprallex                 |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Lithium Carbonate         |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Lithium Carbonate         |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Quetiapine Fumarate       |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Quetiapine Fumarate       |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Ziprasidone Hydrochloride |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Ziprasidone Hydrochloride |                    |                    | S               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Trazodone Hydrochloride   |                    |                    | C               |                                                 |                                                                                 |                 | Not Reported |                |
|                                   | Euthyrox                  |                    |                    | C               |                                                 | Dosage Form: 50mg From<br>2008-09,75 Mg From<br>2009-10,100mg Since<br>2010-Ong |                 | Not Reported |                |
|                                   | Pantoloc                  |                    |                    | C               |                                                 |                                                                                 |                 | Not Reported |                |

| <u>FDA Received Date</u>         | <u>Case #</u>                                                                                                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| 22-May-2012                      | 8573460                                                                                                             | EXPEDITED (15-DAY) | Y                  | HO              | FR-FRI-1000030636    |                      | 75 YR           | Female       | FRA            |
| <u>Preferred Term</u>            | <u>Product</u>                                                                                                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Generalised Tonic-Clonic Seizure | Escitalopram Oxalate                                                                                                |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                  | Risperdal                                                                                                           |                    |                    | S               | Oral                 | 2 Mg                 |                 | Not Reported |                |
|                                  | Keppra                                                                                                              |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                  | Transipeg (Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous) |                    |                    | C               |                      |                      |                 | Not Reported |                |
|                                  |                                                                                                                     |                    |                    |                 |                      |                      |                 |              |                |
|                                  |                                                                                                                     |                    |                    |                 |                      |                      |                 |              |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|----------------------------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-------------------------------------------------|------------------------|-----------------|--------------|----------------|
| 22-May-2012                                                                                              | 8574653              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030315                               |                        |                 | Female       | FRA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Atrial Fibrillation;<br>Ventricular Fibrillation                                                         | Escitalopram Oxalate |                    |                    | S               |                                                 | 20 Mg                  |                 | Forest       |                |
|                                                                                                          | Quetiapine Fumarate  |                    |                    | C               |                                                 |                        |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 22-May-2012                                                                                              | 8588899              | DIRECT             | Y                  | OT              |                                                 |                        | 54 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Cough; Dry Mouth;<br>Feeling Abnormal;<br>Flatulence; Libido<br>Decreased; Product<br>Substitution Issue | Escitalopram Oxalate |                    |                    | S               | Oral                                            | 20mg 2 Tabs Daily Po   |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2012                                                                                              | 8574886              | EXPEDITED (15-DAY) | Y                  | OT              | IN-PAR<br>PHARMACEUTICAL,<br>INC-2012SCPR004388 |                        |                 | Unknown      | IND            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |
| Hypomania                                                                                                | Clonazepam           |                    |                    | S               | Unknown                                         | 0.5 Mg/Day At Bed Time |                 | Par          |                |
|                                                                                                          | Escitalopram Oxalate |                    |                    | S               | Unknown                                         | 10 Mg, / Day           |                 | Not Reported |                |
|                                                                                                          | Amlodipine           |                    |                    | C               | Unknown                                         | 2.5 Mg, / Day          |                 | Not Reported |                |
|                                                                                                          | Losartan Potassium   |                    |                    | C               | Unknown                                         | 25 Mg, / Day           |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                 | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                            | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2012                                                                                              | 8575722              | EXPEDITED (15-DAY) | Y                  | HO              | CH-<br>GLAXOSMITHKLINE-<br>B0801815A            |                        | 57 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                                    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                    | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u>   |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                                                                                           |                |   |         |               |                 |
|---------------------------------------------------------------------------------------------------------------------------|----------------|---|---------|---------------|-----------------|
| Blood Potassium Decreased; Blood Pressure Systolic Decreased; Dizziness; Drug Interaction; Electrocardiogram Qt Prolonged | Deroxat        | S | Oral    | 20mg Per Day  | Glaxosmithkline |
|                                                                                                                           | Pipamperone    | S | Unknown |               | Not Reported    |
|                                                                                                                           | Abilify        | S | Unknown |               | Not Reported    |
|                                                                                                                           | Risperdal      | S | Oral    | 1mg Per Day   | Glaxosmithkline |
|                                                                                                                           | Cipralex       | S | Unknown |               | Glaxosmithkline |
|                                                                                                                           | Metoprolol     | S | Oral    | 25mg Per Day  | Not Reported    |
|                                                                                                                           | Gliclazide     | C | Oral    | 30mg Per Day  | Glaxosmithkline |
|                                                                                                                           | Aspirin Cardio | C | Oral    | 100mg Per Day | Glaxosmithkline |
|                                                                                                                           | Allopurinol    | C | Oral    | 300mg Per Day | Glaxosmithkline |
|                                                                                                                           | Lasix          | C |         |               | Glaxosmithkline |
|                                                                                                                           | Torsemide      | C |         | 5mg Per Day   | Not Reported    |
|                                                                                                                           | Telmisartan    | C | Oral    | 80mg Per Day  | Glaxosmithkline |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-May-2012              | 8576777       | EXPEDITED (15-DAY) | Y                  | HO              | TR-MYLANLABS-2012S1010028 |                      | 54 YR      | Male       | TUR            |

| <u>Preferred Term</u>                       | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                                                    | <u>Duration</u> | <u>Mfr</u>   |
|---------------------------------------------|----------------------|--------------|------------|-------------|--------------|-----------------------------------------------------------------------|-----------------|--------------|
| Drug Interaction; Mania; Psychotic Disorder | Escitalopram Oxalate |              |            | S           | Unknown      | 20 Mg/Day                                                             |                 | Mylan        |
|                                             | Modafinil            |              |            | S           | Unknown      | 200 Mg/Day In The 1st Week Of Treatment; Then Increased To 400 Mg/Day |                 | Not Reported |
|                                             | Modafinil            |              |            | S           | Unknown      | 400 Mg/Day                                                            |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 23-May-2012              | 8588009       | EXPEDITED (15-DAY) | Y                  | HO              | 2012SP025259         |                      | 30 YR      | Male       | CHE            |

| <u>Preferred Term</u>                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Extrapyramidal Disorder; Hallucination; Headache; Intentional Overdose; Sluggishness; Somnolence; Suicide | Remeron              |              |            | S           | Oral         | 20 Df;Once;Po      |                 | Not Reported |
|                                                                                                           | Levetiracetam        |              |            | S           | Oral         | 10 Df;Once;Po      |                 | Not Reported |
|                                                                                                           | Escitalopram Oxalate |              |            | S           | Oral         | 20 Df;Once;Po      |                 | Not Reported |

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|                                                                                                                                            |                               |                    |                    |                 |                      |                                                                         |                 |              |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------|--------------------|-----------------|----------------------|-------------------------------------------------------------------------|-----------------|--------------|----------------|
| Attempt; Vomiting                                                                                                                          | Methylphenidate Hydrochloride | S                  | Oral               | 8 Df;Once;Po    |                      |                                                                         |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2012                                                                                                                                | 8588398                       | DIRECT             | Y                  | OT              |                      |                                                                         | 34 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Condition Aggravated; Depression; Educational Problem; Product Substitution Issue; Suicidal Ideation                                       | Escitalopram Oxalate          |                    |                    | S               | Oral                 | Escitalopram 20mg Once Daily Oral                                       | 2 MTH           |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 23-May-2012                                                                                                                                | 8589139                       | DIRECT             |                    |                 |                      |                                                                         | 80 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Dystonia; Product Substitution Issue; Tremor                                                                                      | Escitalopram Oxalate          |                    |                    | S               | Oral                 | 10 Mg. Od Po                                                            |                 |              | Not Reported   |
| <u>FDA Received Date</u>                                                                                                                   | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                                                    | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2012                                                                                                                                | 7932083                       | EXPEDITED (15-DAY) | Y                  | OT              | AUR-APL-2011-01248   |                                                                         | 75 YR           | Male         | USA            |
| <u>Preferred Term</u>                                                                                                                      | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                                                      | <u>Duration</u> | <u>Mfr</u>   |                |
| Diarrhoea; Drug Ineffective; Muscle Twitching; Nightmare; Suicidal Ideation; Suicide Attempt; Therapeutic Product Effect Decreased; Tremor | Mirtazapine                   |                    |                    | S               |                      |                                                                         |                 |              | Not Reported   |
|                                                                                                                                            | Paroxetine Hydrochloride      |                    |                    | S               |                      |                                                                         |                 |              | Not Reported   |
|                                                                                                                                            | Pristiq Extended Release      |                    |                    | S               | Oral                 | 50 Mg (50 Mg, 1 In 1 D), Oral; Patient Tried Taking Half A Tablet, Oral |                 |              | Not Reported   |
|                                                                                                                                            |                               |                    |                    |                 | Oral                 | 50 Mg (50 Mg, 1 In 1 D), Oral; Patient Tried Taking Half A Tablet, Oral |                 |              |                |
|                                                                                                                                            | Effexor Xr                    |                    |                    | S               | Oral                 | 75 Mg (75 Mg, 1 In 1 D), Oral                                           |                 |              | Not Reported   |
|                                                                                                                                            | Doxepin Hydrochloride         |                    |                    | S               |                      |                                                                         |                 |              | Not Reported   |
|                                                                                                                                            | Zoloft                        |                    |                    | S               |                      |                                                                         |                 |              | Not Reported   |

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|                         |   |              |
|-------------------------|---|--------------|
| Trazodone Hydrochloride | S | Not Reported |
| Wellbutrin              | S | Not Reported |
| Seroquel                | S | Not Reported |
| Lexapro                 | S | Not Reported |
| Cymbalta                | S | Not Reported |
| Prozac                  | S | Not Reported |
| Depakote                | S | Not Reported |
| Paxil                   | S | Not Reported |
| Zyprexa                 | C | Not Reported |
| One-A-Day               | C | Not Reported |
| Fish Oil, Hydrogenated  | C | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8545220       | EXPEDITED (15-DAY) | N                  | OT              | CN-JNJFOC-20110406144 |                      | 16 YR      | Female     | CHN            |

| <u>Preferred Term</u>                                                              | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u>   |
|------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|-----------------------------------------|-----------------|--------------|
| Asthenia; Influenza Like Illness; Myocardial Necrosis Marker Increased; Somnolence | Invega         |              |            | S           | Oral         |                                         |                 | Not Reported |
|                                                                                    | Risperdal      |              |            | S           | Oral         | 0.5 Mg In The Morning And 1 Mg At Night |                 | Not Reported |
|                                                                                    | Lexapro        |              |            | S           | Oral         |                                         |                 | Not Reported |
|                                                                                    | Lexapro        |              |            | S           | Oral         |                                         |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8554570       | EXPEDITED (15-DAY) | Y                  | OT              | AU-FRI-1000030359    |                      |            | Female     | AUS            |

| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Multiple Sclerosis; Off Label Use | Lexapro        |              |            | S           | Oral         | 10 Mg              |                 | Forest       |
|                                   | Nasonex        |              |            | C           |              |                    |                 | Not Reported |
|                                   | Panvax         |              |            | C           |              |                    |                 | Not Reported |
|                                   | Cefaclor       |              |            | C           |              |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8577299       | EXPEDITED (15-DAY) | Y                  | HO, LT          | ES-JNJFOC-20120513868 |                      | 73 YR      | Female     | ESP            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                                             |                                             |   |      |              |
|-------------------------------------------------------------|---------------------------------------------|---|------|--------------|
| Drug Interaction;<br>Hypercreatininaemia;<br>Rhabdomyolysis | Tramadol Hydrochloride And<br>Acetaminophen | S | Oral | Not Reported |
|                                                             | Tramadol Hydrochloride                      | S | Oral | Not Reported |
|                                                             | Pantoprazole                                | S | Oral | Not Reported |
|                                                             | Depakene                                    | S | Oral | Not Reported |
|                                                             | Escitalopram Oxalate                        | S | Oral | Not Reported |
|                                                             | Lescol                                      | S | Oral | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8577436       | EXPEDITED (15-DAY) | Y                  | DS, HO          | CH-JNJFOC-<br>20120509990 |                      | 25 YR      | Male       | CHE            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Anaemia; Suicide Attempt | Risperdal      |              |            | S           | Unknown      |                    |                 | Not Reported |
|                          | Cipraxel       |              |            | S           | Unknown      |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8578291       | EXPEDITED (15-DAY) | Y                  | HO              | FR-ROCHE-1067630     |                      | 59 YR      | Male       | FRA            |

| <u>Preferred Term</u>            | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>   |
|----------------------------------|-----------------------|--------------|------------|-------------|--------------|-------------------------|-----------------|--------------|
| Extrapyramidal Disorder;<br>Fall | Rivotril              |              |            | S           | Oral         |                         |                 | Not Reported |
|                                  | Amisulpride           |              |            | S           | Oral         | 200 Mg; 2 Tablets Daily |                 | Not Reported |
|                                  | Amisulpride           |              |            | S           | Oral         |                         |                 | Not Reported |
|                                  | Amisulpride           |              |            | S           | Oral         |                         |                 | Not Reported |
|                                  | Amisulpride           |              |            | S           |              |                         |                 | Not Reported |
|                                  | Stilnox               |              |            | S           | Oral         |                         |                 | Not Reported |
|                                  | Trimeprazine Tartrate |              |            | S           | Oral         | Strength: 40 Mg/MI      |                 | Not Reported |
|                                  | Trimeprazine Tartrate |              |            | S           |              |                         |                 | Not Reported |
|                                  | Escitalopram Oxalate  |              |            | S           |              |                         |                 | Not Reported |
|                                  | Inexium               |              |            | C           |              |                         |                 | Not Reported |
|                                  | Amlodipine Besylate   |              |            | C           |              |                         |                 | Not Reported |
|                                  | Folic Acid            |              |            | C           |              |                         |                 | Not Reported |
|                                  | Aspirin               |              |            | C           |              |                         |                 | Not Reported |
|                                  | Fungizone             |              |            | C           |              |                         |                 | Not Reported |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| Forlax (France)                                 |                      |                    | C                  |                 |                      | Not Reported         |                 |              |                |
|-------------------------------------------------|----------------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|--------------|----------------|
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2012                                     | 8578922              | EXPEDITED (15-DAY) | Y                  | OT              | FR-FRI-1000030712    |                      | 30 YR           | Female       | FRA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Myopia                                          | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               | Oral                 |                      |                 | Not Reported |                |
|                                                 | Levothyrox           |                    |                    | C               |                      |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2012                                     | 8578923              | EXPEDITED (15-DAY) | Y                  | HO              | SE-FRI-1000030713    |                      | 47 YR           | Male         | SWE            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Insomnia; Intentional Overdose; Mental Disorder | Escitalopram Oxalate |                    |                    | S               | Oral                 | 20 Mg                |                 | Forest       |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               |                      | Overdose: 120 Mg     |                 | Forest       |                |
|                                                 | Escitalopram Oxalate |                    |                    | S               |                      | Overdose: 120 Mg     |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2012                                     | 8578998              | EXPEDITED (15-DAY) | Y                  | HO, LT, OT      | ES-FRI-1000030744    |                      | 71 YR           | Male         | ESP            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Drug Interaction; Epistaxis; Off Label Use      | Escitalopram Oxalate |                    |                    | S               | Oral                 | 10 Mg                |                 | Forest       |                |
|                                                 | Azilect              |                    |                    | S               | Oral                 | 1 Mg                 |                 | Not Reported |                |
|                                                 | Quetiapine           |                    |                    | S               |                      | 50 Mg                |                 | Not Reported |                |
|                                                 | Risperidone          |                    |                    | S               | Oral                 | 0.5 Mg               |                 | Not Reported |                |
|                                                 | Simvastatin          |                    |                    | C               | Oral                 | 20 Mg                |                 | Not Reported |                |
|                                                 | Requip               |                    |                    | C               | Oral                 | 8 Mg                 |                 | Not Reported |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 24-May-2012                                     | 8580157              | EXPEDITED (15-DAY) | Y                  | OT              | FR-JNJFOC-           |                      | 59 YR           | Male         | FRA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

20120515821

| <u>Preferred Term</u> | <u>Product</u>                                         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>   |
|-----------------------|--------------------------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|--------------|
| Amnesia               | Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride |              | Y          | S           | Oral         |                    |                 | Not Reported |
|                       | Cetirizine Hydrochloride\Pseudoephedrine Hydrochloride |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Escitalopram Oxalate                                   |              |            | S           | Oral         |                    |                 | Not Reported |
|                       | Alprazolam                                             |              |            | S           | Oral         |                    |                 | Not Reported |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8590381       | DIRECT           | N                  | OT              |                      |                      | 45 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                                                                                                                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Crying; Depression; Drug Ineffective; Dyspepsia; Flatulence; Headache; Hot Flush; Libido Decreased; Myalgia; Product Quality Issue; Product Substitution Issue; Social Avoidant Behaviour | Escitalopram Oxalate |              |            | S           | Oral         | 1 Tab Bid Po       |                 | Teva       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-May-2012              | 8590406       | DIRECT           | N                  |                 |                      |                      | 49 YR      | Female     | USA            |

| <u>Preferred Term</u>                                                                             | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------------------------------------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Depression; Disease Recurrence; Drug Ineffective; Product Substitution Issue; Withdrawal Syndrome | Lexapro        |              |            | S           |              | 15mg/Day           |                 | Mylan      |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
|--------------------------------------------------------------------------------------|----------------------|--------------------|--------------------|-----------------|-----------------------|----------------------|-----------------|--------------|----------------|
| 25-May-2012                                                                          | 8579720              | EXPEDITED (15-DAY) | Y                  | OT              | CH-JNJFOC-20120510051 |                      | 34 YR           | Female       | CHE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Maternal Exposure During Pregnancy; Premature Labour; Premature Rupture Of Membranes | Topamax              |                    |                    | S               | Oral                  |                      |                 | Not Reported |                |
|                                                                                      | Cipralext            |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
|                                                                                      | Xenical              |                    |                    | S               | Unknown               |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2012                                                                          | 8579721              | EXPEDITED (15-DAY) | Y                  | OT              | CH-JNJFOC-20120518094 |                      | < 1 DAY         | Female       | CHE            |
| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Premature Baby                                                                       | Topamax              |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                      | Cipralext            |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
|                                                                                      | Xenical              |                    |                    | S               | Transplacental        |                      |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2012                                                                          | 8581445              | EXPEDITED (15-DAY) | Y                  | DS              | FR-FRI-1000030784     |                      | 27 YR           | Male         | FRA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Periodontal Disease                                                                  | Escitalopram Oxalate |                    |                    | S               | Oral                  | 5 Mg                 |                 | Forest       |                |
|                                                                                      | Leponex              |                    |                    | S               | Oral                  | 200 Mg               |                 | Not Reported |                |
| <u>FDA Received Date</u>                                                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>   | <u>Country</u> |
| 25-May-2012                                                                          | 8602264              | DIRECT             | Y                  | OT              |                       |                      | 31 YR           | Female       | USA            |
| <u>Preferred Term</u>                                                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>   |                |
| Anxiety; Condition Aggravated; Depression; Drug Ineffective                          | Lexapro              |                    |                    | S               |                       | 20 Mg 1 Dly          |                 | Not Reported |                |